



Decision of the Competition and Markets Authority

Paroxetine – Case CE-9531/11

12 February 2016

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Confidential information in the original version of this Decision has been redacted from the published version on the public register. Redacted confidential information in the text of the published version of the Decision is denoted by [✂].

The names of individuals mentioned in the description of the infringement in the original version of this Decision have been removed from the published version on the public register. Names have been replaced by a general descriptor of the individual's role.

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1. INTRODUCTION

A. The purpose of this document

1.1 As set out in this decision, of which Annexes A to P form a part (the 'Decision'), the Competition and Markets Authority (the 'CMA') has concluded that:

- (a) the undertakings listed at paragraph 1.2 (each a 'Party', together the 'Parties') have infringed the prohibition imposed by section 2(1) of the Competition Act 1998 (the 'Act') (the 'Chapter I prohibition') and, in the case of GSK and GUK,¹ Article 101² of the Treaty on the Functioning of the European Union ('Article 101 TFEU');³ and
- (b) GSK has infringed the prohibition imposed by section 18 of the Act (the 'Chapter II prohibition').

1.2 This Decision is addressed to each Party to which the CMA has attributed liability in respect of one or more of the Infringing Agreements or the Infringing Conduct summarised at paragraphs 1.3 to 1.20 (the 'Infringements'), and for the resulting penalty in each case, namely:

- (a) GlaxoSmithKline plc, GlaxoSmithKline UK Limited, SmithKline Beecham Limited (formerly SmithKline Beecham plc) and Beecham Group plc (together referred to as 'GSK');
- (b) Generics (UK) Limited ('GUK') and Merck KGaA ('Merck') (together referred to as 'GUK-Merck'); and
- (c) Actavis UK Limited ('Actavis'; formerly Alpharma Limited), Xellia Pharmaceuticals ApS ('Xellia'; formerly Alpharma ApS) and Alpharma LLC ('Zoetis'; formerly Zoetis Products LLC, Alpharma LLC and Alpharma Inc) (together referred to as 'Alpharma').

¹ As defined in paragraph 1.2 below.

² Under the Treaty of Lisbon of 13 December 2007 (which entered into force on 1 December 2009), Article 101 TFEU replaced Article 81 of the EC Treaty. The two Articles are, in substance, identical. As a result, even though the agreements in this case were made prior to 1 December 2009, they were subject to the same prohibition. For the purposes of this Decision, references to Article 101 TFEU should be understood as references to Article 81 of the EC Treaty where appropriate.

³ Article 101 TFEU is applied in this case from 1 May 2004.

B. Summary of the Infringing Agreements

- 1.3 This Decision concerns agreements and conduct in the years 2001-2004 between the pharmaceutical originator company GSK and certain generic companies, which relate to the terms on which GSK settled expected or ongoing patent litigation. This Section provides an overview of the key features of this case.
- 1.4 In 1991, GSK launched branded paroxetine ('Seroxat') in the United Kingdom (the 'UK').⁴ Seroxat is an antidepressant medicine that became a 'blockbuster' product for GSK, with UK sales of £91 million in 2001.⁵ GSK's patent on the paroxetine molecule itself (referred to as a 'primary' patent) expired in January 1999, although certain other patents remained for particular forms of paroxetine and for certain production processes.
- 1.5 Between 1997 and 2002, Norton Healthcare Limited ('Norton' – which traded as IVAX Pharmaceuticals UK),⁶ GUK and Alharma (and other generic pharmaceutical suppliers) took steps to enter the UK paroxetine market. Each of IVAX, GUK and Alharma (together the 'Generic Companies') considered that there was a real prospect of placing on the market a generic paroxetine product that would withstand any legal challenge from GSK under patent law, on the basis that relevant GSK patent claims may be found by the courts to be invalid and/or that the product did not infringe any patent claims that were found to be valid.
- 1.6 Their patent disputes were not resolved by the courts. GSK instead entered into agreements⁷ with each of IVAX, GUK and Alharma (the 'Agreements'), providing for the distribution by those Generic Companies of restricted quantities of GSK's product. It is the terms of the agreements that GSK struck with GUK and Alharma (but not IVAX) that are the subject matter of the part of this Decision which is concerned with the applicability of the Chapter I prohibition and Article 101 TFEU, on the basis that those terms had as their object, as well as their effect, the prevention, restriction or distortion (herein

⁴ In this Decision, paroxetine refers to all paroxetine hydrochloride products. Where necessary and relevant paroxetine is further described as paroxetine anhydrate or paroxetine hemihydrate.

⁵ CMA's calculations, based on data provided by relevant Parties.

⁶ Norton was a subsidiary of the IVAX Corporation, a multinational generic pharmaceutical company (later re-named 'IVAX LLC'). Norton and IVAX LLC are together referred to as 'IVAX'.

⁷ See Part 5 in relation to the GUK-GSK Agreement and Alharma-GSK Agreement. Further, in addition to GSK's Agreements with IVAX, GUK and Alharma, GSK also reached an agreement with a company called [REDACTED] in February 2003 which was also attempting to enter the UK paroxetine market. However, the agreement with [REDACTED] is outside the scope of this Investigation, following a prioritisation assessment undertaken by the Office of Fair Trading (the 'OFT') (see paragraph 2.3).

referred to as the ‘restriction’) of competition in the supply of paroxetine in the UK.

- 1.7 IVAX was the first of the three Generic Companies to enter into an Agreement with GSK. At the time it did so, GSK had not instigated patent infringement proceedings against IVAX, and there was no settlement of pending litigation. Under that Agreement, it was agreed that IVAX would distribute limited quantities of GSK’s branded product. That Agreement included provision for significant value transfers, including cash payments, to be made from GSK to IVAX. The CMA considers that the Agreement was of no evident value to GSK, in terms of improving the efficiency of its distribution system in the UK, or its reach. The provisions relating to the transfer of value from GSK to IVAX did not reflect an exchange for any services provided to GSK by IVAX under the Agreement. Those provisions were inducements to IVAX, incentivising it to defer placing on the UK paroxetine market an independent product that would compete against GSK’s product. IVAX would stay off the market as an independent competitor, and would instead derive sufficient remuneration from GSK to make its inaction as a potential generic entrant worthwhile. The CMA does not consider that the terms of the Agreement between GSK and IVAX were competitive. However, the Agreement is excluded from the Chapter I prohibition,⁸ and the CMA does not make a finding of infringement in respect of it under Article 101 TFEU.
- 1.8 The Agreements with GUK and Alpharma respectively were made later, and had certain differences from the Agreement with IVAX. In both cases, GSK had already instigated patent infringement proceedings against them, in view of their concrete efforts to enter the UK paroxetine market with rival products of their own. Those Agreements with GSK were settlement agreements – although, strictly, neither of them resolved the relevant disagreement concerning GSK’s paroxetine patents (‘Patent Dispute’) between the parties; they only deferred the time when any further efforts for independent generic entry could be made. In each case, the terms of the Agreements included provisions for significant value transfers, including cash payments, to be made by GSK to the generic company. Those value transfers were made in return for an express contractual promise, by which the potential competitor agreed not to enter the market on an independent basis for the duration of the relevant Agreement.
- 1.9 In both cases, there was genuine uncertainty as to whether, if litigation had been pursued rather than deferred, GSK would have prevailed. Had GSK not

⁸ By virtue of The Competition Act 1998 (Land and Vertical Agreements Exclusion) Order 2000, SI 2000/310 (the ‘Vertical Agreements Exclusion Order’).

prevailed, the way would have been cleared for one or all of IVAX, GUK and Alpharma to enter the market on an independent and competitive basis. That would have precipitated true generic competition against GSK's product. It was expected to bring about a steep decline in prices and in GSK's market share. The Agreements therefore had manifestly anti-competitive aims (or objects).

- 1.10 While settlements of litigation are generally desirable, it is well established that settlement agreements may not be concluded on terms that infringe the competition rules. It is particularly important to prevent patentees (the incumbents) and challengers from entering into anti-competitive settlement agreements in the pharmaceutical sector. That is because patent challenges, often by companies manufacturing generic versions of drugs, are an important means by which the validity of a 'legal monopoly' in an important economic area can be tested. As such, patent challenges in this field can in themselves be viewed as an important aspect of the competitive process. Settlement agreements that result in patent challenges being 'bought off', on the basis that the challengers will share in the continued 'monopoly' profits made by the patentee, are apt therefore seriously to harm competition and the interests of consumers.
- 1.11 In essence, the CMA finds that, in the present case, GSK paid GUK and Alpharma to desist, during the term of the Agreements, from continuing their efforts to enter the UK paroxetine market independently of GSK, and thereby from offering independent generic competition against GSK. GSK paid (in cash, and by means of the margin that would be achieved on sales of limited supplies of paroxetine under controlled market conditions) to remove the risk that patent litigation would lead to the emergence of true generic competition. *Prima facie* one would not expect significant transfers of value to move from GSK to GUK and Alpharma where, as purported by the parties, there was no potential for them to enter the market independently of GSK. In the present case, it is clear that the substantial value transfers made by GSK to GUK and Alpharma cannot be explained by any legitimate objective on the part of GSK under the Agreements. The only plausible basis for the value transfers from GSK was to induce GUK and Alpharma to delay their efforts to challenge GSK's position and enter the UK paroxetine market independently of GSK.
- 1.12 In these circumstances, the Agreements with GUK and Alpharma had the object of restricting competition, for the purposes of the European Union (the 'EU') and UK rules on competition. Those Agreements also had the likely effect of restricting competition to an appreciable extent since, in the absence of those Agreements, the realistic and likely outcomes were that GSK would have had to settle the litigation on less restrictive terms (that is, terms that did

not include 'exclusion payments', and which therefore reflected, in legitimate and pro-competitive ways, the commercial risks that were faced by GSK); or else that GSK's patent rights would have been tested in court, with the real possibility that they would have been found invalid and/or not infringed.

- 1.13 The result of the Agreements with GUK and Alpharma was clearly anti-competitive. Both GUK and Alpharma delayed their efforts to enter the UK paroxetine market independently of GSK. On entering the market with a restricted volume of GSK product, neither Generic Company had a discernible impact on market prices for paroxetine in the UK during the term of the Agreements. The position did not change until another generic supplier, Apotex Europe Limited ('Apotex'), eventually prevailed in litigation with GSK. GSK successfully used these anti-competitive Agreements to preserve its market power and to maintain prices at the prevailing supra-competitive levels. GSK shared its supra-competitive profits with GUK and Alpharma through the value transfers under the Agreements with GUK and Alpharma.
- 1.14 For the detailed reasons set out in this Decision, the CMA therefore makes the following findings:
- (a) GSK and GUK infringed the Chapter I prohibition and/or Article 101 TFEU, by participating in an agreement (the 'GUK-GSK Agreement') that had as its object and/or effect the prevention, restriction or distortion of competition. The CMA has concluded that this Infringement lasted for the duration of the GUK-GSK Agreement from 13 March 2002 to 1 July 2004.
 - (b) GSK and Alpharma infringed the Chapter I prohibition,⁹ by participating in an agreement (the 'Alpharma-GSK Agreement') that had as its object and/or effect the prevention, restriction or distortion of competition. The CMA has concluded that this Infringement lasted for the duration of the Alpharma-GSK Agreement from 12 November 2002 to 13 February 2004.
- 1.15 The GUK-GSK Agreement and the Alpharma-GSK Agreement are hereafter referred to as the 'Infringing Agreements'.
- 1.16 The IVAX-GSK Agreement (as described at paragraph 2.10) is excluded from the Chapter I prohibition by virtue of the Vertical Agreements Exclusion Order, and the CMA does not proceed to make a finding of infringement in respect of it under Article 101 TFEU.

⁹ As explained in paragraph 10.9, Article 101 TFEU has not been applied to the Alpharma-GSK Agreement from 1 May 2004, since that Agreement terminated before 1 May 2004.

C. Summary of GSK's Infringing Conduct

- 1.17 The CMA finds that GSK infringed the Chapter II prohibition¹⁰ by making cash payments and other value transfers to induce three potential competitors (IVAX, GUK and Alparma, the Generic Companies) to delay their potential independent entry to the UK paroxetine market (the 'Infringing Conduct'). The CMA has concluded that the Infringing Conduct lasted from 3 October 2001 until 30 November 2003.
- 1.18 GSK was dominant in the supply of paroxetine in the UK. Prior to the emergence of true generic competition in December 2003, GSK was able to sustain significantly higher prices and profits than it could thereafter. The only reasonable explanation of the observed trends is that other medicines in the broad treatment area were not sufficiently close competitors that they should be regarded as belonging to the same relevant market, and that GSK had substantial market power prior to generic entry.
- 1.19 GSK's cash payments and other value transfers to the Generic Companies are summarised above. The level of the cash payments and other value transfers that GSK made to the Generic Companies cannot be explained on any legitimate commercial basis. They can only be explained on the basis that it would be profitable to delay the threat of independent generic entry by paying each of them to delay its efforts to enter the market independently of GSK.
- 1.20 The CMA finds that the purpose of GSK's value transfers to IVAX, GUK and Alparma was to induce them to delay their efforts to enter the UK paroxetine market independently of GSK and thereby protect GSK from such competition. In having recourse to methods different from those which condition 'normal competition', GSK's conduct tended to restrict competition or was capable of having that effect, and deviated from GSK's special responsibility not to allow its conduct to impair genuine undistorted competition. GSK's conduct therefore constituted an abuse of a dominant position in contravention of the Chapter II prohibition, and is hereafter referred to as the 'Infringing Conduct'.

¹⁰ Article 102 of the Treaty on the Functioning of the European Union ('Article 102 TFEU') has not been applied from 1 May 2004, since GSK's dominant position ended prior to 1 May 2004.

D. Summary of the action being taken

- 1.21 The CMA has found that each Party committed the relevant Infringement(s) intentionally, or at the very least negligently.
- 1.22 The CMA considers that the Infringements are serious in nature and it is appropriate to impose financial penalties in respect of the Infringements. At the time of the Infringements, it was well established that restricting the entry of potential competitors onto a market was likely to infringe competition law (particularly where such a restriction was induced through a payment from one party to another).
- 1.23 Consequently, the CMA has imposed a penalty on each Party, as set out at paragraph 11.94.
- 1.24 The CMA has had regard to the seriousness of the Infringements and the need to deter not just the Parties, but also other undertakings more generally, from engaging in similar infringements in the future. In particular, substantial gains can be made from deferring the full development of true generic competition in the pharmaceutical sector, since such competition can be expected to result in significant price decreases. As such, sustaining substantially higher pharmaceutical prices, via so-called 'pay for delay' arrangements, can enable the participating originators and generic companies to realise significant financial gains through sharing profits at levels that are far higher than would exist after the emergence of true generic competition, at the expense of the NHS.
- 1.25 However, the CMA also notes that at the time of the Infringements, there had been no finding that this specific form of anti-competitive agreement infringed the Chapter I prohibition, Article 101 TFEU, the Chapter II prohibition or Article 102 TFEU. The CMA has taken this into account in the round when setting the level of penalty imposed in this case.
- 1.26 In addition, the CMA is mindful of the passage of time between the period encompassing the various durations of the Infringements, together being the period from 3 October 2001 to 1 July 2004 (the 'Relevant Period') and the launch of this investigation, as further described in Part 2 (the 'Investigation'). While each Party has been able to identify and provide a substantial volume of contemporaneous evidence relevant to the Investigation, the CMA recognises that, given the passage of time, searching for contemporaneous evidence and/or data relevant to this Investigation may have involved an increased administrative burden for the Parties.

- 1.27 Having had regard to all relevant circumstances of the case, and having assessed the penalties in this case in the round, the CMA considers each penalty to be at an appropriate level to deter the Parties (and other undertakings) from breaching competition law in the future, without being disproportionate or excessive.

E. The Annexes to the Decision

- 1.28 In making this Decision, the CMA has carefully considered information from a wide range of sources provided during its administrative procedure preceding this Decision. In particular, it has considered the written and oral representations made by the Parties and IVAX ('SO Addressees'). The CMA's responses to the main representations are contained in the Annexes. The Annexes do not repeat all of the facts on which the CMA bases this Decision or its reasons for making the Decision. The facts and the CMA's reasons are contained in the main body of the Decision, and are also relevant to the CMA's disagreement with certain legal and factual points taken by the SO Addressees. The Annexes adopt the same abbreviations and terminology as, and should be read with, the main body of the Decision.

2. THE CMA'S INVESTIGATION

A. The origins and scope of the Investigation

- 2.1 The Infringements which are the subject of this Decision were brought to the OFT's¹¹ attention by the European Commission ('Commission').¹² The Agreements were then provided to the OFT by the Commission on 26 July 2010.¹³
- 2.2 Following a preliminary investigation and prioritisation assessment,¹⁴ the OFT commenced the Investigation on 11 August 2011, under section 25 of the Act in relation to:
- (a) GSK
 - (b) Norton
 - (c) GUK
 - (d) Actavis
 - (e) [REDACTED]
- 2.3 During the course of the Investigation, the scope of the Investigation was revised on the grounds of administrative priorities as follows:
- On 9 December 2011, the OFT decided not to include [REDACTED] in the Investigation, after consideration of its ownership structure. This was on the basis that [REDACTED] and Alpharma are both now owned by the same corporate group, thereby reducing the incremental direct deterrent effect of any enforcement action under the Act regarding Alpharma.

¹¹ Responsibility for the Investigation passed to the CMA on 1 April 2014. From that date, the functions of the Competition Commission, and the competition and certain consumer functions of the OFT, were transferred to the CMA. The CMA was established under the Enterprise and Regulatory Reform Act 2013.

¹² [REDACTED].

¹³ Following an OFT request under Article 12 of the Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ L 1/1, 4 January 2003 ('Modernisation Regulation').

¹⁴ Conducted by reference to the *OFT Prioritisation Principles* (OFT953, October 2008). The CMA has now adopted its own prioritisation principles which are substantially the same as those adopted by the OFT. See *Prioritisation principles for the CMA* (CMA16, April 2014).

- On 5 March 2012, the OFT decided not to pursue the Investigation against GSK under Chapter II of the Act and Article 102 TFEU on the grounds that it was not at that time an administrative priority for the OFT.
- On 31 January 2013, following further analysis of evidence obtained during the Investigation to that point and a re-assessment by reference to its prioritisation principles, the OFT decided to re-prioritise the Chapter II and Article 102 TFEU elements of the Investigation.¹⁵
- Between 11 and 13 March 2013, the OFT informed Xellia, Zoetis (then named, and since re-named again, Alpharma LLC), Merck and IVAX LLC, that the Investigation had been extended to include those parties, in the light of the OFT's proposed findings with respect to attribution of liability. (See Part 9).

2.4 Before the issue of the Statement of Objections (the 'SO') on 19 April 2013, the OFT considered whether to include AL Industrier AS ('AL Industrier') as a party to the Investigation on the basis that AL Industrier was a significant shareholder in Alpharma Inc during the Relevant Period. However, the OFT considered that further investigation and information gathering would have been necessary to establish any such potential liability on the part of AL Industrier which was not justified by the negligible beneficial direct or indirect impact of doing so. The OFT therefore concluded in February 2013, following an assessment undertaken by reference to its prioritisation principles,¹⁶ that extending the scope of the Investigation to include AL Industrier did not constitute an administrative priority for the OFT.¹⁷

B. Information gathering by the OFT prior to the issue of the SO

2.5 Prior to the issue of the SO, the OFT sent formal notices requiring documents and information under section 26 of the Act ('Section 26 Notices'), and in relation to inspections carried out at the SO Addressees premises under section 27 of the Act ('Section 27 Notices').

¹⁵ Following further consideration, the OFT determined that Article 102 TFEU should not be applied in light of its then proposed findings on dominance (see paragraphs 4.98–4.128).

¹⁶ See footnote 14 for a link to the OFT's Prioritisation Principles.

¹⁷ Footnote 1512 of the SO stated that: *'The OFT has also considered the attribution of parental liability to AL Industries AS, which is based in Norway, on the grounds that it exercised control over Alpharma Inc in the Relevant Period. However, the OFT considers that further work to establish such liability on the part of AL Industries AS, which would require further detailed information, does not constitute an administrative priority for the OFT.'* The reference to AL Industries AS was a typographical error, and references in the SO to AL Industries AS should be read as referring to AL Industrier AS.

- 2.6 The OFT also held state of play meetings and teleconferences with representatives of the SO Addressees, both to gather further substantive evidence and to discuss procedural steps relevant to the Investigation.
- 2.7 The OFT conducted taped interviews with a number of employees and ex-employees from the SO Addressees on a voluntary basis. These interviews were held in the presence of legal advisers and subsequently these individuals approved transcripts. In some instances, witnesses also provided statements. The OFT also requested voluntary witness interviews with a number of other employees and ex-employees of the SO Addressees to the Investigation or, in one case, a third party to the Investigation. However, those individuals, or their employer in the case of GSK,¹⁸ declined such requests.
- 2.8 Prior to the issue of the SO, the OFT sent Section 26 Notices to a number of other parties to obtain information which was relevant to the Investigation. The OFT also sent informal requests for information to BASF AG ('BASF'),¹⁹ the Department of Health ('DH') and the Medicines and Healthcare products Regulatory Agency ('MHRA'). The OFT also had various discussions with the Intellectual Property Office ('IPO') with respect to the patent issues arising in the Investigation.

C. Issue of the SO and the appointment of a Case Decision Group

- 2.9 On 19 April 2013, the OFT issued an SO setting out its provisional findings to the SO Addressees. In the SO, the OFT set out the facts (including the evidence) on which it relied, the objections it raised in terms of the alleged infringements of the Chapter I prohibition, Article 101 TFEU and the Chapter II prohibition, the action it proposed to take and its reasons for the proposed action.
- 2.10 The SO alleged the following infringements:
- GSK and IVAX participated in an agreement (the 'IVAX-GSK Agreement') and/or concerted practice that had as its object and/or effect the prevention, restriction or distortion of competition in breach of the Chapter

¹⁸ In GSK's case, it declined such interviews having '*decided that we do not think it is appropriate in this particular case*' given that '*[t]he events concerned took place some ten years ago and it is difficult for individuals to recall on the spot the details regarding the various arrangements and/or discussion with the generic suppliers. Moreover, this is not a case which turns on facts such as attendance at meetings and so forth, so even with the benefit of advance documents we do not think voluntary interviews are appropriate*'. See email from [external GSK lawyer] to the OFT dated 5 April 2012 (document 0723).

¹⁹ An informal request for information was sent to BASF on 26 July 2012 (document 2184) and a response was received on 16 August 2012 (document 2185).

I prohibition and/or Article 101 TFEU in relation to the supply of paroxetine in the UK which lasted for the duration of the IVAX-GSK Agreement from 3 October 2001 to 29 June 2004.

- GSK and GUK participated in an agreement (the GUK-GSK Agreement) and/or concerted practice that had as its object and/or effect the prevention, restriction or distortion of competition in breach of the Chapter I prohibition and/or Article 101 TFEU in relation to the supply of paroxetine in the UK which lasted for the duration of the GUK-GSK Agreement from 13 March 2002 to 1 July 2004.
- GSK and Alparma participated in an agreement (the Alparma-GSK Agreement) and/or concerted practice that had as its object and/or effect the prevention, restriction or distortion of competition in breach of the Chapter I prohibition in relation to the supply of paroxetine in the UK which lasted for the duration of the Alparma-GSK Agreement from 12 November 2002 to 13 February 2004.
- GSK engaged in conduct which constitutes an abuse of a dominant position in breach of the Chapter II prohibition by making value transfers to induce IVAX, GUK and Alparma to delay their potential entry to the UK paroxetine market which lasted from October 2001 until November 2003.

2.11 Following the issue of the SO, a Case Decision Group was appointed within the OFT (and subsequently the CMA) to act as the decision-maker on whether or not, based on the facts and evidence before it, and taking account of the SO Addressees' representations, the legal test for establishing an infringement had been met, and whether the Investigation remained an administrative priority.²⁰

2.12 Following the issue of the SO, the SO Addressees submitted written and oral representations to the OFT on the matters referred to in the SO. Following the oral hearings on the SO, the OFT requested written responses from the SO Addressees to certain questions raised by the OFT during the oral hearings.

²⁰ The role of the Case Decision Group is described in *Guidance on the CMA's investigation procedures in Competition Act 1998 cases* (CMA8, March 2014) ('CMA8'), paragraphs 9.11 and 11.30–11.34, as it relates to the period from 1 April 2014. The role of the Case Decision Group prior to that date is described in *A guide to the OFT's investigation procedures in competition cases* (OFT1263rev, October 2002), paragraphs 9.11 and 11.27–11.31. The roles of the Case Decision Group at each of the OFT and CMA are substantially the same.

D. Further information gathering by the OFT and CMA following the representations on the SO

- 2.13 The OFT closed on 31 March 2014, after which responsibility for the Investigation passed to the CMA. The OFT (prior to 1 April 2014) and the CMA (from 1 April 2014) sent further Section 26 Notices to the SO Addressees to obtain further information which was relevant to the Investigation. Those addressees provided the OFT/CMA with additional information, in response to these requests for information.
- 2.14 The CMA conducted further taped interviews with a number of employees and ex-employees from the SO Addressees, both on a voluntary basis and also using its formal powers under section 26A of the Act.²¹ These individuals subsequently approved transcripts of the interviews and provided witness statements.
- 2.15 Following consideration of the SO Addressees' written and oral representations and the additional evidence gathered, the CMA held further state of play meetings with representatives of the SO Addressees in June and July 2014 at which the CMA informed the SO Addressees that it was proposing to issue a Letter of Facts and a Supplementary Statement of Objections (the 'SSO') in the Investigation.²²

E. Issue of the First Letter of Facts

- 2.16 On 27 August 2014, the CMA sent a Letter of Facts (the 'First Letter of Facts') to the SO Addressees which identified additional evidence supporting the CMA's provisional findings as set out in the SO on which it proposed to rely.²³
- 2.17 The SO Addressees submitted written representations to the CMA on the matters referred to in the First Letter of Facts between 17 and 19 September 2014.

²¹ Section 26A of the Act empowers the CMA to compel a witness to attend an interview. This section formed part of the Enterprise and Regulatory Reform Act 2013 and became effective on 1 April 2014.

²² In addition, following consideration of representations from Xellia and Zoetis on the SO, the CMA re-considered whether extending the scope of the Investigation to include AL Industrier was an administrative priority for the CMA by reference to its prioritisation principles. In October 2014, the Case Decision Group concluded that it was not an administrative priority for the CMA to include AL Industrier within the scope of the Investigation, on the basis that AL Industrier had at that point been dissolved and the inclusion of AL Industrier would require further investigation and information gathering while leading to a negligible beneficial direct or indirect impact on consumers. See email correspondence on 28 August 2014 between the CMA and [external lawyers for A.L. Industrier] (document 3241), page 1: 'A.L. Industrier was notified to the Norwegian Company Registration Office as being dissolved as of 14 June 2014.'

²³ For further detail on the procedure relating to a letter of facts, see CMA8, paragraph 12.27.

F. Issue of the SSO

- 2.18 On 21 October 2014, the CMA issued an SSO, in particular in respect of the IVAX-GSK Agreement, to the SO Addressees under section 31 of the Act.²⁴
- 2.19 At the same time as issuing the SSO, the CMA sent Section 26 Notices and informal information requests to the SO Addressees, requesting additional turnover information.
- 2.20 The SO Addressees made written and oral representations²⁵ on the matters set out in the SSO²⁶ between 18 November and 19 December 2014.

G. Further information gathering by the CMA following the representations on the SSO

- 2.21 The CMA sent Section 26 Notices and informal information requests to the SO Addressees to obtain further information about points raised in their representations, and requesting clarification of turnover information.
- 2.22 The CMA also conducted a taped interview, using its formal powers under section 26A of the Act.

H. Issue of the NGFA Decision

- 2.23 On 30 June 2015, the CMA issued a proposed no grounds for action decision (the 'Proposed NGFA Decision') which explained that the CMA was minded to close its case in respect of the IVAX-GSK Agreement under the Chapter I prohibition and Article 101 TFEU on the basis that there were no longer grounds for action by the CMA.
- 2.24 The SO Addressees submitted written representations on the Proposed NGFA Decision between 28 July 2015 and 25 August 2015.
- 2.25 On 12 February 2016, the CMA issued a final no grounds for action decision (the 'NGFA Decision') finding that:

²⁴ For further detail on the procedure relating to a SSO, see CMA8, paragraphs 12.28–12.30.

²⁵ GSK chose not to make oral representations, however attended a state of play meeting with the Case Decision Group on 22 January 2015 (see Transcript of state of play meeting (document 3895)).

²⁶ Competition Act 1998 (Competition and Markets Authority's Rules) Order 2014 (SI 2014/458), CMA Rules 5 and 6(1), (3) and (4).

- the Vertical Agreements Exclusion Order²⁷ applied to the IVAX-GSK Agreement and consequently the Chapter I prohibition does not apply to it; and
- the SO Addressees' representations and the CMA's further analysis have cast doubt on the CMA's proposed finding of an infringement of Article 101 TFEU in relation to the IVAX-GSK Agreement during the period from 1 May 2004 (when the Modernisation Regulation became applicable) to 29 June 2004 (when the IVAX-GSK Agreement terminated), and consequently there are no longer grounds for action in relation to Article 101 TFEU.

I. Issue of the Draft Penalty Statements

- 2.26 On 30 June 2015, the CMA issued a Draft Penalty Statement to each of GSK (the 'GSK DPS'), GUK and Merck (the 'GUK DPS') and Actavis, Xellia and Zoetis (then named Zoetis Products LLC, since re-named Alpharma LLC)²⁸ (the 'Alpharma DPS') (together, the 'Draft Penalty Statements'). The Draft Penalty Statements set out the CMA's provisional view that it was considering reaching an infringement decision and imposing a penalty on each of the entities comprising GSK, GUK-Merck and Alpharma.
- 2.27 The Parties made written and oral representations on the matters set out in the relevant Draft Penalty Statements between 29 July 2015 and 23 September 2015.

J. Further information gathering by the CMA following the representations on the Draft Penalty Statements

- 2.28 The CMA sent Section 26 Notices and informal information requests to GSK, Actavis, IVAX and GUK to obtain further information about points raised in the representations in response to the Draft Penalty Statements, and requesting clarification of turnover information.

K. Issue of the Second Letter of Facts

- 2.29 On 1 September 2015, the CMA sent a Second Letter of Facts (the 'Second Letter of Facts') to the SO Addressees which identified additional evidence

²⁷ The Competition Act 1998 (Land and Vertical Agreements Exclusion) Order 2000, SI 2000/310.

²⁸ On 6 July 2015, Zoetis Products LLC was re-named Alpharma LLC (Xellia-Zoetis Response dated 14 August 2015 to the Alpharma DPS ('Xellia-Zoetis DPS Written Response') (document 4055), footnote 1, and Annex 1 to that response – Certificate of amendment filed with, and delivered to, the Delaware Department of State on 6 July 2015 (document 4057). Zoetis Inc remains the ultimate parent company of Alpharma LLC.

supporting the CMA's provisional findings as set out in the SO and SSO on which it proposed to rely.

- 2.30 The SO Addressees submitted written representations to the CMA on the matters referred to in the Second Letter of Facts between 25 September 2015 and 5 October 2015.

L. Issue of the Third Letter of Facts

- 2.31 On 12 January 2016, the CMA sent a Third Letter of Facts (the 'Third Letter of Facts') to the SO Addressees (excluding IVAX) which identified additional evidence supporting the CMA's provisional findings as set out in the SO and SSO on which it proposed to rely.
- 2.32 The SO Addressees submitted written representations to the CMA on the matters referred to in the Third Letter of Facts between 19 January 2016 and 21 January 2016.

3. BACKGROUND INFORMATION AND THE FACTS

3.1 This Part of the Decision sets out relevant background to the Investigation, focusing on the key factual background, and includes the following information:

- Section A briefly describes the Parties that are the subject of this Investigation, and the other parties that are relevant to the Investigation.
- Section B describes the product that is the subject of this Investigation, namely paroxetine.
- Section C describes the process and benefits of generic competition.
- Section D describes the various aspects of the regulatory framework that are relevant to competition in the pharmaceutical sector, in particular those relating to the granting of patents, methods of challenging patents, marketing authorisations ('MAs'), General Practitioner ('GP') prescribing habits, pharmacy dispensing and medicine pricing.
- Section E presents an overview of the events relevant to the Patent Disputes which led up to the Agreements between GSK and the Generic Companies and the content of those Agreements.
- Section F presents an outline of the Agreements between GSK and the Generic Companies.
- Section G presents an overview of trends in the supply of paroxetine between 1998 and 2005, that is, the period before, during and immediately after the Agreements came into effect.

A. The Parties

3.2 The Decision relates to the Parties listed in paragraph 1.2. This Section includes brief background information regarding both those Parties and certain third parties who were involved in the key events of relevance to this Investigation. Further information about the Parties to the Investigation can be found in Part 2.

i) *The Parties to the Investigation*

a) *'GSK'*

3.3 GlaxoSmithKline Plc was during the Relevant Period, and remains, one of the world's leading research-based pharmaceutical and healthcare companies, and is active in the development and manufacturing of pharmaceutical products.²⁹

3.4 In the UK, during the Relevant Period, it also operated through a number of subsidiaries, including GlaxoSmithKline UK Limited, SmithKline Beecham Limited (formerly SmithKline Beecham Plc during the Relevant Period) and Beecham Group Plc, which are relevant to the key issues in the Decision.

b) *'GUK-Merck'*

3.5 During the Relevant Period, GUK was a leading UK developer and supplier of generic medicines and was an indirect 100% owned subsidiary of Merck KGaA, a major global provider of pharmaceutical products. All of Merck's generics businesses (the 'Merck Generics Group') were under the control of one holding company, Merck Generics Holding GmbH ('MGH').³⁰

3.6 In October 2007, Merck sold the Merck Generics Group and all of Merck's shareholding in GUK, to Mylan Inc. Mylan Inc is the ultimate parent company of a group focused on the production and sale of generic medicines. Since its sale by Merck, GUK has continued to exist (as a separate legal entity with its own turnover and assets) and to remain active in the supply of generic pharmaceutical products.

c) *'Alpharma'*

3.7 During the Relevant Period, Alpharma Limited was the UK business of Alpharma Inc, a US company, and supplied generic and branded medicines to wholesale customers in the UK.³¹ Alpharma Limited was wholly owned by

²⁹ GSK was created by the merger of SmithKline Beecham ('SB') and Glaxo Wellcome in 2000.

³⁰ See Chart of Merck KGaA's group structure dated 31 December 2002 (document A 0071), which illustrates that, as at 31 December 2002, Merck KGaA owned 100% of MGH, which in turn owned 100% of Merck Generics Group BV, which in turn owned 100% of GUK. See also Merck Response dated 7 August 2013 to the SO ('Merck SO Written Response') (document 2764), paragraph 6.37. Merck is listed as the ultimate controlling parent of GUK at Note 24 to the financial statements in the GUK Directors Annual Report and Financial Statements for the year ended 31 December 2001 (as lodged at Companies House on 20 June 2002), page 17 (as printed), and GUK Directors Annual Report and Financial Statements for the year ended 31 December 2004 (as lodged at Companies House on 28 October 2005), page 19 (as printed).

³¹ The immediate parent company of Alpharma Limited was Cox Investments Limited in the UK. See Alpharma Limited, Report of the Directors and Financial Statements for the year ended 31 December 2001 (as lodged at Companies House on 19 September 2002), page 19 (as printed).

Alpharma ApS³² which also owned several other subsidiaries of the Alpharma group of companies, notably in Belgium, Finland, France, Germany, the Netherlands, Norway and Sweden.³³ In March 2008, Alpharma ApS was sold to an international investment group, after which Alpharma ApS was first re-named Axellia Pharmaceuticals ApS and then, as of 2010, Xellia Pharmaceuticals ApS. In 2013, Xellia was sold to Novo A/S, a holding company of the Novo Group.

- 3.8 On 19 December 2005, the Actavis group acquired the underlying assets of the worldwide human generics business of Alpharma Inc including Alpharma Limited, but not including Alpharma Inc or Alpharma ApS. Subsequently, Alpharma Limited changed its name to Actavis UK Limited on 18 May 2006.³⁴
- 3.9 Alpharma ApS was an indirectly wholly-owned subsidiary of Alpharma Inc, a major global pharmaceutical company during the Relevant Period. Alpharma Inc was subsequently acquired by another US company, King Pharmaceuticals Inc in December 2008. King Pharmaceuticals Inc in turn was acquired by Pfizer Inc in February 2011. In April 2010, Alpharma Inc changed from a US corporation into a US limited liability company, Alpharma LLC. In April 2013, Alpharma LLC changed its name to Zoetis Products LLC.³⁵ In July 2015, Zoetis Products LLC changed its name to Alpharma LLC.³⁶ It continues to exist as a discrete entity within the Zoetis group of companies.

ii) Other relevant parties

a) 'IVAX'

- 3.10 During the Relevant Period, Norton traded as IVAX Pharmaceuticals UK and was a subsidiary of the IVAX Corporation, a multinational generic pharmaceutical company (now 'IVAX LLC'). Norton and IVAX LLC are together referred to as 'IVAX'. In 2006, IVAX was acquired by Teva Pharmaceutical Industries Limited ('Teva'), a major developer of generic medicines based in Israel. Norton and IVAX LLC remain entities within the Teva group.

³² See Alpharma Limited Report of the Directors and Financial Statements for the year ended 31 December 2003 (as lodged at Companies House on 30 October 2004), page 9 (as printed).

³³ See Alpharma ApS, Annual Report for 2003 (document 2587), page 6.

³⁴ See Actavis UK Limited (formerly Alpharma Limited) Report of the Directors and Financial Statements for the year ended 31 December 2005 (document 2588), page 1.

³⁵ Certificate of amendment filed with, and delivered to, the Delaware Department of State on 15 April 2013 (document 2789).

³⁶ Xellia-Zoetis DPS Written Response (document 4055), footnote 1, and Annex 1 to that response – Certificate of amendment filed with, and delivered to, the Delaware Department of State on 6 July 2015 (document 4057).

- 3.11 As stated above, Norton and IVAX LLC were SO Addressees. The CMA has concluded that there are no grounds for action in relation to the IVAX-GSK Agreement, as set out in the separate NGFA Decision.
- 3.12 IVAX was the first undertaking to enter into a supply agreement with GSK in relation to paroxetine in the UK. The terms of the IVAX-GSK Agreement are set out in paragraph 3.219. Under those terms, IVAX became the exclusive distributor in the UK for GSK's unbranded paroxetine and subsequently supplied Tillomed Laboratories Limited ('Tillomed'), GUK and Alpharma with GSK's unbranded paroxetine under the terms of separate supply agreements with each of those companies as described in paragraphs 3.380 to 3.398.

b) *Hexal and Tillomed*

- 3.13 In 2001, Hexal AG ('Hexal') was a large generics company based in Germany. Hexal was one of the first companies to begin developing generic paroxetine, using paroxetine active pharmaceutical ingredient ('API') sourced from BASF.
- 3.14 Hexal began selling generic paroxetine in Denmark in February 2001 through its Danish subsidiary A/S GEA Farmaceutisk Fabrik ('GEA').³⁷ However, that product was withdrawn from sale later in 2001.³⁸ Subsequently, Hexal entered into agreements with GSK in several European countries in which Hexal agreed to sell GSK's product instead of Hexal's own.³⁹
- 3.15 Hexal's subsidiary GEA applied, in January 2001, for an MA to sell its paroxetine in the UK. In January 2002, GEA was granted an MA in the UK, with Tillomed named on that licence as a distributor (the 'Tillomed MA').⁴⁰ However, in December 2001, Tillomed had already agreed with IVAX that it would sell paroxetine sourced from IVAX in return for a profit share agreement with IVAX and an agreement to transfer to IVAX exclusive rights to its UK MA. In 2005, Hexal was acquired by Sandoz.⁴¹
- 3.16 In 2001, Hexal owned 50% of Tillomed. Tillomed specialised, and remains active, in the licensing, marketing and supply of generic and branded

³⁷ See witness statement of [GSK's Marketing Manager A for Seroxat] in the GUK litigation, dated 19 September 2001 ('[redacted] WS') (document 0150), paragraph 4.8.

³⁸ See [redacted] WS (document 0150), paragraph 4.8.

³⁹ GSK and Hexal reached co-marketing agreements in Germany and the Netherlands in July 2001, in Ireland in August 2001, in Denmark in December 2001 and in Spain in January 2002. See GSK document entitled 'Patent Overview 2002' dated 3 July 2002 (document 0282). See also the response dated 30 January 2013 to the Section 26 Notice dated 18 December 2012 sent to GSK (document 2515).

⁴⁰ See Tillomed response dated 4 December 2012 to the Section 26 Notice dated 14 November 2012 (document 2337).

⁴¹ See www.sandoz.com/about_us/Sandoz_history.shtml

pharmaceutical products to hospitals, wholesalers and pharmacies in the UK.⁴²

c) BASF

3.17 BASF is a major chemical company based in Germany. In 2001, BASF was a leading producer of APIs for generic suppliers. In relation to paroxetine, BASF and its subsidiary Knoll were involved in developing paroxetine API. During the Relevant Period, BASF supplied paroxetine API directly to IVAX and Hexal and indirectly to Alpharma, through Delta Ltd ('Delta').

3.18 Between 2001 and 2003, BASF was involved in litigation with GSK. In particular BASF petitioned that GSK's Anhydrate Patent (as described and defined at paragraph 3.119 of this Decision) be revoked on 1 July 2001, with that action (the 'BASF Litigation') subsequently being joined to the GUK Litigation (as described and defined at paragraph 3.129 of this Decision).⁴³ BASF argued that certain claims in GSK's patent were invalid on the grounds that the inventive step was obvious.⁴⁴ BASF was successful in arguing that some of GSK's patent claims were invalid and the patent was subsequently amended. This litigation is discussed further in paragraphs 3.116 to 3.136.

3.19 BASF subsequently reached a worldwide settlement with GSK in relation to paroxetine in 2005.⁴⁵

d) Apotex, Neolab and Waymade

3.20 Apotex is a large chemical company based in Canada. Neolab Limited ('Neolab') and Waymade Healthcare Plc ('Waymade') are independent generic distributors based in the UK.

3.21 Apotex developed and intended to launch its paroxetine product in the UK, prior to it being injuncted from entry by the High Court in November 2002. Apotex, alongside Neolab and Waymade, was later successful in arguing before the High Court and the Court of Appeal that Apotex's paroxetine

⁴² See email from [the Company Secretary] of Tillomed to the OFT dated 12 September 2012 (document 2305): in 2001, Hexal owned 50% of Tillomed Holdings Limited which owned 100% of Tillomed; since 3 April 2006, there has been no formal relationship between Tillomed and Hexal.

⁴³ Part two of the response dated 4 May 2012 to the Section 26 Notice dated 23 March 2012 sent to GSK ('GSK Second Response, Part Two') (document 0734), paragraph 5.7.

⁴⁴ Section 3 of the Patents Act 1977 provided that an invention involved an inventive step if it was not obvious to a skilled person '*having regard to any matter which formed part of the state of the art*'. See *BASF AG v SmithKline Beecham Plc* [2002] EWHC 1373 (Ch).

⁴⁵ BASF's response dated 16 August 2012 to the OFT's informal request for information dated 26 July 2012 (document 2185).

anhydrate product did not infringe valid patent claims held by GSK.⁴⁶ Following the High Court's judgment in December 2003, Neolab and Waymade began supplying paroxetine in the UK, leading to the introduction of true generic competition and significant reductions in the prices for paroxetine in 2004.

B. The product – paroxetine

i) *Paroxetine characteristics*

3.22 Paroxetine is the international non-proprietary name of an antidepressant molecule. In the Relevant Period, GSK marketed paroxetine under the brand name Seroxat in the UK as tablets of 20mg and 30mg in packs of 30 tablets and as an oral liquid 20mg formulation.⁴⁷ It was indicated for the treatment of the following conditions, some of which were added during the Relevant Period:

- depression and depression accompanied by anxiety;
- obsessive compulsive disorder;
- panic disorder with or without agoraphobia;
- social anxiety disorder or social phobia;
- general anxiety disorder; and
- post-traumatic stress disorder.⁴⁸

3.23 For these indications, paroxetine was primarily prescribed by GPs in primary care. However, it was sometimes prescribed by specialists, mainly psychiatrists, in hospitals.⁴⁹

⁴⁶ See *SmithKline Beecham Plc and others v Apotex Europe Ltd and others* [2003] EWHC 2939 (Ch); *SmithKline Beecham Plc and others v Apotex Europe Ltd and others* [2004] EWCA Civ 1568. See paragraphs 3.135–3.136 for further details of the progression of that litigation.

⁴⁷ GSK submitted to the OFT that '20mg and 30mg tablets were not substitutable other than in very limited circumstances': GSK submission to the OFT dated 21 September 2012, 'Response to OFT's analysis of GSK's Customer price reduction paper' (document 0783), paragraph 3.4.

⁴⁸ See witness statement of [GSK's Finance Director A] in the GUK Litigation, dated 25 September 2001 ('[GSK]WS1 (GUK)') (document 0885), paragraph 2.4. See also GlaxoSmithKline Plc Annual Report 2001 dated 28 March 2002 (document 2592) page 8.

⁴⁹ In the UK, the vast majority of paroxetine was prescribed by GPs and approximately a third was prescribed by psychiatrists. For example, sales to hospitals accounted for approximately 2.9% of GSK's sales by value in 2002 (calculated based on the response dated 31 August 2012 to the Section 26 Notice dated 3 August 2012 sent to GSK (document 0772)).

3.24 Paroxetine in itself cannot be applied as a medicine; it first needs to be transformed into a salt (that is, combined with an acid). Paroxetine hydrochloride can be produced in three main salt forms: anhydrate, hemihydrate and mesylate.⁵⁰ All three forms of paroxetine are therapeutically equivalent.

ii) Types of antidepressant medicines

3.25 There were four major classes of antidepressant medicines available for prescription during the Relevant Period:⁵¹

- monoamine oxidase inhibitors ('MAOIs');
- tricyclic antidepressants ('TCAs');
- selective serotonin re-uptake inhibitors ('SSRIs'), including paroxetine; and
- serotonin norepinephrine re-uptake inhibitors ('SNRIs').

3.26 These antidepressants can be divided into two generations:

- MAOIs and TCAs are generally referred to as first generation antidepressants. MAOIs were the first type of antidepressant to be developed and were introduced in the 1950s. TCAs were the next type of antidepressants to be introduced.
- SSRIs and SNRIs, which became available in the UK in the 1990s, are referred to as second generation antidepressants. A market report from 2004 notes that '*[t]he introduction of the SSRIs in the late 1980s radically changed the treatment of MDD [Major Depressive Disorder] worldwide and SSRIs have emerged as the first-line treatment for depressive disorders (Vaswani et al., 2003).*'⁵²

3.27 Aside from paroxetine, other SSRIs sold in the Relevant Period in the UK included citalopram (Lundbeck's brand Cipramil), escitalopram (Lundbeck's brand Cipralex), fluoxetine (Eli Lilly's brand Prozac), fluvoxamine (Solvay's

⁵⁰ [REDACTED] Finance Director [A] of GSK, stated '*the anhydrate and hemihydrate are therapeutically equivalent and are to all intents and purposes interchangeable. In particular, a prescription for "Paroxetine" is not likely to specify the form, and can be fulfilled by either the anhydrate or the hemihydrate form.*' [REDACTED]WS1 (GUK) (document 0885), paragraph 2.2.

⁵¹ World Health Organization (WHO) ATC third-level class N06A, European Pharmaceutical Market Research Association ('EPhMRA') ATC category N6A and the British National Formulary guidelines 2001 (BNF guidelines) (document 2505), Antidepressant drugs, section 4.3. See tables at Annex N. See also 'Seroxat/Paxil Global 3/1 Product Plan (2001/2003)' dated April 2000 (document 0118), page 7 and (document 0119), page 62.

⁵² Datamonitor, Commercial Insight: Antidepressants, February 2004, Reference Code: DMHC1942, page 26.

brand Fevarin) and sertraline (Pfizer's brand Lustral). Venlafaxine (Pfizer's brand Effexor) was an SNRI sold in the Relevant Period.⁵³

3.28 The modes of action, prescribing guideline recommendations and side effect profiles of the different antidepressant classes and molecules are presented below. The level of substitutability between these medicines is considered in Part 4.

a) Modes of action

3.29 According to a GSK internal document, paroxetine is believed to operate in the following manner:⁵⁴

'The efficacy of Paroxetine [...] is presumed to be linked to potentiation of serotonergic activity in the CNS [Central Nervous System] resulting from inhibition of neuronal reuptake of Serotonin (5-hydroxy tryptamine, 5-HT). Studies at clinically relevant doses in humans have demonstrated that Paroxetine blocks the uptake of Serotonin into human platelets.'

3.30 More generally, antidepressants work by increasing the levels of chemicals called neurotransmitters, such as serotonin or noradrenaline, in the brain. Since neurotransmitters play a role in mood regulation and control, and low levels of neurotransmitters are sometimes associated with depression, correcting these imbalances is considered to have an important effect on mood.⁵⁵

3.31 However, antidepressants have different modes of action, depending on whether they act to prevent the re-uptake of neurotransmitters or to increase them.

3.32 In the first category, those acting to prevent the re-uptake of neurotransmitters, the mode of action differs based upon the neurotransmitter targeted (serotonin, noradrenaline, monoamine) and whether the inhibitors are selective or not. The following groups are included in this category:

- SSRIs, which work by inhibiting the re-uptake of serotonin in the brain.

⁵³ Venlafaxine is listed as an SNRI in the EPhMRA ATC classification system, but is under the category 'other antidepressants' in both the WHO ATC classification and the BNF guidelines.

⁵⁴ See GSK internal paroxetine report entitled 'Integrated Project Plan, Paroxetine/Paxil/Seroxat' dated 2 August 2002 (document 0301), page 10.

⁵⁵ See www.nhs.uk/Conditions/Antidepressant-drugs/Pages/How-do-they-work.aspx.

- SNRIs, which act upon two neurotransmitters in order to provide a more clinically effective antidepressant than SSRIs.
 - Non-selective monoamine re-uptake inhibitors (for example, TCAs), which work by preventing the absorption of serotonin and norepinephrine and partially inhibiting the reabsorption of dopamine in the brain.
 - Selective and non-selective MAOIs, which work by preventing the breakdown of all monoamine neurotransmitters including serotonin and norepinephrine in the brain.
 - Most antidepressants that do not fit neatly into the categories above work in similar ways to one or more of these groups.
- 3.33 The second category, those acting to increase re-uptake of neurotransmitters, includes medicines whose modes of action are slightly differentiated. For example, agomelatine works by acting as a disinhibitor and tryptophan works by increasing the level of neurotransmitters.
- 3.34 Most mood stabilisers are anticonvulsants and therefore have a distinct mode of action to other antidepressants. There is controversy about the exact mode of action of herbal antidepressants such as St. John's Wort.

b) Side effects

- 3.35 During the Relevant Period, side effects differed between different antidepressant classes, and between different antidepressant molecules within classes, for example:
- According to the British National Formulary ('BNF') guidelines: '*SSRIs have fewer antimuscarinic side-effects than the older tricyclics and they are also less cardio-toxic in overdose [...] SSRIs do, however, have characteristic side-effects of their own; gastro-intestinal side-effects such as nausea and vomiting are common.*'⁵⁶
 - The World Federation of Societies of Biological Psychiatry ('WFSBP') guidelines noted that '*Antidepressants differ in their side effect profile, potential to interact with other drugs and safety in overdose.*'⁵⁷

⁵⁶ BNF guidelines (document 2505), Antidepressant drugs, section 4.3.

⁵⁷ World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Unipolar Depressive Disorders, Part 1: Acute and Continuation Treatment of Major Depressive Disorder 2013, WFSBP Guidelines for Biological Treatment of Unipolar Depressive Disorders, Part 1: Acute and Continuation Treatment of Major Depressive Disorder 2002 (document 2507), page 5–43.

- Further information on specific differences in side effects is presented in Annex O.

c) Prescribing guidelines

- 3.36 This sub-section considers the position of paroxetine within the relevant classification systems during the Relevant Period, and then presents therapeutic uses as set out in the prescribing literature, for the different antidepressant classes and molecules.
- 3.37 The CMA has consulted the Anatomical Therapeutic Chemical ('ATC') classification system, which is recognised and used by the European Pharmaceutical Market Research Association ('EPHRA'), and the corresponding system maintained by the World Health Organization ('WHO'). The CMA has also referred to the relevant paragraphs of the BNF guidelines. The classification systems indicate that paroxetine belongs to the 'Antidepressants' class (WHO ATC N06A, EPHRA ATC N6A, BNF section 4.3), along with other SSRIs, tricyclic medicines, MAOIs and SNRIs.⁵⁸ However, while in all three classification systems SSRIs constitute one sub-class, at the next level SSRIs do not belong to the same category as other antidepressants:
- In the EPHRA ATC classification system antidepressants are listed together with mood stabilisers in the N6A class ('Anti-depressants and Mood stabilisers'). Paroxetine belongs to the subgroup N6A4 ('Selective Serotonin Reuptake Inhibitors (SSRIs) antidepressants'). SNRIs such as venlafaxine are listed in the N6A5 class. Tricyclic antidepressants as well as MAOIs are listed in the 'antidepressants, all others' N6A9 class. The other two classes include herbal antidepressants (N6A2) and Mood stabilisers (N6A3).
 - In the WHO ATC system, antidepressants are listed as the third-level class N06A ('Antidepressants'). Paroxetine belongs to the fourth-level class N06AB which only includes SSRIs. Other antidepressants are divided at this level between the four remaining classes, which are 'Non-selective monoamine reuptake inhibitors' (N06AA), 'MAOIs, non-selective' (N06AF), 'MAOIs' (N06AG) and 'Other antidepressants' (N06AX).
 - In the BNF guidelines, antidepressants are covered in section 4.3, within which there are four sub-sections. Paroxetine belongs to sub-section 4.3.3 ('Selective serotonin re-uptake inhibitors (SSRIs)'). Other antidepressants

⁵⁸ See also tables at Annex N.

are divided between the remaining sub-sections, which are 4.3.1 ('Tricyclic and related antidepressant drugs'), 4.3.2 ('Monoamine-oxidase inhibitors (MAOIs)'), and 4.3.4 ('Other antidepressant drugs').

- 3.38 The primary guidelines available at the time providing information on therapeutic indications were the BNF guidelines on antidepressants.⁵⁹ In addition to the BNF guidelines, the CMA has also consulted other guidelines and articles that were available at the time and which provide advice on prescribing antidepressants.⁶⁰
- 3.39 In terms of recommendations over which antidepressants to prescribe, the WFSBP guidelines state '*[i]n general there are no clinically significant differences in efficacy and effectiveness between tricyclic antidepressants and SSRIs*' and that '*[t]here is no decisive evidence that any class of antidepressants is more efficacious or has a more rapid onset than another, although there may be slight differences for clinical subtypes.*'⁶¹ The WFSBP guidelines also state that '*[a]lthough robust differences in tolerability, side effects and theoretical risk of drug-drug interactions are lacking, subtle differences exist and may be important in selecting the appropriate SSRI compound for the individual patient.*'⁶²
- 3.40 The Journal of Psychopharmacology guidelines state that '*Antidepressant drugs have similar efficacy for the majority of patients with major depression.*'⁶³
- 3.41 The BNF guidelines note that '*[e]ither tricyclic and related antidepressants or [SSRIs] are generally preferred because [MAOIs] may be less effective and show dangerous interactions with some food and drugs.*'⁶⁴
- 3.42 It also states that '*[a]lthough SSRIs appear to be better tolerated than older medicines, the difference is too small to justify always choosing an SSRI as*

⁵⁹ BNF guidelines (document 2505), Antidepressant drugs, section 4.3. Although more recent BNF guidelines exist which may provide different advice, we have referred to the March 2001 guidelines because they fall within the period of the Agreements (2001–04) and therefore represent the information available to prescribers during the Relevant Period.

⁶⁰ In particular, the CMA has consulted the WFSBP Guidelines (see footnote 57), Evidence-based guidelines for treating depressive disorders with antidepressants: a revision of the 1993 British Association for Psychopharmacology guidelines 2000, 14:3 (document 2506) and The South London and Maudsley NHS Trust Prescribing Guidelines 2001 ('Maudsley Guidelines') (document 3255).

⁶¹ WFSBP Guidelines for Biological Treatment of Unipolar Depressive Disorders, Part 1: Acute and Continuation Treatment of Major Depressive Disorder 2002 (document 2507), pages 7 and 16.

⁶² WFSBP Guidelines for Biological Treatment of Unipolar Depressive Disorders, Part 1: Acute and Continuation Treatment of Major Depressive Disorder 2002 (document 2507), page 15.

⁶³ Evidence-based guidelines for treating depressive disorders with antidepressants: a revision of the 1993 British Association for Psychopharmacology guidelines 2000 (document 2506), page 8.

⁶⁴ BNF guidelines (document 2505), Antidepressant drugs, section 4.3.

first-line treatment and that SSRIs are *'no more effective'* than older antidepressants. The BNF guidelines do however acknowledge that side effects may have been an issue for some patients in the case of older tricyclic antidepressants, in which case *'an SSRI or one of the newer classes of antidepressants may be appropriate'*.⁶⁵

3.43 The Maudsley Guidelines indicate that the starting point for prescribing drugs for the treatment of depression is to *'[g]ive an antidepressant'*.⁶⁶ The guidelines also recommend that an SSRI should be used as a first line pharmacological treatment, after cognitive behaviour therapy, for certain anxiety disorders (panic disorder, social phobia or social anxiety disorder and obsessive compulsive disorder). The use of an SSRI or other alternative drugs is recommended for generalised anxiety disorder (an SSRI or SNRI) and post-traumatic stress disorder (an SSRI or nefazodone or venlafaxine).⁶⁷

3.44 In terms of specific recommendations, the WFSBP guidelines note the following:⁶⁸

'There is evidence that some tricyclic antidepressants (TCAs) (amitryptiline and clomipramine), and venlafaxine are more effective than SSRIs in severely depressed, hospitalized patients.'

'Depressed patients with atypical features particularly benefit from the irreversible monoamine oxidase inhibitors (MAOIs).'

'Second and third generation ("newer") antidepressants (e.g., SSRIs, mirtazapine, nefadozone, reboxetine and venlafaxine) are generally better tolerated than the first generation ("older") TCAs and tetracyclic antidepressants, and are less likely to be discontinued.'

3.45 The Journal of Psychopharmacology guidelines note that *'Newer antidepressants are better tolerated than older TCAs and are safer in overdose'* and *'[v]enlafaxine, at a dose of 150mg or greater, may be more effective than SSRIs for major depression of at least moderate severity'*.⁶⁹

⁶⁵ BNF guidelines (document 2505), Antidepressant drugs, section 4.3.

⁶⁶ Maudsley Guidelines (document 3255) page 59.

⁶⁷ Maudsley Guidelines (document 3255), Part IV – Treatment of Anxiety.

⁶⁸ WFSBP Guidelines for Biological Treatment of Unipolar Depressive Disorders, Part 1: Acute and Continuation Treatment of Major Depressive Disorder 2002 (document 2507), page 7.

⁶⁹ Evidence-based guidelines for treating depressive disorders with antidepressants: a revision of the 1993 British Association for Psychopharmacology guidelines 2000 (document 2506), page 9.

3.46 In recommending how physicians should decide which formulation to prescribe to a particular patient, the various guidelines available during the Relevant Period made recommendations as follows:

- BNF guidelines recommended '*Choice of antidepressant should be based on the individual patient's requirements, including the presence of concomitant disease, existing therapy, suicide risk, and previous response to antidepressant therapy.*'⁷⁰
- The Journal of Psychopharmacology guidelines recommended considering the following factors in choosing an antidepressant:⁷¹

- '- *previous treatment response to a particular drug..*
- *tolerability and adverse effects of a previously given drug..*
- *likely side-effect profile (e.g. sedation, weight gain)..*
- *low lethality if history or likelihood of overdose..*
- *concurrent physical illness or condition that may make the antidepressant noxious or less well-tolerated..*
- *concurrent medication that may interact with the antidepressant drug..*
- *associated psychiatric disorder that may specifically respond to a particular class of antidepressant (e.g. obsessive compulsive disorder and serotonin reuptake inhibitors)..*
- *patient preference..'*

- WFSBP guidelines recommended that '*[c]hoosing an antidepressant depends on various factors that should be considered: prior experience with medication (response, tolerability, adverse effects), concurrent medical conditions and concomitant use of nonpsychiatric medications, a drug's short and long-term side effects, atypical features of the depressive episode, clinical subtype of depression, physician's experience with the medication, patient's history of adherence to medication, history of first-*

⁷⁰ BNF guidelines (document 2505), Antidepressant drugs, section 4.3.

⁷¹ Evidence-based guidelines for treating depressive disorders with antidepressants: a revision of the 1993 British Association for Psychopharmacology guidelines 2000 (document 2506), page 10.

*degree relatives responding to a medication, patient preferences, and the cost and availability of specific antidepressants.'*⁷²

C. The process and benefits of generic competition

i) Introduction

3.47 This Section begins with an overview of the lifecycle of a medicine, and goes on to consider the process of generic competition and its potential benefits.

ii) The lifecycle of a medicine

3.48 The Commission's Pharmaceutical sector inquiry (the 'Sector Inquiry')⁷³ described the lifecycle of a pharmaceutical product as constituting three main phases: (i) the Research and Development ('R&D') phase up to market launch; (ii) the period between launch and loss of exclusivity (patent expiry); and (iii) the period following the loss of exclusivity, when generic products can enter the market.

3.49 During the first phase, originator companies seek to ensure that they obtain maximum patent protection for the output of their R&D efforts.

3.50 During the second phase, following the launch of the product, the manufacturer looks to generate sufficient revenue from the medicine to cover its R&D costs and to earn a profit, before the medicine becomes subject to competitive pressure from generic equivalents. It is, therefore, often in the interests of manufacturers to prolong and maximise this phase, and to carry out strategies known as 'lifecycle management' to extend the period of market exclusivity. An example would be to carry out further R&D, known as 'incremental innovation', with a view to improving the medicine or finding new uses for it and filing resulting associated 'secondary patent' applications.⁷⁴ This is described in internal GSK documents, as it relates to paroxetine, as follows:⁷⁵

'The philosophy within the group responsible for paroxetine is to patent every possible process, compound, form, aspect of the product, its

⁷² WFSBP Guidelines for Biological Treatment of Unipolar Depressive Disorders, Part 1: Acute and Continuation Treatment of Major Depressive Disorder 2002 (document 2507), page 7.

⁷³ Sector Inquiry Final Report.

⁷⁴ See, for example, GSK's strategy to establish new indications referred to in 'Seroxat/Paxil Global 3/1 Product Plan (2001/2003)' dated April 2000 (documents 0118 and 0119).

⁷⁵ See extract from GSK internal report dated 12 March 2001 (document 0107), paragraph 4.2. This is consistent with a GSK internal paroxetine report entitled 'Integrated Project Plan, Paroxetine/Paxil/Seroxat' dated 2 August 2002 (document 0301), page 12, in which it is noted that one of GSK's stated strategies for its lifecycle management of paroxetine was to '[d]evelop line extensions and indications in order to protect the brand from generic and competitor erosion'.

production and its alternatives and derivatives which could conceivably provide some form of protection to Seroxat/Paxil. The success of this group is demonstrated by the expectation of additional years of exclusivity after basic patent expiry.

[...]

To date patents have been filed on the compound per se, primary manufacturing processes, secondary manufacturing processes, formulations, tablet designs, and Seroxat/Paxil therapeutic uses. In future, patentable opportunities will be sought and pursued whenever additional protection can be obtained and competitive barriers raised.'

3.51 During this second phase, GSK engaged in legal challenges which a GSK internal document explained could be used 'to prevent/delay' generic entry.⁷⁶ This Decision is concerned with one aspect of this strategy.

3.52 In the third phase, manufacturers of generic medicines will, subject to restrictions around data exclusivity,⁷⁷ have the opportunity to apply for MAs⁷⁸ for generic equivalents of the branded medicine and, if successful, can then market them.

iii) Competition between branded medicines

3.53 When only a branded version of a medicine is available, manufacturers of therapeutically substitutable medicines often compete with each other by seeking to influence GPs' prescribing behaviour. This is achieved through expenditure on marketing aimed at increasing GPs' awareness of a medicine's attributes, including its approved indications, effectiveness and side effects. For example, [X]GSK's Marketing Manager [A] for Seroxat, described GSK's marketing efforts in relation to Seroxat in 2001 as follows:

*'Marketing of SEROXAT, as with other prescription medicines, is primarily done by sales forces of medical representatives, responsible for "detailing" hospital consultants and general practitioners. Detailing involves educating doctors using information about the performance of a product, and, where appropriate, new approved indications.'*⁷⁹

⁷⁶ GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100).

⁷⁷ See paragraphs 3.90–3.92.

⁷⁸ See paragraphs 3.85–3.89.

⁷⁹ [X]WS (document 0150), paragraph 3.1.

- 3.54 Increasing brand awareness is particularly important to branded manufacturers, since, as noted in paragraph 3.95, doctors do not tend to be aware of the price of competing medicines, and primarily prescribe based on factors other than price. Therefore, marketing is an important way to influence prescribing, and one of the main ways in which GPs become aware of new medicines (see paragraph 3.94).
- 3.55 Therefore, prior to generic entry, branded manufacturers compete to some extent through the sums they spend on marketing. For example, [GSK's Marketing Manager A for Seroxat] noted that *'for promotion to be effective it has to be noticed, and to be noticed it has to be comparable in level to that undertaken by SEROXAT's competitors'*.⁸⁰
- 3.56 The CMA notes that while doctors may not choose which medicine to prescribe based on prices (or indeed have limited awareness of the prices of different pharmaceutical products), their prescribing behaviour may nevertheless be indirectly informed by price insofar as they are increasingly encouraged to follow prescribing guidelines (for example, through use of pre-approved formularies) and to meet certain budgetary objectives at local level (as well as to prescribe generic (rather than branded) products).
- 3.57 Once generic competition has emerged, marketing expenditure generally ceases to be as valuable for a branded manufacturer,⁸¹ as marketing spending would benefit both the branded manufacturer and generic suppliers.⁸²

iv) Competition between branded and generic medicines

- 3.58 After patent expiry, GPs are encouraged to prescribe generically where possible (see paragraphs 3.96 to 3.99), and pharmacies are typically incentivised (through higher margins) to dispense the cheapest applicable medicine.⁸³ Where GPs provide an open prescription, that is, where the

⁸⁰ [X]WS (document 0150), paragraph 4.6.

⁸¹ The differences between generic competition and competition between branded manufacturers were noted by [X], an independent industry consultant who provided evidence for GSK in paroxetine patent litigation, in the witness statement of [GSK's independent expert] in the GUK Litigation, dated 13 September 2001 ('[X] WS') (document 0143), paragraph 12 as follows: *'Generic marketing differs from brand marketing in two main respects: firstly, generics gain market share by price cutting, provided doctors can be induced to prescribe generically; secondly, the majority of cut-price generics are unbranded and are not promoted to doctors, only to pharmacists in order to persuade them to stock the generic competitor's product.'*

⁸² For example, GSK's [Marketing Manager A for Seroxat] noted that: *'In the face of generic competition there is automatically a dilution of the effect of marketing on the level of sales achieved, so that the marketing expenditure benefits the generic companies as much as it benefits SB.'* ([X]WS, (document 0150), paragraph 4.6).

⁸³ For each product dispensed against a generic prescription, pharmacies would be reimbursed at the Drug Tariff price rather than the Pharmaceutical Price Regulation Scheme ('PPRS') price (see paragraphs 3.100–3.102 for further details).

prescription refers to the generic name of a product, rather than to a particular brand, pharmacies are free to choose to dispense either a relevant generic product or the relevant originator medicine. Under this scenario, manufacturers have an incentive to engage in strong price competition in order to encourage pharmacies to dispense their products and ‘true generic competition’ can be said to exist.

v) *The benefits of generic competition*

3.59 The process of generic competition is expected to lead to lower prices and reduced market shares for the branded supplier in the following way:

- Where a therapeutically equivalent generic product is available, pharmacies are able to dispense either a generic or a branded product against open prescriptions.
- Where pharmacies can choose whether to dispense a branded or a generic medicine, they have a strong incentive to dispense the cheapest medicine available.
- The first generic entrant would therefore seek to lower prices by a sufficient margin to compensate pharmacies for stocking a generic product alongside the branded product. In doing so, the first generic entrant would be expected to capture a significant volume of sales from the branded supplier.⁸⁴
- Subsequent generic entrants would have an incentive to engage in strong price competition in order to encourage pharmacies to dispense their products. As a result, prices would be competed down even further, with more pharmacies switching away from the branded supplier for their supply.

3.60 The Sector Inquiry reports that the average time to generic entry after patent expiry is about 13 months,⁸⁵ although it takes less time for high value products to be faced with generic entry (for example, for the highest value products the average time before generic entry (on a weighted value basis) was only about

⁸⁴ [The Finance Director A] of GSK noted in a witness statement in the GUK Litigation that a generic entrant initially makes a high volume of sales: *‘It is well known in the industry that wholesalers and retail chains run down their stocks of branded product (including parallel imports) in anticipation of the launch of generic products, and as a result, the initial sales of generic products tend to be disproportionately high.’* Second witness statement of [GSK’s Finance Director A] in the GUK Litigation, dated 20 October 2001 (‘[REDACTED]WS2 (GUK)’) (document 0182), paragraph 6.4.

⁸⁵ When this analysis is adjusted to weight the medicines in relation to their sales levels in the year before loss of exclusivity, the average drops to just under eight months (Sector Inquiry Final Report, paragraph 192).

four months).⁸⁶ Moreover, the time taken for generic entry in the UK is relatively short in comparison with other EU Member States.⁸⁷

- 3.61 On average⁸⁸ in the EU, about four to five generic entrants are typically present in the market one year after the loss of exclusivity, and the number of firms entering increases with the value of the product in question. Within three years of the loss of exclusivity the ratio of generic suppliers to originators is about 6:1. The ratio is likely to be higher in the case of high value products than it is with other lower value products.⁸⁹
- 3.62 The enhanced competition leads, on average, to considerable price declines both for branded and generic medicines, as demonstrated by the following examples.
- In the EU, generic medicines typically come onto the market at prices that are about 25% lower than the price of the originator product immediately prior to the loss of exclusivity.
 - Generic entry also has the effect of decreasing the price of the originator product. In markets where generic entry occurs, average prices drop by almost 20% one year after the loss of exclusivity and about 40% after two years.⁹⁰ In some cases the decrease can be as much as 80-90%.⁹¹ Such reductions can lead to significant savings to public healthcare systems. In markets where generic medicines become available, the average EU saving to the health system (as measured by the development of a weighted price index of originator and generic products) is almost 20% one year after the first generic entry, and about 25% after two years.⁹²
 - In the UK, in the period 2000-04 the average (weighted by sales) price reduction for a medicine in the UK one year after generic entry was 15%.⁹³ The same report found that for the period 2004-06, the average (weighted by sales) price reduction for a medicine in the UK one year after generic entry had risen to 42%.

⁸⁶ Sector Inquiry Final Report, paragraph 193.

⁸⁷ Sector Inquiry Final Report, paragraph 194. The average time in the UK is just under four months whereas it exceeds six months in many EU Member States.

⁸⁸ On the basis of an average weighted by product value.

⁸⁹ Sector Inquiry Final Report, paragraphs 201–202.

⁹⁰ Sector Inquiry Final Report, Executive Summary, section 2.1.2.

⁹¹ Sector Inquiry Final Report, paragraph 212.

⁹² Sector Inquiry Final Report, Executive Summary, section 2.1.2.

⁹³ Report entitled 'Competition in the off-patent market post generic entry', CRA International, September 2008; report prepared for Baker & McKenzie CVBA/SCRL, Page 40, Figure 16: 'The impact of generic entry 2000-2003 vs. 2004-2007 in UK' (cited data source: Intercontinental Medical Statistics ('IMS') and CRA analysis).

- 3.63 [X], an expert witness appointed by GSK in 2001 in the GUK Litigation, expected generic entry to cause a significant price fall for paroxetine. In particular, [GSK's independent expert's] expectation, based on four case studies, was that⁹⁴ *'generics will probably undercut the pre-generic price of Seroxat by around 30% within 6 months of launch, by 45 to 50% after 12 months and by 60% after 24 months.'*⁹⁵

D. Regulatory framework

- 3.64 This Section considers the regulatory framework relevant to competition in the pharmaceutical sector during the Relevant Period. It sets out: (i) an introduction to patents and UK patent law as it applied in the Relevant Period specifically in relation to the pharmaceutical sector;⁹⁶ (ii) the rules relating to MAs for bringing pharmaceutical products to market; (iii) the prescribing framework for new pharmaceutical products; (iv) the rules, guidelines and processes relevant to GP prescribing; (v) the rules, guidelines and processes relevant to pharmacy dispensing; and (vi) the regulatory pricing mechanism relevant to branded medicines and generic medicines.

i) Patents

- 3.65 A patent is a legal right protecting an invention, which can be a product or a process.⁹⁷ Where the subject matter of the patent is a product, the patent grants its proprietor the right to prevent third parties from making, using, offering for sale, selling or importing for these purposes the product without the proprietor's consent.⁹⁸ Where the subject matter of the patent is a process, the patent grants its proprietor the right to prevent third parties from using the process or from using, offering for sale, selling or importing for these purposes at least the product obtained directly by that process.⁹⁹

- 3.66 In order to incentivise innovation, patent law gives the patent holder a period of exclusivity in which it can exercise control over the commercial exploitation of the invention; that period is 20 years in the UK and the European Economic

⁹⁴ [X]WS (document 0143), paragraph 20.

⁹⁵ The CMA also notes that GSK used the generic entry of fluoxetine as an example in its internal modelling of the potential impact of generic entry on paroxetine anhydrate, suggesting for example that a loss in market share of 60 to 80% over the first few months might be observed. (Email from [GSK's Marketing Manager A for Seroxat] to [GSK Group Director (Global Market Access)], 'Generic Competition' dated 5 January 2001 (document 0122)).

⁹⁶ The CMA has used the present tense to describe the regulatory framework as it applied in the Relevant Period. This is because the legal framework as it applied in the Relevant Period remains applicable to date.

⁹⁷ World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (the 'TRIPS Agreement'), Article 27(1).

⁹⁸ TRIPS Agreement, Article 28(1)(a).

⁹⁹ TRIPS Agreement, Article 28(1)(b).

Area (EEA), although that can be extended for a further five years through a Supplementary Protection Certificate ('SPC').¹⁰⁰ Commercial exploitation includes the originator's production and marketing of products based on the invention and the originator's granting of licences to third parties allowing the latter to use the invention, usually in return for royalty payments.

Patents in the pharmaceutical sector

- 3.67 During the period of exclusivity,¹⁰¹ the patent holder may be able to charge a price for the medicine resulting from the invention that is far higher than its marginal cost of production. This allows the originator company to recoup the significant investment it makes in the R&D of new medicines (not just the particular product that is being successfully marketed, but also numerous projects that never reach the marketing stage). The length of this period of exclusivity reflects a balance between the cost to society of continued patent protection, in the form of extra profits to the originator company from its exclusive position, and the benefits to society in the form of innovation.¹⁰²
- 3.68 Once the patent or SPC period has expired and the API is no longer protected, that API can, in principle, be used by generic pharmaceutical suppliers to produce and sell generic medicines containing the identical API in question. It should be noted, in this respect, that the original patent application covering the compound must also indicate how the invention can be reproduced, that is, in the case of APIs how the active ingredient can be produced.¹⁰³ The right of society to freely reproduce the invention after patent expiry is what society gains in return for guaranteeing the inventor an initial period of exclusive use. Patent protection for the original production method of the API therefore normally expires at the same time as the protection for the API itself. From that moment on, the market is in principle open for entry of generic versions of the API concerned.
- 3.69 As long as patent or SPC protection for the API exists, it will normally not be possible for a generic supplier to enter the market with a medicine containing

¹⁰⁰ An SPC is a form of Intellectual Property that extends the protection of patented active ingredients present in pharmaceutical or plant protection products in order to compensate for the delays associated with obtaining regulatory approval for products.

¹⁰¹ Referred to in paragraph 3.66 as being from the moment the patent holder (or 'originator' in the pharmaceutical industry) has obtained an MA for a medicinal product to the expiry of the SPC (or of the patent if no SPC was granted).

¹⁰² This balance is also referred to in Commission Regulation (EC) No 1610/1996 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a SPC for plant protection products, OJ L 198 of 08.08.1996, recital 10.

¹⁰³ Patents Act 1977, section 14(3).

the compound concerned without causing an infringement of the patent; that is, unless a generic supplier proves that the patent is invalid.

- 3.70 In addition to what are sometimes known as primary patents over the API, it is also common for originator companies to apply for other patents (often called secondary patents) – for example in respect of new manufacturing processes to produce the API.¹⁰⁴ As a result, secondary patents may extend the overall protection provided by patents for a particular medicine.¹⁰⁵
- 3.71 Therefore, even after the primary patent has expired, intellectual property obstacles for generic suppliers can still arise, in particular if patents, usually belonging to the originator company, are still in force that cover different production methods of producing the compound which itself is no longer patent protected.¹⁰⁶ It may be the case, for instance, that the production method disclosed in the original patent application is sufficient to reproduce the API in a laboratory, but is unsuitable to industrial production on a large scale. In that case, the originator company may have obtained additional secondary patents in developing an efficient industrial production method for the API. If a production method was still under the protection of a valid patent and such a production method were used by a generic supplier to produce the compound that was no longer patent protected, the generic supplier would still be committing a patent infringement of the process concerned and as a result could be legally stopped from making or selling the product resulting from that process.
- 3.72 Generic suppliers are, on the other hand, free to develop another production method for the product that is not patent protected. Much of the development work of generic suppliers is therefore focussed on 'inventing around' other existing secondary patents of the originator company concerned. If a generic supplier succeeds in inventing a new production process it may apply for a patent for that process. Alternatively, the generic supplier may challenge the validity of a secondary patent. In order to prove that a patent should not be regarded as valid, the challenger is required to demonstrate that, for instance,

¹⁰⁴ Patent law does not make a distinction between 'primary' and 'secondary' patents, and patents need to be evaluated on the basis of the statutory patentability criteria, not on the basis of the stage in which applications are made. The notion of 'secondary patent' should therefore not be understood to mean that these patents are of a lower quality or value, but merely that – from a time perspective – they follow the primary patent. Secondary patents may concern new forms, formulations, particle sizes, dosage regimes, delivery modes or medical uses of the API.

¹⁰⁵ A medicine or medicinal product which is administered to patients will comprise the product or API and a variety of other components, often referred to as excipients, which make the medicine digestible, improve its taste, solubility, appearance etc.

¹⁰⁶ Patents Act 1977, section 72.

the patent is not 'new' or 'inventive'.¹⁰⁷ Such challenges are also an important part of the competitive process between originator and generic suppliers and have benefits to society in potentially eliminating unmerited patents that form an unjustified obstacle to effective competition in the market for the compound concerned. Indeed, this principle was recognised by the Court of Justice ('CJ') in Case C-193/83, *Windsurfing International v Commission*:¹⁰⁸

'...it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error.'

- 3.73 The generic supplier may also seek a declaration of non-infringement by writing to the patent holder or, if the patent holder refuses or fails to respond, by applying to the IPO or the Patent Court.¹⁰⁹
- 3.74 A further option is to launch a generic product 'at risk' of a claim of infringement by the originator company.¹¹⁰ When a generic supplier launches – or is about to launch – a generic product on the national market in a situation where the patent holder still holds a number of potentially relevant patents, the patent holder may react by initiating, or threatening to initiate, an action before the court for infringement of one or more of those patents against the generic supplier concerned as well as possibly against other companies involved in the production and marketing of the product.¹¹¹
- 3.75 In an infringement proceeding, the originator company may ask for an interim injunction to prevent (further) damage to its commercial interests.¹¹² In deciding whether to grant an interim injunction, the judge will consider whether the originator has an arguable case of infringement.¹¹³ The judge will also consider the adequacy of damages and the relevant harm caused to each party by the grant or refusal of such relief (also known as the balance of convenience). As a condition of an interim injunction being granted in England and Wales, the originator will usually be asked to offer a cross-undertaking in

¹⁰⁷ See Patents Act 1977, sections 72, 74, 77 and 89 which allow third parties to bring revocation proceedings in respect of UK patents before the UK courts or the Intellectual Property Office ('IPO'). See also European Patent Convention ('EPC'), Articles 99–105 which allow third parties to oppose a granted 'European' patent at the European Patent Office ('EPO') within nine months of grant to secure its limitation or revocation.

¹⁰⁸ Judgment in *Windsurfing International v Commission*, C-193/83, EU:C:1986:75, paragraph 92.

¹⁰⁹ Patents Act 1977, section 71.

¹¹⁰ An exclusive licensee can also initiate an action for infringement in its own name (Patents Act 1977, section 67).

¹¹¹ Patents Act 1977, sections 61 and 70.

¹¹² The originator company may ask for an interdict in Scotland.

¹¹³ *American Cyanamid Co (No 1) v Ethicon Ltd* [1975] UKHL 1. See also Corrigendum to Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of IP rights, OJ L 195, 02.06.2004, Article 9, pages 16 to 26. This gives judicial authorities of Member States the power to require the originator to provide reasonably available evidence that the originator is the right holder and that the applicant's right is being infringed, or that such infringement is imminent.

damages; this is an undertaking that the originator will compensate the generic supplier for any damages suffered as a result of the interim injunction, should the court find for the generic supplier after the final hearing.¹¹⁴

- 3.76 If an interim injunction is granted, the judge will order that the generic supplier must stop marketing its product until the main proceedings have been decided. The Sector Inquiry found that 112 of the 255 reported requests for interim injunctions made by originator companies in the EU from 2000–07 were granted.¹¹⁵ In these cases, 46% of the subsequent court proceedings ended in judgments or settlements that were favourable or appeared favourable to the generic supplier.¹¹⁶
- 3.77 In the main proceedings, the originator company may, apart from a finding of infringement, also ask for damages amongst other relief.¹¹⁷ As for the defending generic party, apart from arguing that the invoked patent has not been infringed, it can – and often does – also make a counterclaim that the invoked patent is invalid.¹¹⁸ The judge will then decide, first, whether interim measures are justified and secondly, in the main proceedings, whether the patent is valid and whether it has been infringed. As is the case with most litigation in the UK, costs tend to follow the event; that is, the successful party is entitled to recover a proportion of its costs from the losing party.¹¹⁹
- 3.78 A generic supplier that enters the market 'at risk' may have made a prior assessment that a relevant patent is invalid and/or not infringed. If this assessment is incorrect, the generic supplier stands to pay damages to the originator company for patent infringement. The Sector Inquiry found that the risk of paying such a sum, together with legal costs, was a major deterrent to generic suppliers seeking to enter the market.¹²⁰ On this basis, generic

¹¹⁴ See *SmithKline Beecham Plc and others v Apotex Europe Ltd and others* [2006] EWCA Civ 658. In *Wake Forest University Health Sciences and others v Smith & Nephew Plc and another* [2009] EWHC 45, a cross-undertaking was framed more widely, allowing customers of a pharmaceutical company to claim damages should a preliminary interim injunction be wrongly imposed. In Scotland, there is no separate requirement for the claimant to give a cross-undertaking for an interim interdict to be granted; however, it is a relevant factor when determining the balance of convenience.

¹¹⁵ See Sector Inquiry Final Report, figure 84, page 230. In the UK specifically, approximately six of the 17 reported requests for interim injunctions made by originator companies from 2000–2007 were granted.

¹¹⁶ Sector Inquiry Final Report, page 248. There is no UK specific data regarding the outcome of the subsequent court proceedings.

¹¹⁷ Patents Act 1977, section 61(1). Other remedies include a final injunction or interdict against continued infringement, an account of the profits derived from the infringement, an order for delivery up or destruction of infringing goods or a declaration that the patent is valid and has been infringed by the defendant. The latter is a precautionary measure, which can be used by the proprietor of the patent to secure a greater proportion of its legal costs in the event that another third party later challenges the patent's validity on the same grounds and loses.

¹¹⁸ Patents Act 1977, sections 60 and 74.

¹¹⁹ See for example *SmithKline Beecham Plc and others v Apotex Europe Ltd and others* [2004] EWCA Civ 1703.

¹²⁰ See Sector Inquiry Final Report, page 263.

suppliers would be expected to only enter a market 'at risk' where they have a sufficiently high degree of confidence that a court would find in its favour (should its entry be litigated by the relevant originator) and that its exposure to damages is therefore limited.

3.79 Before the courts, a patent right is often less certain than legal rights to physical objects, such as property. There are two main reasons for this:

- The first main reason relates to the very nature of a patent right: a patent is only merited if an invention has been made which is new, involves a genuine inventive step and is capable of industrial application.¹²¹ The requirement of novelty means that the claimed invention should not form part of the 'state of the art', which includes everything already made available previously to the public anywhere in the world. With the ever increasing size of patent and non-patent databases it is a challenge for patent offices to identify the entire relevant prior art¹²² and it is possible that relevant prior art will be missed.¹²³ In the UK and EEA, the difficulties facing patent offices may be exacerbated by the fact that there is no requirement for the applicant to disclose knowledge of prior art. Furthermore, the requirement of inventive step means that, having regard to the state of the art, the claimed invention should not be obvious to a person skilled in the art. Clearly, whether something should or should not be obvious to a skilled person can be a matter of debate and disagreement between experts.
- The second main reason for the relative uncertainty of patent rights lies in the two-step nature of the process for examining patent applications/patents. Essentially, the process for examining patent applications is an *ex parte* process, that is, a process between the applicant and the IPO only. Although third parties – such as (potential) competitors – have an opportunity to make written observations before the IPO makes a decision on the patent application, third parties do not have the right to discuss those observations with the IPO or the applicant before a decision on the application is taken. Nor is there at this stage a

¹²¹ Patents Act 1977, section 1(1).

¹²² IPO Consultation Document, Expansion of the IPO Patent Opinions Service (available at www.ipo.gov.uk/consult-2012-opinion.htm). This consultation was launched on 12 June 2012. Although this consultation is more recent, similar difficulties would have been applicable in the relevant period. The IPO has been proactive in recent years in seeking help with this through, for example, making third party observations easier to file and by piloting peer reviews of patent applications. Consequently, various changes to primary legislation were made by the Intellectual Property Act 2014 (of which almost all sections came into force on 1 October 2014), and the IPO continues to propose to make changes to the secondary legislation (see https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/314707/19463_Amendment_of_the_Patent_Rules_Consultation_Doc.pdf).

¹²³ IPO Consultation Document, Expansion of the IPO Patent Opinions Service.

possibility for expert witnesses of third parties to be heard. It is only after the patent has been granted that third parties can formally oppose it. Such opposition (followed if necessary by an appeal) may, normally several years later, lead to a decision of the IPO or the national court to revoke the patent. Oppositions may also lead to a narrowing of the claims in the patent. This two-step procedure, of which only the second part is *inter partes*, obviously makes the status of patents, to some degree, uncertain. Indeed, of the patents reportedly challenged by generic suppliers through opposition in the period 2000–2007 before the European Patent Office ('EPO'), 60% were revoked and 15% were amended. Only 25% of challenged patents remained intact.¹²⁴

- 3.80 Nevertheless, despite their sometimes uncertain status, as soon as patents have been granted, they can and often will immediately be invoked by patent holders against third parties, including before national courts.
- 3.81 This assumption of validity of patents does not mean, however, that a generic supplier which believes that a patent is invalid or, considers that it does not infringe a valid patent, would not have the right to try to sell its product in the market. Indeed, in deciding whether to grant an MA to a generic supplier for a particular medicinal product, the bodies granting MAs in the UK and EEA are not allowed to take the patent status of that product into account.¹²⁵ Nor does the assumption of validity mean that a generic supplier would not have the right to challenge the validity of a patent invoked against it or to challenge a claim that it had infringed a patent. The assumption of validity simply reflects the general legal principle that a party making a claim before the court bears the burden of proving it. Thus, an originator company claiming before a court that a patent has been infringed bears the burden of proving title and infringement on the balance of probabilities;¹²⁶ just as a generic supplier (counter-) claiming that a patent is invalid bears the burden of proving invalidity on the balance of probabilities.¹²⁷ When it comes to substance, however, the judge in question will examine without preconception whether the patent is truly valid and/or has indeed been infringed. The Sector Inquiry

¹²⁴ Sector Inquiry Final Report, pages 395–410. These statistics are based on responses to questionnaires sent by the Commission to various companies in relation to the Sector Inquiry; in total, 43 originator companies and 27 generic companies submitted comprehensive replies to the questionnaires. The CMA recognises that challenges are most likely in relation to those patent claims which are perceived to be 'weaker'.

¹²⁵ Sector Inquiry Final Report, Executive Summary, page 23: '*[A]ccording to Community legislation, marketing authorisation bodies cannot take the patent status of the originator medicine into account when deciding on marketing authorisations of generic medicines.*'

¹²⁶ Under section 100(1) of the Patents Act 1977, if the patent held by the originator company involves a process for obtaining a new product and the same product has been produced by the generic company, the onus shifts to the generic company to prove that the product was obtained by a different process.

¹²⁷ Halsbury's Laws of England Volume 35 (4th edition re-issue, Butterworths 1994), paragraph 623.

found for the period 2000–2007 that whilst the vast majority of litigation in the EEA in the pharmaceutical sector were infringement cases initiated by originator companies against generic suppliers,¹²⁸ generic suppliers in fact won 62% of all cases that resulted in a ruling.¹²⁹

- 3.82 Patent disputes or patent litigation can also lead to a settlement between the parties. A settlement seeks an amicable resolution of the dispute between the parties with a view to avoiding (further) litigation and the risk of a potentially adverse ruling (for either party) by the court. The Sector Inquiry found that, in 2000–07, 223 of the 698 reported cases of patent litigation between originator companies and generic suppliers were settled.¹³⁰
- 3.83 A patent settlement between an originator company and a generic supplier could, for instance, in the light of each party's assessment of the chance that the court will hold claims in the patent (in)valid and/or (not) infringed, agree on an entry date for the generic product at a point in time between immediate entry and entry at the expiry of the patent protection of the invoked patent(s). A settlement may also include a licence from the originator company to the generic supplier authorising the latter to use the invention, with or without royalties.
- 3.84 In Case 65/86, *Bayer AG and Maschinenfabrik Hennecke v Heinz Süllhöfer*, the CJ held that an agreement does not fall outside the scope of Article 101 TFEU simply because it is a settlement agreement or an agreement related to intellectual property rights. The CJ held that "[i]n its prohibition of certain "agreements" between undertakings, Article 85(1) [now Article 101(1) TFEU] makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind."¹³¹ Thus, while companies have the right to settle their patent disputes or patent litigation, just as they have the right to conclude other kinds of agreements, even if they are (potential) competitors, in doing so they must respect competition law.

ii) Marketing Authorisations

- 3.85 During the Relevant Period, as is the case now, in order for pharmaceutical products to be made available to patients, it was necessary for the

¹²⁸ Sector Inquiry Final Report, page 215. In the UK specifically, the majority of cases were initiated by generic companies.

¹²⁹ Sector Inquiry Final Report, pages 223–224. There is no UK data regarding the outcome of litigation. The CMA recognises that challenges are most likely in relation to those patent claims which are perceived to be weaker.

¹³⁰ Sector Inquiry Final Report, page 223.

¹³¹ Judgment in *Bayer AG and Maschinenfabrik Hennecke GmbH v Heinz Süllhöfer*, 65/86, EU:C:1988:448, paragraph 15.

pharmaceutical company to obtain an MA in the country of intended sale. An MA will only be granted if the competent authority providing the authorisation concludes that the pharmaceutical product concerned shows satisfactory safety, quality and efficacy in treating the disorder(s) for which it is intended.

3.86 There are a number of ways a pharmaceutical company can apply for an MA:¹³²

- A national application consisting of a single application to a national competent authority for an MA that is valid only in the country in which the competent authority is based. In the UK this was the Medicines Control Agency ('MCA'), during the Relevant Period (and is now the MHRA).
- A so-called centralised or Community application, consisting of a single application to the European Medicines Agency for an MA that is valid simultaneously in all EU Member States.¹³³
- A decentralised application, consisting of an application for simultaneous authorisation in more than one EU country.
- A Mutual Recognition application, where, once a product is authorised in one EU country, MAs in other EU countries can be granted following a Mutual Recognition Procedure, on the basis of recognition of the validity of the original MA.¹³⁴

3.87 Once granted, an MA is valid for five years before a renewal is needed.¹³⁵

3.88 Applications for MAs for innovator products (eg consisting of a new active substance or for a new indication), involve in-depth reviews and professional assessments of toxicology, pharmacology and clinical data. National

¹³² See <https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk> for further information.

¹³³ The authorisation would also be valid in Iceland, Lichtenstein and Norway. For further information see the Commission's preliminary report, *Pharmaceutical Sector Inquiry Preliminary Report*, published 28 November 2008, section B 2.2.1.

¹³⁴ Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136 of 30.04.2004 and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 of 28.11.2001, Article 28. See the Commission's preliminary report, *Pharmaceutical Sector Inquiry Preliminary Report*, published 28 November 2008, section B 2.2.2 for further information.

¹³⁵ See <https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk>. During the Relevant Period, authorisations could only be renewed for another five year period; however, under current legislation renewal can be for an unlimited period. See Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 of 28.11.2001, Article 24 and the amendments in Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136 of 30.04.2004.

competent authorities are required to reach their decision on new MA applications in 210 days.¹³⁶ This period does not include the clock stop periods when an applicant is required to respond to questions arising from the application.¹³⁷

- 3.89 Generic suppliers can also apply for MAs using an abridged procedure, subject to data exclusivity restrictions (see below). Under the abridged procedure medical products which are generic versions of products that have been authorised in an EU Member State do not have to submit non-clinical (toxicological or pharmacological tests), or clinical data (other than the clinical data that may be needed to demonstrate that the generic product may be used interchangeably with the already authorised 'reference' product) for assessment.¹³⁸ MAs sought under the Mutual Recognition procedure have a shorter process (regardless of whether the product is an innovator or generic); applications have to be determined within 90 days of receipt.¹³⁹ For a generic supplier, obtaining an MA is a necessary step before entering the national market in that country. [GSK's Finance Director A], in his witness evidence in the 2001 GUK Litigation, estimated that the granting of MAs for 'essentially similar' products could take as little as seven months from the date of application,¹⁴⁰ which was also the average length of time found by the Sector Inquiry.¹⁴¹

¹³⁶ Applications should be determined within 210 days of a valid submission (Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 of 28.11.2001, Article 17 and amendments in Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136 of 30.04.2004). Applications, under certain circumstances, can be fast tracked, see <https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk>.

¹³⁷ See Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 of 28.11.2001, Article 19(3) and amendments in Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136 of 30.04.2004.

¹³⁸ Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136 of 30.04.2004, Article 10. However, where an 'essentially similar' product is intended to be used for a different therapeutic purpose or administered by a different route or different dosages than the product already on the market, the results of tests and clinical data must be submitted (10)(3). See <https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk>.

¹³⁹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 of 28.11.2001, Article 28 and Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136 of 30.04.2004. See <https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk>.

¹⁴⁰ [Redacted] WS1 (GUK) (document 0885), paragraph 7.7.

¹⁴¹ Executive Summary, Sector Inquiry Final Report, section 2.1.2.

Data exclusivity¹⁴²

- 3.90 Data exclusivity (or data protection) refers to the period during which the data of the original MA holder relating to non-clinical and clinical testing is protected. Rules on data exclusivity prevent bodies which can grant MAs from accepting abridged applications for generic medicines for a certain number of years after the initial grant of the MA to the innovator product.¹⁴³
- 3.91 In the UK, during the Relevant Period, such data exclusivity ran for 10 years from the date of the MA being granted. This meant that generic suppliers had to wait until after 10 years had passed before they could file an application for authorisation to bring their product on the market using the abridged authorisation procedure, referred to in paragraph 3.89.¹⁴⁴
- 3.92 According to the witness evidence of [GSK's Finance Director A] in 2001 in the GUK Litigation, the original MA for Seroxat was granted in 1991, and covered depression and depression with accompanying anxiety.¹⁴⁵ His evidence went on to state that the 10 year period of regulatory 'data exclusivity' for Seroxat expired in December 2000.¹⁴⁶

iii) Framework for the supply of pharmaceutical products in Primary Care

- 3.93 Antidepressant medicines, such as paroxetine, are not available for purchase by consumers 'Over-The-Counter'. They need to be prescribed to patients by a GP or another qualified healthcare professional.¹⁴⁷
- 3.94 Information about new pharmaceuticals is provided to GPs by pharmaceutical companies' marketing, including visits from sales representatives and adverts in trade publications, and also through prescribing databases and guidelines, the most important of which are the BNF guidelines¹⁴⁸ and the Monthly Index

¹⁴² It was introduced in 1987 by Directive 87/21/EEC of 22 December 1986 amending Directive 65/65 EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, OJ L 15 of 17.01.1987.

¹⁴³ See Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 of 28.11.2001 and The Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human, CMDh Questions and Answers Generic Applications, document reference CMDh/272/2012, Rev0, October 2012.

¹⁴⁴ Generics companies would be able to file for MA before the ten year period expired, but they would not be able to use the abridged authorisation processes ie they could not rely on the tests and information from the original MA holder. This would mean that generic suppliers would have to do their own extensive tests, which may be uneconomical. See the Commission's preliminary report, *Pharmaceutical Sector Inquiry Preliminary Report*, published 28 November 2008, page 106, footnote 154.

¹⁴⁵ [REDACTED]WS1 (GUK) (document 0885), paragraph 2.4.

¹⁴⁶ [REDACTED]WS1 (GUK) (document 0885), paragraph 5.1.

¹⁴⁷ Paroxetine is listed as a prescription only medicine in the Prescription Only Medicine (Human Use) Order 1997, SI 1830/1997, Schedule 1.

¹⁴⁸ Published by the BNF, a public body based at the Royal Pharmaceutical Society of Great Britain. See BNF guidelines (document 2505), Antidepressant drugs, section 4.3.

of Medical Specialities which is a prescribing database for all healthcare professionals.

3.95 The pharmaceutical sector has certain specific features that impact upon the prescribing and dispensing decisions of doctors and pharmacies under the NHS:¹⁴⁹

- For products which are dispensed by prescription the ultimate consumer (the patient) is usually not the same person choosing the medicine (the doctor).
- While doctors are the main determinant of demand for pharmaceutical products by prescription, their decisions are not typically driven primarily by price considerations:
 - A study by the OFT in 2007 found that doctors' ability to rank branded drugs, which included SSRIs, in order of price was generally no better than chance,¹⁵⁰ and
 - A DH study published in 2002 found that *'Most prescribers did not assimilate information on drug costs and price changes and were often unaware of prices or price changes'*. Indeed, in relation to SSRIs the DH study found that *'the percentage of correct rankings [of prices] is only marginally above 50%, which is what would be expected if GPs had no knowledge of price and simply guessed.'*¹⁵¹

Instead, doctors tend to choose between different medicines depending on which product is therapeutically most appropriate and effective.¹⁵²

- Doctors' awareness of new products or price reductions is very dependent on whether they read 'new information' in monthly publications such as Monthly Index of Medical Specialities. If not, they may not learn of the

¹⁴⁹ These were noted in Department of Health & Association of the British Pharmaceutical Industry (2002), PPRS: The study into the extent of competition in the supply of branded medicines to the NHS (document 3204), page 84.

¹⁵⁰ *The Pharmaceutical Price Regulation Scheme, an OFT market study* (OFT885, February 2007), box 2.3, page 23 and Annex C. These findings are based on a survey 1,000 English GPs conducted as part of research by the National Audit Office into value for money in primary care.

¹⁵¹ See Department of Health & Association of the British Pharmaceutical Industry (2002), PPRS: The study into the extent of competition in the supply of branded medicines to the NHS (document 3204), pages 16 and 162. The CMA notes that although the data used to inform the study covered the period up to 2000, the findings are still relevant to GPs' behaviour during the Relevant Period given the proximity of the timing of this report.

¹⁵² While doctors may not choose which medicine to prescribe based on prices (or indeed have limited awareness of the prices of different pharmaceutical products), their prescribing behaviour may nevertheless be indirectly informed by price insofar as they are increasingly encouraged to prescribe generic (rather than branded) products, to follow prescribing guidelines (for example, through use of pre-approved formularies) and to meet certain budgetary objectives at local level.

change until advice comes from local organisations such as the relevant health authority¹⁵³ or from a pharmaceutical company.

- Non-price influences on prescribing can, depending on their nature, either dampen or invigorate price competition. Manufacturers seek to establish their brands in the minds of prescribing doctors using marketing activities such as publications, conferences, symposia, doctors' meetings and seminars at which research on new treatments is presented.¹⁵⁴
- Once a patient is established on a particular medicine therapy, there can be expected to be significant medical reasons why it is disadvantageous to alter their medication. Added to this, are the costs in GP time in effecting a switch, and associated patient confusion and/or unwillingness to change. Switching costs vary between classes. For example, for many psychiatric products the difficulties associated with changes in medication are particularly high in terms of the negative clinical effects that can result, with patients' tolerance of, and reaction to, new products or different formulations having to be carefully monitored.

iv) GP prescribing

3.96 GPs (and other prescribers, such as consultants) are encouraged to write generic prescriptions using a medicine's international non-proprietary name, whether or not the product in question is in or out of patent, unless there are specific clinical reasons not to.¹⁵⁵

3.97 In total, prescribing by generic name in relation to paroxetine accounted for the large majority of prescriptions during the Relevant Period. In the witness evidence of [GSK's Finance Director A] in September 2001, he confirmed that:¹⁵⁶

¹⁵³ Such as primary care trusts ('PCTs') from 2001 to 2013; PCTs were abolished on 31 March 2013 as part of the Health and Social Care Act 2012, with their work taken over by clinical commission groups.

¹⁵⁴ The CMA notes various such marketing materials on the file from GSK in relation to paroxetine. These are discussed in Part 4 of this Decision.

¹⁵⁵ *The Pharmaceutical Price Regulation Scheme, an OFT market study* (OFT885, February 2007), paragraph 2.34.

¹⁵⁶ [REDACTED]WS1 (GUK) (document 0885), paragraph 4.1. [GSK's Finance Director A] subsequently amended this statement as follows: '*I have noted a discrepancy in my first statement between the figures given in paragraphs 4.1 and 4.8 for the percentages of paroxetine prescriptions written generically. SB use two different commercial sources for this data, Scriptcount (from Taylor Nelson Sofres Plc) and Dinlink. Scriptcount data shows that since about 12 to 18 months ago 85% (and currently 87%) of prescriptions for paroxetine have been written using the generic name "paroxetine", and currently only 13% are written using the brand name SEROXAT. However, Dinlink data shows that since about 12 to 18 months ago 90% (and currently 93%) of prescriptions for paroxetine have been written using the generic name "paroxetine", and currently only 7% are written using the brand name SEROXAT.*' [REDACTED]WS2 (GUK) (document 0182), paragraphs 8.1 and 8.2.

'Since about 12 to 18 months ago over 85% (and currently 87%) of prescriptions for paroxetine have been written using the generic name "paroxetine", and currently only 7% are written using the brand name SEROXAT (according to ScripCount figures published by the Taylor Nelson Sofres PLC).'

- 3.98 This policy is motivated by safety, availability and cost considerations. In particular, in relation to cost considerations, when a branded medicine's patent expires, generic equivalents which appear in the market are usually cheaper for the NHS.¹⁵⁷
- 3.99 To facilitate generic prescribing, GPs' prescribing software is usually able to identify if a generic product is available, so where a prescriber types in a brand name, they can use a function key to prompt them with the generic name, enabling the pharmacy to dispense any applicable product.¹⁵⁸ This preference for generics in GPs' prescribing practice, when combined with the manner in which pharmacies are also incentivised to dispense generic medicines, leads to the rapid impact of generic substitutes, once they become available, on the price of brand name medicines (as discussed at paragraphs 3.59 to 3.62).

v) Pharmacy dispensing

- 3.100 Pharmacy dispensing is heavily regulated. In England and Wales, the activities of pharmacies were, during the Relevant Period, governed by various regulations, particularly the National Health Service (Pharmaceutical Services) Regulations 1992.¹⁵⁹
- 3.101 If a branded medicine is prescribed, that branded medicine must be dispensed. Although pharmacies are unable to substitute a generic product for a medicine prescribed by brand name, pharmacies are able to dispense a parallel imported product provided the parallel import is marketed under exactly the same brand as that for which the prescription is written. One of the reasons pharmacies may choose to do this is if sourcing the product from overseas offers a better profit margin.

¹⁵⁷ *The Pharmaceutical Price Regulation Scheme, an OFT market study* (OFT885, February 2007), paragraph 2.35.

¹⁵⁸ Decision No: CA98/02/2011, *Reckitt Benckiser*, 12 April 2011, paragraph 2.103.

¹⁵⁹ The National Health Service (Pharmaceutical Services) Regulations 1992, SI 1992/662 as amended by 1993/2451, 1994/2402, 1995/644, 1996/698, 1998/681, 1998/2224, 1999/696, 1999/2563, 2000/121, 2000/593, 2001/2888, 2002/551, 2002/888, 2002/2016, 2002/2469, 2002/2861, 2003/699, 2003/1084, 2004/922, and 2005/28. Similar provisions were in place in Scotland and Northern Ireland.

3.102 On receipt of a generic prescription, it is permissible to dispense any branded or generic medicine that falls within the relevant descriptor. However, where there is a generic reimbursement price listed under Part VIII of the Drug Tariff, the pharmacy will only be paid this Drug Tariff price regardless of whether they dispense a branded medicine or a generic medicine. As explained in more detail below, pharmacies therefore have the incentive to dispense the cheaper generic medicine, where available.

vi) Pricing Framework

3.103 There were two relevant pharmaceutical pricing frameworks in place during the Relevant Period; the Pharmaceutical Price Regulation Scheme ('PPRS'), and the Drug Tariff.

a) PPRS

3.104 The PPRS is a voluntary arrangement between UK health bodies, as represented by the DH, and the pharmaceutical industry, as represented by the Association of the British Pharmaceutical Industry ('ABPI'). The principal aim of the PPRS is to strike a balance to ensure that the interests of patients, the NHS, industry and taxpayers are promoted for each other's mutual benefit.¹⁶⁰

3.105 The scheme comprises two key components which relate to the entire portfolio of branded, licensed medicines (both in- and out- of patent) sold by a medicines manufacturer to the NHS:¹⁶¹

- A profit cap: this is based on a target rate of return¹⁶² and applies to all the branded products sold by a company to the NHS. There are allowances for R&D, marketing and information costs.
- A range of price controls: there is freedom to set the initial list price of new active substances, but there are restrictions on subsequent increases to the list price.¹⁶³ One-off price cuts are periodically agreed at the time of scheme renegotiations. In the 1999 and 2005 PPRS, the cuts were 4.5%

¹⁶⁰ See, for example, the objectives in the 2009 PPRS scheme *The PPRS 2009*, paragraph 2.1 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/207462/dh_098498.pdf

¹⁶¹ Further information about the operation of the PPRS can be found at *The Pharmaceutical Price Regulation Scheme, an OFT market study* (OFT885, February 2007), see in particular Annexes G, H and J.

¹⁶² In the 1999 PPRS this was a maximum of 21% return on capital (ROC) and 6% return on sales (ROS) to the NHS and a minimum of 17% ROC and 4.9% ROS, with a margin of tolerance (MOT) of 50% to 140% of the target level. In the 2005 PPRS it was 21% ROC and 6% ROS with a MOT of 40% to 140% of target.

¹⁶³ Companies operating under the PPRS will typically sell their medicines to pharmacies/wholesalers at a discount to the relevant list price. The level of discount is determined by the relevant company, and can vary between medicines.

and 7% respectively. As an alternative to an across the board reduction, it has been an option for scheme members to deliver the price cuts by modulating the prices of some or all of their products covered by the PPRS.

b) Drug Tariff

- 3.106 The Drug Tariff was, and is, produced monthly by the Prescription Pricing Authority.¹⁶⁴ It outlines, amongst other things, the amounts pharmacy contractors (or dispensing doctors) are to be reimbursed for the cost of medicines which they have supplied against NHS prescriptions.
- 3.107 The Drug Tariff provides that a contractor is reimbursed for medicines dispensed at a 'basic price' minus discount. The 'basic price' of branded medicines is that published under the PPRS. The basic price for the vast majority of products prescribed as a generic were listed under Part VIII of the Drug Tariff. Generic products listed under Part VIII are placed in different categories depending on how the reimbursement price has been determined.
- 3.108 Both paroxetine 20mg and 30mg tablets were initially in category C of the Drug Tariff. Paroxetine 20mg moved into category A on 1 June 2002, and paroxetine 30mg moved into category A on 1 November 2004. Both paroxetine 20mg and 30mg moved into category M on 1 April 2005 when it was created.¹⁶⁵ The descriptions of the relevant categories are as follows:¹⁶⁶
- Category A – lists prices of commonly used generics that are usually readily available from several sources. Category A prices are set using a weighted average of prices from a 'basket' of two wholesalers and three generic manufacturers.¹⁶⁷ There is a minimum requirement that products in category A are listed either (i) by both wholesalers, or (ii) by one wholesaler and by two manufacturers.
 - Category C – products that are commonly used but which do not fulfil the criteria for category A or M. This is most often seen when a product is only available as a branded product or from one or two sources. The price will be based on the list price of a particular brand, manufacturer or supplier.

¹⁶⁴ See www.nhsbsa.nhs.uk/prescriptionservices.aspx

¹⁶⁵ For more information see, for example: www.psn.org.uk/pages/category_m.html

¹⁶⁶ See www.nhsbsa.nhs.uk/PrescriptionServices/documents/Drug_Tariff_Guidance_Notes.doc

¹⁶⁷ During the Relevant Period, the 'basket' consisted of AAH, Unichem, APS, Alpharma and IVAX. This was confirmed to the OFT by DH.

- Category M – lists prices of commonly used generics that are usually readily available from several sources. Category M prices are set using a weighted average from retrospective sales and volume data supplied to the DH by manufacturers under scheme M. These prices are then adjusted by a formula to ensure that pharmacy contractors retain the profit margin agreed as part of the funding of the community pharmacy contractual framework.¹⁶⁸

3.109 The operation of the Drug Tariff creates significant incentives for pharmacies to supply medicines as a generic, where they are available. As [GSK's Finance Director A] explained in his September 2001 witness evidence:¹⁶⁹

'If the Drug Tariff price actually corresponds to the prevailing published generic list price, then the pharmacist will make a loss if he dispenses the more expensive brand in fulfilling a generically written prescription. However, even if the Drug Tariff price lags behind the generic price so that the reimbursement would cover the cost of buying the branded product, it is still in the interest of the pharmacist to dispense the cheaper generic product if he can, because the difference in price between the latter and the Drug Tariff would in principle be his to keep.'

c) Application of the discount scale

3.110 It is recognised that pharmacies can buy their medicines cheaper than the NHS reimbursement price. Before 2005 an invoice inquiry was carried out (usually every year) to consider the discount contractors received on their purchases. In England, this discount was translated into a 'discount scale' (Part V of the Drug Tariff) that was applied to a pharmacy's total 'basic price' reimbursements (as referred to in paragraph 3.107). The discount applied to each pharmacy depended on the value of their total reimbursements, such that the higher the reimbursement value the greater the discount applied.¹⁷⁰

3.111 In England, the invoice inquiry was carried out confidentially between the DH and the pharmacy contractor representative body – the Pharmaceutical

¹⁶⁸ Each year in conjunction with the PSNC, DH conducts a 'margins survey' to investigate how much medicine margin (that is, the difference between what they have bought the product for and how much they have been reimbursed) the average pharmacy contractor has retained in the previous year.

¹⁶⁹ [REDACTED]WS1 (GUK) (document 0885), paragraph 4.5.

¹⁷⁰ The CMA notes that the discount applied to each pharmacy was sometimes referred to as 'clawback'. For example, in 2000, an email from [GSK's Finance Director A] containing modelling on the potential impact of generic paroxetine entry refers to 'clawback' as follows: 'reimbursement is paid net of a clawback percentage, which is ostensibly to recognise that pharmacists are able to negotiate discounts when they buy products. Clawback, although complicated, is generally understood to be approx 11%.' (Email from [GSK's Marketing Manager A for Seroxat] to [GSK Group Director (Global Market Access)], 'Generic Competition' dated 5 January 2001 (document 0122)).

Services Negotiating Committee ('PSNC'). The invoice inquiry considered a sample of pharmacies and sample of medicines and considered pharmacies' invoices showing purchases and price lists that were not necessarily available to the DH on setting reimbursement prices.

d) Brand equalisation deals

3.112 Brand equalisation deals are a common feature of competition between branded and generic medicines. They are agreements between manufacturers of branded medicines and pharmacies whereby the manufacturer offers the pharmacy a single 'blended' or average price for the supply of an off-patent branded medicine on the condition that the medicine is dispensed against both branded and generic prescriptions. The blended or average price would typically be higher than the price of the competing generic (as listed in the Drug Tariff) but lower than the list price of the branded product (as constrained by the PPRS). To secure the 'blended' price, pharmacies must purchase an assigned volume of the branded product. Such deals are constructed to provide pharmacies with an incentive to dispense the branded medicine against a given volume of the generically written open prescriptions that they receive.

3.113 Such deals are described as follows in the witness evidence of [GSK's Finance Director A] in September 2001:¹⁷¹

'SB [SmithKline Beecham] and other suppliers of branded products respond to generic competition by seeking to negotiate "brand equalisation" discounts which work in the following manner.

Although SB's customers buy a large number of different products from SB, discounts, especially on the more important products, are generally negotiated separately for each product. In the case of branded products where a generic equivalent is available, pharmacists have to stock the branded product to fulfil prescriptions written using the brand name, but can fulfil prescriptions written with the generic name with either the branded product or a generic equivalent, subject to being reimbursed for generic prescriptions at the Drug Tariff price rather than the branded list price. SB, in common with many other pharmaceutical companies, therefore offers its patent-expired branded medicines to pharmacists at a "blended" discounted price which is calculated so that a pharmacist dispensing the branded product against all prescriptions (branded or generic) will be in the same financial position as if he had purchased

¹⁷¹ [REDACTED]WS1 (GUK) (document 0885), paragraphs 4.6 and 4.7.

generic products at the prevailing discounted price to dispense against generic prescriptions and branded products at the appropriate discount off list price to dispense against branded prescriptions. This has the advantage to the pharmacist of simplifying ordering and stock control.'

3.114 This obviously has significant implications for the branded manufacturer once discounted generics enter the market, as [GSK's Finance Director A] goes on to explain:¹⁷²

*'In this way, when generic equivalents to a branded product become available, SB is obliged, in order to compete, to drop its price to customers to match the discounted generic price, in respect of that proportion of its former sales which would correspond to the percentage of prescriptions written generically – Furthermore, "brand equalisation" deals can only be negotiated with pharmacy chains who purchase direct from SB. Since, in practice, the blended discount is usually negotiated on a monthly basis, it is not practicable to negotiate such discounts with wholesalers. In this way, there will be not only a fall in SB's selling price, but also a contraction in the number of potential customers.'*¹⁷³

3.115 As [GSK's Finance Director A] explains in his witness evidence in the GUK Litigation in October 2001, brand equalisation deals could also be used in order to compete with parallel imports of paroxetine:¹⁷⁴

'Parallel imports of SB's paroxetine are sourced in a number of different countries.... In order to maintain our market share against these lower priced products, we offer our customers discounts similar to brand equalisation deals...'

¹⁷² [REDACTED]WS1 (GUK) (document 0885), paragraph 4.8.

¹⁷³ In a separate witness statement [GSK's Finance Director A], noted that the proportion of customers it would be unable to negotiate brand equalisation discounts with was in the region of 40%: *'there is a large number of pharmacists - about 40% of the market - in respect of whom it is impracticable to negotiate such discounts [brand equalisation discounts].'* Witness statement of [GSK's Finance Director A] in the Alpha Pharma Litigation, dated 10 June 2002 ('[REDACTED]WS1 (Alpha Pharma)') (document 0241), paragraph 5.4.

¹⁷⁴ [REDACTED]WS2 (GUK) (document 0182), paragraphs 3.2 and 3.3.

E. Background to the Patent Disputes

i) *The patents at issue*

3.116 This Section considers the various patents which are of relevance to this Investigation and the disputes between GSK and the Generic Companies, and others, in relation to them.¹⁷⁵

3.117 The paroxetine hydrochloride molecule was originally patented by the Danish company Ferrosan A/S in 1973.¹⁷⁶ GSK acquired the rights to the paroxetine hydrochloride patent (the 'Initial Patent') from Ferrosan A/S in 1979 under certain licensing arrangements.¹⁷⁷ The Initial Patent covered paroxetine hydrochloride (free base), and also information in relation to different salt formulations.¹⁷⁸ In the UK, the Initial Patent expired in January 1999,¹⁷⁹ and the data exclusivity expired in December 2000.¹⁸⁰

3.118 As set out in paragraph 3.24, paroxetine hydrochloride in itself cannot be applied as a medicine: it first needs to be transformed into a salt (that is, combined with an acid). Such salts may be patented, if they are novel, non-obvious and susceptible of industrial application.

3.119 Accordingly, in addition to the Initial Patent, GSK successfully applied for the following patents in relation to two separate salt formulations of paroxetine hydrochloride and one tableting patent listed.¹⁸¹

(a) Hemihydrate – European Patent EP 0 223 403 (the 'Hemihydrate Patent'): the claims of that patent cover a particular crystalline form of paroxetine. It was granted to GSK in 1986 and expired on 14 October 2006.¹⁸²

(b) Anhydrate – Patent GB 2 297 550 (the 'Anhydrate Patent'): the claims of that patent cover various polymorphs of paroxetine anhydrate (referred to as Form A, B, C and D) and cover a process to displace bound organic solvate (known as the 'displacement step') to produce paroxetine anhydrate. The Anhydrate Patent was granted on 11 March 1997 and, to

¹⁷⁵ A detailed description of the patent position in relation to paroxetine and its various salts can be found in GSK Second Response, Part Two (document 0734), page 7.

¹⁷⁶ Patent GB 1422263 available at <http://worldwide.espacenet.com>

¹⁷⁷ See GSK Second Response, Part Two (document 0734), paragraph 4.9.

¹⁷⁸ Patent GB 1422263 available at <http://worldwide.espacenet.com>

¹⁷⁹ The Initial Patent was due to expire on 22 January 1994 but an SPC (SPC/GB93/010) was issued granting protection until 22 January 1999 available at www.ipo.gov.uk/p-ipsum

¹⁸⁰ See [X]WS1 (GUK) (document 0885), paragraph 5.1.

¹⁸¹ In addition, GSK was granted a patent in relation to the mesylate salt of paroxetine (GB 2336364). This patent is not relevant for the purposes of this Decision.

¹⁸² Further details regarding GSK's Hemihydrate Patent are included in GSK Second Response, Part Two (document 0734), response to question 4.

the extent it remained valid after the BASF Litigation, was due to expire in 2016 but following the non-payment of renewal fees expired in January 2013.¹⁸³ This patent was subject to amendment in both 2001 and 2003.

- (c) The Dry Tablet Process (or 'Dry Tableting Patent') – Patent EP 0 734 260: the claims of that patent cover a process for formulating tablets containing paroxetine in the absence of water.¹⁸⁴ It was granted in June 1999, following which various pharmaceutical suppliers, including BASF and IVAX, brought opposition proceedings before the EPO seeking the revocation of that patent. The Dry Tableting Patent was subsequently revoked by the Opposition Division of the EPO on 15 May 2003. Following an appeal against that revocation decision by GSK, and the decision of the pharmaceutical suppliers which brought opposition proceedings to either withdraw their opposition to the Dry Tableting Patent or otherwise not participate in the oral proceedings during the appeal, the Dry Tableting Patent was subsequently restored in 2006 and maintained as amended in 2008.¹⁸⁵

3.120 GSK's version of paroxetine, Seroxat, is a hemihydrate salt of paroxetine hydrochloride and it was this salt on which GSK focussed its commercial development. Seroxat was granted an MA in the UK in December 1990 and was first marketed in the UK in February 1991.¹⁸⁶

ii) The Patent Disputes¹⁸⁷

3.121 Both in anticipation of, and following, the expiry of the Initial Patent in January 1999 and of data protection in December 2000, a number of generic suppliers considered that they had sufficient information in order to supply and/or produce a generic version of paroxetine hydrochloride.

3.122 In the UK, generic suppliers mainly concentrated on launching an anhydrate salt of paroxetine, due to the fact that the already expired Initial Patent contained some information on that salt and because this salt also provided some other advantages (for example, relating to the ability of generic

¹⁸³ The IPO lists the Anhydrate Patent as being no longer in force from 31 January 2013 (see <https://www.ipo.gov.uk/p-ipsum/Case/PublicationNumber/GB2297550>). Further details regarding GSK's Anhydrate Patent are included in GSK Second Response, Part Two (document 0734), response to question 4.

¹⁸⁴ Alpha internal document entitled, 'Paroxetine hydrochloride anhydride patent situation in the European Alpha markets' dated 4 September 2002 (document 1344).

¹⁸⁵ Further details in relation to the Dry Tableting Patent are available at <https://register.epo.org/application?number=EP95904476>. Details of the opposition proceedings in relation to the Dry Tableting Patent are available at: <http://www.epo.org/law-practice/case-law-appeals/pdf/t030870eu1.pdf>

¹⁸⁶ [S]WS1 (GUK) (document 0885), paragraph 2.2.

¹⁸⁷ This section considers the disputes in relation to the Anhydrate Patent and Hemihydrate Patent. The EPO administrative procedure in relation to the Dry Tableting Patent is summarised at paragraph 3.119(c).

suppliers to obtain an MA). This was confirmed by [GSK's Finance Director A] in his witness evidence as follows:¹⁸⁸

'I believe that most generic companies will choose to offer a hydrochloride salt of paroxetine, either the hemihydrate, or the anhydrate (it is comparatively straightforward to argue that the anhydrate is "essentially similar" to GSK's product for the purposes of the regulatory authorisation).'

[GSK's Finance Director A] also indicated that:

'The hemihydrate and anhydrate are therapeutically equivalent and are, to all intents and purposes, interchangeable. In particular, a prescription for "paroxetine" is not likely to specify the form, and can be fulfilled by dispensing either the hemihydrate or the anhydrate form.'

3.123 GSK subsequently became involved in a number of disputes and/or legal proceedings in which it contemplated, or otherwise faced or brought, legal claims that products produced by a number of generic companies infringed its various patents for paroxetine hydrochloride in the UK.¹⁸⁹ This was part of a wider pan-European project by GSK by which it was considering and implementing various means to continue to seek to sustain its exclusivity for sales of paroxetine. This project was referred to within GSK as 'Project Dyke' and is further referred to at paragraphs 3.144 to 3.154.

a) IVAX

3.124 From 1999 to 2001, IVAX made commercial preparations to launch a generic paroxetine product independently of GSK.

3.125 In the period August 2001–October 2001, a number of discussions took place between employees at GSK and IVAX concerning IVAX's proposed supply of paroxetine in the UK (see paragraphs 3.157 and 3.217 for further details). GSK has indicated that, if IVAX had, in fact, launched a generic paroxetine product, GSK would have commenced litigation.¹⁹⁰ Following IVAX's entry into the IVAX-GSK Agreement on 3 October 2001, and IVAX's decision not to

¹⁸⁸ WS1 (Alpharma) (document 0241), paragraphs 8.7 and 3.2.

¹⁸⁹ GSK was involved in litigation worldwide to defend its paroxetine patents, as can be seen, for example, in the GSK document entitled 'Patent Overview 2002' dated 3 July 2002 (document 0282). An overview of the European litigation as at 23 January 2004 is also provided in GSK document entitled, 'Key Events Potentially Impacting Paroxetine Market in Europe' dated 23 January 2004 (document 0457), and GSK document entitled 'Synthon STP' dated 16 January 2004 (document 0456). See also a litigation overview in GSK document entitled 'Synthon STP' dated 16 January 2004 (document 0456), Appendix 1.

¹⁹⁰ GSK Second Response, Part Two (document 0734), paragraph 4.19: 'Ivax took an aggressive stance and, had it persisted in launching a generic, GSK would have litigated.'

supply paroxetine in the UK independently of GSK, no such litigation took place. The details of the IVAX-GSK Agreement are set out at paragraphs 3.219 to 3.227.

b) GUK

- 3.126 From 1997–2001, GUK made plans to begin selling a generic version of paroxetine in the UK.¹⁹¹
- 3.127 On 18 September 2001, GSK initiated patent infringement proceedings against GUK, invoking the Anhydrate Patent. On 23 September 2001, GSK made an application for an interim injunction to restrain GUK from selling paroxetine (the ‘GUK Interim Injunction’).¹⁹² On 23 October 2001, GSK’s application for an injunction was granted, which prevented GUK from launching generic paroxetine hydrochloride in the UK subject to the outcome of the trial. In response to the action from GSK, GUK counter-claimed that the Anhydrate Patent should be revoked.
- 3.128 In November 2001, GSK made an application to add to the proceedings against GUK invoking the Anhydrate Patent, an action against GUK for infringement of the Hemihydrate Patent; that application was rejected on 30 November 2001.¹⁹³ On 4 December 2001, GSK brought a separate action against GUK for infringement of the Hemihydrate Patent; that separate action was stayed, pending a decision on the Anhydrate Patent.¹⁹⁴
- 3.129 GSK’s actions against GUK for infringement of the Anhydrate Patent and the Hemihydrate Patent and GUK’s counterclaim (the ‘GUK Litigation’) were settled on 13 March 2002, and GUK entered into a ‘settlement’ agreement with GSK, the GUK-GSK Agreement, pursuant to which GUK became a sub-distributor of IVAX (recorded in the sub-distribution agreement between GUK and IVAX dated 14 March 2002 (the ‘GUK-IVAX Agreement’)). A more

¹⁹¹ According to the witness statement in the GUK Litigation of [REDACTED] (who was General Manager/Sales and Marketing Director at GUK), GUK was making preparations to enter the market as early as February 1997. See witness statement of [GUK’s General Manager] in the GUK Litigation, dated 15 October 2001 (‘[REDACTED]WS’), Exhibit [REDACTED]1 (document 0796), Tab 2, ‘Paroxetine 20mg Tablets Timeline’.

¹⁹² See, for example, GSK’s Claim Form in the GUK Litigation dated 4 December 2002 (document 0944). Many of the GUK/GSK court documents were exhibited in the BASF claim, see Exhibit [REDACTED]2 referred to in the witness statement of [BASF external lawyer] dated 21 November 2001 (document 0933). See also GUK’s Skeleton Argument in the GUK Litigation for the hearing on 23 October 2001 (document 0907).

¹⁹³ See GSK’s Amended Claim Form in the GUK Litigation dated 18 September 2001 (document 0878). See also GUK submission to the OFT dated 22 February 2012 (document 1214), page 4.

¹⁹⁴ GUK submission to the OFT dated 22 February 2012 (document 1214), pages 3–5. See also *SmithKline Beecham Plc v Generics (UK) Limited*, transcript of hearing before Jacob J, dated 23 October 2001 (document 0911), page 27: GUK’s Counsel indicated during that hearing that it would be likely to oppose any application for an interim injunction in relation to the hemihydrate claim on the basis that any application should have been brought before November 2001.

detailed description of the GUK Litigation is set out at paragraphs 3.265 to 3.280. The details of the GUK-GSK Agreement are set out at paragraphs 3.305 to 3.310.

c) BASF

3.130 BASF brought a revocation action against certain claims in the Anhydrate Patent in the UK on 27 July 2001.¹⁹⁵ BASF applied to join GUK's counterclaim that the Anhydrate Patent should be revoked, resulting in both actions being ordered to be heard at the same time.¹⁹⁶

3.131 On 17 July 2002, Mr Justice Pumfrey found that, of the various claims in the Anhydrate Patent, only claim 10(i) and claim 11 were valid, and that the remaining patent claims should be revoked.¹⁹⁷ GSK appealed the judgment, but the appeal was dismissed in July 2003 and the original judgment upheld.¹⁹⁸

3.132 A number of other companies and litigants, including Alparma (see below), were awaiting the outcome of the BASF Litigation.¹⁹⁹ Subsequently, GSK applied to amend the Anhydrate Patent in line with the judgment.²⁰⁰ BASF later reached a worldwide settlement with GSK in relation to paroxetine.²⁰¹

d) Alparma

3.133 GSK initiated an infringement action against Alparma in relation to the Anhydrate Patent on 11 June 2002.²⁰² The claim was subsequently re-served prior to a hearing on 1 August 2002. In that re-served claim GSK dropped a separate claim for infringement of the Hemihydrate Patent and significantly changed the nature of its claim against Alparma with respect to the Anhydrate Patent.²⁰³ At that time, anticipating that a GSK application for an

¹⁹⁵ See BASF Claim Form in the BASF Litigation dated 27 July 2001 (document 0861).

¹⁹⁶ GUK submission to the OFT dated 22 February 2012 (document 1214), page 4.

¹⁹⁷ See *BASF AG v SmithKline Beecham Plc* [2002] EWHC 1373 (Ch).

¹⁹⁸ See *BASF AG v SmithKline Beecham Plc* [2003] EWCA Civ 872.

¹⁹⁹ See, for example, GSK internal documents that say that the BASF case is significant for other cases, as it uses the same patent: GSK internal document entitled 'European Commercial Development June Monthly Report' (document 0089), page 4.

²⁰⁰ Witness statement of [GSK's Patent Attorney] in the Alparma Litigation, dated 27 March 2003 (document 1113), paragraph 26. A number of parties including Alparma contested GSK's proposals for amendment. See, for example, Alparma's Skeleton Argument in the proceedings for the amendment dated 16 October 2002 (document 1099).

²⁰¹ BASF's response dated 16 August 2012 to OFT informal request for information dated 26 July 2012 (document 2185).

²⁰² See GSK's Amended Claim Form in the Alparma Litigation dated 1 August 2002 (document 0298) and GSK's Amended Particulars of Claim in the Alparma Litigation dated 1 August 2002 (document 0299).

²⁰³ See GSK's Amended Claim Form in the Alparma Litigation dated 1 August 2002 (document 0298) and GSK's Amended Particulars of Claim in the Alparma Litigation dated 1 August 2002 (document 0299). See also Alparma's Skeleton Argument in the Alparma Litigation dated 31 July 2002 (document 1328).

injunction would be granted, Alparma undertook, on 1 August 2002, not to sell or supply any paroxetine product in the UK until judgment was handed down following trial (the 'Alparma Undertaking').²⁰⁴

3.134 GSK's action against Alparma for infringement of the Anhydrate Patent and Alparma's counterclaim (the 'Alparma Litigation') was settled on 12 November 2002, and Alparma entered into a settlement agreement with GSK, the Alparma-GSK Settlement Agreement, pursuant to which Alparma became a sub-distributor of IVAX (recorded in the Alparma-IVAX Agreement). A more detailed description of the Alparma Litigation is set out at paragraphs 3.326 to 3.354. The details of the Alparma-GSK Agreement are set out at paragraphs 3.319 to 3.379.

e) *Apotex, Neolab and Waymade Healthcare*

3.135 On 9 October 2002, Apotex, Neolab and Waymade (together, the 'Apotex Parties'), gave three weeks' notice to GSK of a launch by them of a paroxetine hydrochloride product, and on the same day commenced an action against GSK to revoke the Anhydrate Patent.²⁰⁵ On 22 October 2002, GSK brought an action against the Apotex Parties alleging infringement of the Anhydrate Patent (the 'Apotex Litigation'). GSK applied for an interim injunction against the Apotex Parties to restrain them from infringing the Anhydrate Patent by supplying paroxetine hydrochloride in the UK. That interim injunction was granted on 28 November 2002.²⁰⁶

3.136 On 5 December 2003, Mr Justice Pumfrey held that the remaining claims in the Anhydrate Patent (following the BASF Litigation) were invalid and not infringed by the defendants.²⁰⁷ On 18 December 2003, the interim injunction against the Apotex Parties was removed, after GSK indicated to the High Court that it would not seek to maintain the injunction pending an appeal against the first instance judgment. Following an appeal by GSK, the Court of Appeal held that the Anhydrate Patent (as amended) was valid but had not

²⁰⁴ According to the Draft Minute of Order attached to the Alparma-GSK Settlement Agreement (document 1397), the undertaking given by Alparma set out in the Order of Mr Justice Jacob dated 1 August 2002 was '*not to sell or supply any crystalline paroxetine hydrochloride pharmaceutical preparation in the United Kingdom*'.

²⁰⁵ See Apotex Parties Claim Form against GSK dated 9 October 2002 (document 1094).

²⁰⁶ See *SmithKline Beecham Plc and Others v Apotex Europe Ltd and Others* [2002] EWHC 2556 (Ch). The application for an interim injunction was based, in part on the second witness statement of [GSK's Finance Director A] in the litigation between GSK and the Apotex Parties, dated 11 November 2002 ('[redacted]WS2 (Apotex)') (document 0352).

²⁰⁷ *SmithKline Beecham Plc v Apotex Europe Ltd* [2003] EWHC 2939.

been infringed by the Apotex Parties.²⁰⁸ Subsequently, GSK was liable to pay damages to the Apotex Parties.²⁰⁹

F. Outline of the Agreements between GSK and the Generic Companies

3.137 The Investigation has focussed on the following agreements:

- the IVAX-GSK Agreement;
- the GUK-GSK Agreement; and
- the Alpharma-GSK Agreement.

3.138 A summary of the main terms of the Agreements, and the background to the Agreements, including the nature of the generic threat to GSK from generic paroxetine, is set out below.

3.139 To assist with understanding the sequencing of the key events, and for convenience, a chronological table of those key events is below.

Table 3.1: Key events with respect to the Agreements

Date	Event	Brief Description
January 1999	GSK's Initial Patent expired	GSK's Initial Patent for the paroxetine molecule expired although certain other patents remain in respect of particular paroxetine salt forms (anhydrate, hemihydrate and mesylate).
December 2000	Seroxat data exclusivity expired	The 10 year period of regulatory 'data exclusivity' for Seroxat expired.
1997 – 2002	IVAX, GUK, Alpharma and Hexal developed paroxetine products	IVAX, GUK, Alpharma and Hexal developed their own generic products independently of GSK.

²⁰⁸ *SmithKline Beecham Plc and others v Apotex Europe Ltd and others* [2003] EWHC 2939 (Ch).

²⁰⁹ Apotex later attempted to join two Canadian companies to the judgment in order to benefit from the cross-undertaking and any damages, however the application failed because the Court of Appeal ruled that Apotex had left it too late to amend the names of the parties (ie after the decision of non-infringement and invalidity on 8 December 2003). See *SmithKline Beecham Plc and others v Apotex Europe Ltd and others* [2006] EWCA Civ 658.

Date	Event	Brief Description
April 2001	GUK's MA granted	GUK's sister company Scand Pharm was granted an MA in Denmark in relation to paroxetine. GUK applied for mutual recognition in the UK (and other countries).
September 2001	IVAX's MA granted	IVAX was granted an MA in Ireland in relation to paroxetine.
3 October 2001	IVAX and GSK entered into the IVAX-GSK Agreement	IVAX was appointed as GSK's exclusive distributor of unbranded paroxetine in the UK. GSK agreed to provide IVAX with a restricted volume of paroxetine and to make value transfers to IVAX.
4 October 2001	IVAX and Tillomed enter into the IVAX-Tillomed Heads of Agreement	IVAX and Tillomed reached a Heads of Agreement for Tillomed to supply IVAX with paroxetine for distribution in the UK.
September – October 2001	GUK Litigation	GUK offered to supply generic paroxetine to customers in the UK. GSK initiated patent infringement proceedings against GUK, and obtained the GUK Interim Injunction in respect of GUK's proposed supply of paroxetine on 23 October 2001.
29 October 2001	GUK's MA granted in the UK	GUK's UK MA was granted but GUK was prevented, by GSK's earlier interim injunction, from supplying paroxetine in the UK independently of GSK.
December 2001	IVAX began to supply paroxetine	IVAX began to supply, as GSK's exclusive distributor, unbranded paroxetine in the UK sourced from GSK.
December 2001	IVAX and Tillomed entered into a revised agreement (the IVAX-Tillomed Supply Agreement)	IVAX and Tillomed entered into the IVAX-Tillomed Supply Agreement; under its terms, instead of Tillomed supplying IVAX with paroxetine, IVAX agreed to provide Tillomed with paroxetine sourced from GSK. In addition to Tillomed's own UK paroxetine sales, Tillomed

Date	Event	Brief Description
		received a share of the profit from IVAX's UK paroxetine sales in the UK. In return, Tillomed agreed to provide IVAX with exclusive rights to the Tillomed MA.
13 March 2002	GUK and GSK entered into the ('GUK-GSK Settlement Agreement')	Very shortly before trial in the GUK Litigation, GUK agreed to become a sub-distributor of IVAX. GSK agreed to provide GUK with a restricted volume of paroxetine (via IVAX) and to make value transfers to GUK.
14 March 2002	GUK and IVAX entered into the GUK-IVAX Agreement	GUK and IVAX entered into the GUK-IVAX Agreement as a condition precedent to the GUK-GSK Settlement Agreement.
29 April 2002	Alpharma's MA granted	Alpharma was granted an MA in the UK in relation to paroxetine.
June – August 2002	Alpharma-GSK Litigation commenced	Alpharma offered to supply generic paroxetine to customers in the UK. Alpharma subsequently agreed not to supply paroxetine pending trial in the Alpharma Litigation, following a hearing on 1 August 2002.
July 2002	The High Court invalidates most of GSK's Anhydrate Patent	Following a challenge brought by BASF, the High Court invalidated all but two claims in GSK's Anhydrate Patent.
October 2002	Apotex Litigation commenced	An injunction was granted on 28 November 2002 preventing the Apotex Parties from bringing paroxetine to the UK market.
12 November 2002	Alpharma and GSK entered into the Alpharma-GSK Settlement Agreement	Alpharma agreed to become a sub-distributor of IVAX. GSK agreed to provide Alpharma with a restricted volume of paroxetine (via IVAX) and to make value transfers to Alpharma.

Date	Event	Brief Description
20 November 2002	Alpharma and IVAX entered into the Alpharma-IVAX Agreement	Alpharma and IVAX entered into the Alpharma-IVAX Agreement as a condition precedent to the Alpharma-GSK Settlement Agreement.
December 2003	GSK's remaining claims in the Anhydrate Patent found invalid by the High Court	Apotex's distributors, Neolab and Waymade, subsequently began supplying paroxetine in the UK, and prices fell considerably during 2004.
February 2004	Termination of the Alpharma-IVAX Agreement and, consequently, the Alpharma-GSK Settlement Agreement	Alpharma terminated its agreement with IVAX and GSK, and began to supply its own generic paroxetine in the UK independently of GSK.
29 June 2004	Termination of the IVAX-GSK Agreement	IVAX terminated its Agreement with GSK and subsequently began to supply its own generic paroxetine in the UK independently of GSK.
1 July 2004	Termination of the GUK-IVAX Agreement and the GUK-GSK Settlement Agreement	GUK terminated its agreements with GSK and IVAX, and subsequently began to supply its own generic paroxetine in the UK independently of GSK.
November 2004	Apotex paroxetine found not to infringe GSK's patents (Court of Appeal)	The High Court's decision that the remaining claims in GSK's Anhydrate Patent were invalid was overturned by the Court of Appeal. However, the Court of Appeal found that Apotex did not infringe those patent claims.

i) The generic threat to Seroxat and GSK's strategy

a) The generic threat

3.140 GSK's branded paroxetine product, Seroxat, was a so-called blockbuster medicine.²¹⁰ As a result, GSK expected generic suppliers to seek to begin supplying paroxetine in the UK. Giving witness evidence in 2001, [GSK's Finance Director A] stated:²¹¹

'Paroxetine is one of the best selling medicines in the UK, and the World, and is therefore a very attractive target for all UK and European generic pharmaceutical companies.'

3.141 In 2001, GSK was aware of a number of suppliers that were able to supply bulk paroxetine. For instance, in September 2001, [GSK's Finance Director A] stated:²¹²

'...there are already several known suppliers of bulk paroxetine hydrochloride suitable for formulation: one in Europe (Knoll), one in the United States (Brantford Chemicals) and two in Japan (Sumika and Asahi).'

3.142 As well as identifying that it was possible to source bulk paroxetine, GSK recognised that other barriers to entry (other than patent protection) for a generic supplier were low.²¹³

'There are no significant technical difficulties in producing paroxetine [...]. Transport of the active ingredient in bulk in the quantities necessary to manufacture tablets for the UK is relatively simple and so the wide geographic spread of bulk manufacturers would be no obstacle to generic companies wishing to manufacture and sell generic paroxetine tablets in Europe.'

3.143 With reasonably ready access to the bulk paroxetine ingredients, GSK faced the threat of generic entry in the UK by a number of potential entrants including IVAX, GUK and Alpharma.²¹⁴

²¹⁰ A blockbuster medicine has been defined by the Commission as a medicine whose annual global turnover exceeds US\$1 billion: Commission (2009), Executive Summary of the Pharmaceutical Sector Inquiry, page 3.

²¹¹ [REDACTED]WS1 (GUK) (document 0885), paragraph 7.4.

²¹² [REDACTED]WS1 (GUK) (document 0885), paragraph 7.4.

²¹³ [REDACTED]WS1 (GUK) (document 0885), paragraph 7.4.

²¹⁴ For further details relating to GSK's worldwide litigation involving its paroxetine patents, see footnote 189.

b) GSK's strategy

3.144 In April 1999, in response to the threat of generic entry, GSK established an internal project team called '*Project Dyke*', which was tasked with defending Seroxat from generic competition and with sustaining patent protection for Seroxat. Project Dyke involved a global team from within GSK that held regular telephone conferences and meetings between 1999-2004²¹⁵ and had two key functions of particular relevance to the issues in this Decision:

- co-ordinating the legal defence of patent rights; and
- co-ordinating GSK's entry into '*co-marketing*' agreements (see paragraphs 3.146 to 3.154).²¹⁶

3.145 In 2001, generic suppliers began attempts to supply paroxetine in certain European countries such as Denmark and Germany. GSK was aware that it would need to rely on its patent position to challenge that entry. In a GSK presentation dated 2 December 2002, [GSK's Pricing Manager for Europe] sets out the threat to Seroxat from potential generic entrants for both paroxetine anhydrate and paroxetine mesylate. In order to defend against generic entry, the presentation considers possible defence strategies for Seroxat, including:²¹⁷

- *Maintain monopolistic position*
 - *Legal challenges, court injunctions, threat of legal action.*
 - *Third party supply agreement*
- *New market opportunities*
 - *PLEs [Product Line Engineering] and differentiation (new doses and forms 30 mg, 10 mg strengths and new indications in GAD [General Anxiety Disorder], SAD [Seasonal Affective Disorder], PTSD [Post Traumatic Stress Disorder])*
 - *OTC [Over The Counter] switch*

²¹⁵ See extract from EU Commission questionnaire dated October 2006 (document 0631), page 39, question 25 '*in relation to Project Dyke, provide the following information*'.

²¹⁶ Extract from CNS Psychiatry - Depression and Anxiety document (document 0105); GSK document headed '*Project Dyke – Europe maintains Seroxat franchise despite generic launches!*' (document 0108).

²¹⁷ GSK presentation entitled '*Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec*' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100).

- *Second Fighter Brand - compete on price*
- *Marketing and promo effort*
- *Financial incentives and NSP [Net Selling Price] discounts*
- *List price cuts'*

3.146 In taking these steps, GSK's strategy was to protect against the possible significant decline in prices which would follow generic entry. In a GSK Seroxat Brand Strategy document in December 2002, for example, GSK notes that the '*Defences undertaken to date [including co-marketing] are crucial to protect Seroxat prices*'.²¹⁸ Connected with that, GSK recognised the possible significant loss of profit that it would potentially suffer from a reduction of Seroxat sales if generic entry occurred (as described below in some detail by [GSK's Finance Director A] in a witness statement of 20 October 2001, shortly after entering into the IVAX-GSK Agreement).²¹⁹

3.147 On this basis, in order to '*maintain [GSK's] monopolistic position*', GSK either needed to (i) challenge any potential generic entrants using GSK's patent rights; or (ii) cooperate with the potential generic entrants by entering into '*supply agreements*' (also referred to as '*co-marketing agreements*').²²⁰

3.148 Under the supply agreement route, GSK would offer to supply potential generic entrants with paroxetine hemihydrate which the generic companies could then sell under their own name. Under the heading '*Co-marketing Strategies*', the presentation continues:²²¹

'• Deals to supply paroxetine hemihydrate to generic Co [company] to be marketed under new brand name.

- *Gives generic Co early access to market.*

²¹⁸ GSK presentation entitled 'Seroxat Brand Planning, Europe' by [GSK's Brand Manager (Neurosciences) Europe] dated December 2002 (document D124)

²¹⁹ See [§]WS2 (GUK) (document 0182), paragraphs 2.4–2.9.

²²⁰ GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100).

²²¹ GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100). This is an extract from the slide which includes other bullet points.

- *Avoids most price referencing, expensive legal action, risk of loss, maintains market volume.*²²²

3.149 In addition, GSK had identified that the supply agreement route would 'optimise market share'.²²³ GSK estimated that supply agreements could 'stabilise molecule market share of GSK compound at 70-80 per cent'.²²⁴ A market share loss of 20-30% is far lower than GSK could have suffered if faced with true generic competition. For example, in relation to one of Seroxat's competitors, Prozac, the branded company, Eli Lilly, lost around 80% of its market share once generic companies entered the market in 2000.²²⁵

3.150 Recognising the benefits of supply agreements, GSK decided during 2001 that it would explore supply agreements with third parties in the Netherlands, Denmark, Ireland, and 'GB'.²²⁶

3.151 Under the supply agreement route, GSK decided that rather than deal with several potential generic suppliers in each country, it would appoint one distributor as a 'hub' in each country. The benefits of this approach were described in an internal GSK presentation as follows:²²⁷

- *Use one generic as a "hub" for all other generic labels/wholesalers (eg Hexal) [in Germany]*
- *Invest in the relationship*
- *Keen supply price*
- *European wide co-ordination*
- *Generics with dominant market position most attractive*
- *Legal guidance to avoid anti-competitive agreements*

²²² 'Price referencing' refers to the process by which certain countries set the price (or more commonly the reimbursable price) of a medicine by referencing the price of the same product in different countries.

²²³ GSK presentation entitled 'Seroxat – Sales 2002 and future budget' dated 2002 (document 0194).

²²⁴ GSK presentation entitled 'How do LOC's Cope with the Generic Attack?' (document 0110).

²²⁵ [X]WS, Confidential exhibit [X]2 (document 0874), page 4.

²²⁶ GSK document entitled 'Seroxat patent' dated 11 May 2001 (document 0133). It also appears that such an agreement may have also been in contemplation in Australia – see email from [GSK's Senior Vice President Patents & Trademarks] to [GSK's Patent Attorney] and others dated 20 July 2001, saying that the GM of Australia favours the 'deal route' (document 0139).

²²⁷ GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100).

• *Spare licences must exist'*

3.152 Prior to entering into supply agreements in the UK, GSK had already entered into supply agreements relating to paroxetine with Hexal in Germany, the Netherlands and Ireland by August 2001.²²⁸ Under those agreements, GSK supplied Hexal with paroxetine hemihydrate for resale in these three countries. In Germany, discounts were given to Hexal for it to compete against parallel traders: *'Discounts to NSP [Net Selling Price] to compete with PT [Parallel Trade]*.²²⁹

3.153 Hexal had successfully developed a form of paroxetine anhydrate for which it had received an MA in Denmark. Hexal's subsidiary, GEA, subsequently launched a paroxetine anhydrate product called 'Optipar' in Denmark in early 2001. Hexal had by then applied for mutual recognition in a number of EU countries which it completed in May 2001. GSK then entered into negotiations with Hexal to discuss the possibility of GSK supplying Hexal with paroxetine on a country-by-country basis rather than Hexal supplying its own generic version of paroxetine anhydrate. As mentioned above, Hexal had agreed settlements with GSK in Germany, the Netherlands and Ireland by August 2001. Hexal later reached additional settlements with GSK in relation to Denmark and Spain by December 2001.

3.154 By pursuing its strategy of legal action and supplying generic suppliers, GSK considered that it could *'[m]aintain peace and quiet, both in GSK and in the market*.²³⁰

ii) The background to the IVAX-GSK Agreement

3.155 Prior to entering into the IVAX-GSK Agreement, GSK identified a number of generic suppliers including IVAX, Hexal and GUK that were taking steps to launch generic versions of paroxetine in the UK independently of GSK.²³¹

3.156 It appears that GSK's Project Dyke team first identified IVAX, the second largest supplier of generic medicines in the UK, as a potential generic threat in relation to paroxetine in 2000. An internal GSK email in July 2000 records the

²²⁸ GSK presentation entitled 'Seroxat Salts Update' dated 14 December 2001 (document 0192).

²²⁹ GSK presentation entitled 'Seroxat Price Strategy Gothenburg 29th August' by [GSK's Pricing Manager for Europe] dated 29 August 2002 (document 0313).

²³⁰ GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100).

²³¹ [redacted]WS1 (GUK) (document 0885), paragraphs 7.5, 7.6 and 7.10.

agenda for a teleconference to discuss the 'potential anhydrate threat posed by' IVAX (also referred to as 'Norton').²³²

- 3.157 GSK, when describing the initial discussions with IVAX regarding paroxetine, stated that it was IVAX's 'clear intention' to launch. GSK stated that IVAX's claims that it could launch became increasingly credible when IVAX succeeded in obtaining an MA in Ireland. On this basis, GSK considered that IVAX would be in a position to launch paroxetine in the UK 'in a matter of months'. An extract from GSK's response to the OFT is set out below.²³³

'[...] When Ivax first approached GSK, in 2000 its approach was very aggressive and it evinced a clear intention to launch. GSK was initially sceptical of the claims but could not dismiss them as implausible, since they came from a company which GSK considered had general commercial credibility, and from individuals within that company whom GSK regarded as commercially capable.

Over some months, Ivax continued to claim to have a paroxetine product and had produced a sample in a meeting, but refused GSK's repeated requests for a sample to test. GSK was not in a position to carry out a test by acquiring the proposed product in another market as it was able to do subsequently in the case of GUK, which already had product on the market in Australia.

The plausibility of Ivax's claims became increasingly stronger. As early as June 2000 GSK had confirmation, from [Director] at Norton (Ivax), that it had submitted a file for market authorisation for generic paroxetine and by 7 September 2001, it was publicly known that Ivax had obtained market authorisation in Ireland. GSK knew that a license in Ireland would enable Norton to apply for market authorisation in the UK (and other EU Member States), through the Mutual Recognition procedure in a matter of months.

In addition, by the time of the Ivax Agreement, Ivax had told GSK that it had a potential alternative source through GUK, backed by an indemnity against patent infringement. GSK had by this time acquired and tested tablets sourced from GUK's sister company Alphapharm in Australia.

²³² Email from [the Marketing Director for Seroxat] to [GSK's Vice President – R&D Legal Operations], [GSK President (Pharmaceuticals International)], [GSK's Chief Executive Officer] and other GSK employees dated 21 July 2000 (document 0121) entitled 're: Paroxetine anhydrate telecon – 28th July'.

²³³ The response dated 16 July 2012 to the Section 26 Notice dated 18 June 2012 sent to GSK ('GSK Third Response') (document 0750), paragraphs 1.2–1.6.

At the time of the Ivax Agreement therefore, GSK considered that Ivax was genuinely intending to launch with an anhydrate product that was likely to infringe its patents. As stated in Witness Statements, had Ivax launched in the UK, GSK would have taken infringement action.'

3.158 In a later witness statement provided as an Annex to the GSK Response dated 7 August 2013 to the SO ('GSK SO Written Response'), [GSK's Finance Director A] stated that:²³⁴

'I recall that [Managing Director] of IVAX first approached GSK in mid-2000. I had a series of discussions with [IVAX's Managing Director] and [IVAX's Commercial Director] over the period that followed. They said they had a paroxetine product. In one meeting they put a vial on the table but they would not let us take it away for testing. They were very aggressive - they said they would break our patents and launch independently.'

3.159 GSK considered that if GSK and IVAX did not enter into a supply arrangement, IVAX would have launched its own generic paroxetine product in the UK, in competition with Seroxat. In 2001, [GSK's Finance Director A] gave witness evidence in the GUK Litigation that: *'in the absence of an agreement, they [IVAX] would launch their own generic paroxetine.'*²³⁵

3.160 In the same witness statement in September 2001, [GSK's Finance Director A] stated that independent entry by a generic supplier would *'result in the introduction of other generic products onto the marketplace shortly thereafter with a further wave following as little as 7 months later once relevant marketing authorisations are in place.'*²³⁶ [GSK's Finance Director A] stated that he believed *'that a number of suppliers of generic paroxetine will enter the UK marketplace within the next few months.'*²³⁷

3.161 GSK therefore expected that independent generic entry would harm its business both by reducing the amount of Seroxat that GSK could supply and lowering the price at which it could be supplied. Indeed, GSK said that its lost revenue as a result of entry by an independent supplier of generic paroxetine, and subsequent entry by other generic suppliers, would be very substantial.²³⁸ This is consistent with the evidence provided by [REDACTED], an expert witness

²³⁴ Witness statement of [GSK's Finance Director A] dated 1 August 2013 (document A 0059), paragraph 3.5.

²³⁵ [REDACTED] WS2 (GUK) (document 0182), paragraph 2.3.

²³⁶ [REDACTED] WS1 (GUK) (document 0885), paragraph 7.10.

²³⁷ [REDACTED] WS1 (GUK) (document 0885), paragraph 8.6.

²³⁸ [REDACTED] WS1 (GUK) (document 0885), paragraph 8.3.

appointed by GSK during the GUK Litigation. [GSK's independent expert's] principal conclusions were as follows:²³⁹

'If several competitors enter the market with generic paroxetine, the effect on Seroxat is certain to be serious. In terms of the questions asked [...] the impact would in my opinion be broadly as follows:

- (i) The volume of Seroxat sales can be expected to drop sharply [...] This loss of sales volume is likely to be in the region of 62% to 77% after 12 months.*
- (ii) [...] An attempt to compete with generics by cutting the price of Seroxat would merely intensify the severity of price cutting by generic competitors. [...]*
- (iii) Based on the course of events in the case studies, generic paroxetine can be expected first to offer price discounts. Later, when these are reflected by the National Health Service in reducing the official drug tariff price of paroxetine, generics will probably undercut the pre-generic price of Seroxat by around 30% within 6 months of launch, by 45 to 50% after 12 months and by 60% after 24 months.'*

3.162 By analogy, [GSK's independent expert] highlighted the fall in price, of some 57% in nine months, that had been observed when a patent expired on another SSRI antidepressant, Prozac, and generic competition occurred.²⁴⁰

3.163 [GSK's Finance Director A] described the process through which a loss of sales volume and reduction in the price of paroxetine would occur when a number of generic suppliers enter the market:²⁴¹

'Second and subsequent generic entrants into the marketplace for any given pharmaceutical product can take sales away from the first, or incumbent, generic supplier(s) only by pitching their entry price (and discounts) below that of the incumbent(s).'

3.164 [GSK's Finance Director A] stated that GSK's likely response would have been to *'drop its price to customers to match the discounted generic price'*.²⁴² GSK considered that not only would its selling price fall, but it would have

²³⁹ [REDACTED]WS (document 0143), paragraph 20.

²⁴⁰ [REDACTED]WS, Confidential exhibit [REDACTED]2 (document 0874), paragraph 2.4.

²⁴¹ [REDACTED]WS1 (GUK) (document 0885), paragraph 8.1.

²⁴² [REDACTED]WS1 (GUK) (document 0885), paragraph 4.8.

experienced a contraction in its number of customers as it would not be practical to negotiate brand equalisation deals with all of its customers.²⁴³ GSK estimated that it *'could retain 40-60 per cent of the present level of unit sales for Seroxat, but the income from those sales will be very much smaller than the current sales income.'*²⁴⁴

3.165 Similarly, IVAX anticipated that independent entry by generic suppliers of paroxetine would have resulted in price falls. In particular, IVAX believed that the speed and scale of price falls observed would depend on the number of generic entrants. For example, when IVAX was contemplating generic entry before the IVAX-GSK Agreement was terminated in 2003, IVAX's forecasts suggest that price cuts ranging between 15% to 30% would result from entry of each independent generic supplier.²⁴⁵

a) IVAX's commercial position in relation to paroxetine

3.166 IVAX commenced work in 1999 on developing a generic version of paroxetine anhydrate in anticipation of the expiry of GSK's data exclusivity in relation to paroxetine in December 2000.²⁴⁶ To assist with the development of the product, IVAX established a paroxetine project team led by [REDACTED] [the Head of Intellectual Property].²⁴⁷

3.167 According to IVAX employees in witness evidence, IVAX's commercial goal was to be the first independent generic supplier of a paroxetine product in the UK.²⁴⁸

3.168 An internal IVAX note prepared by [IVAX's Managing Director], on 14 March 2001, provides a summary of IVAX's consideration of IVAX's paroxetine position at that time. The note recorded GSK's view that it was not possible to

²⁴³ [REDACTED]WS1 (GUK) (document 0885), paragraph 4.8.

²⁴⁴ [REDACTED]WS1 (GUK) (document 0885), paragraph 8.2.

²⁴⁵ See spreadsheet entitled 'Paroxetine 2004 A.S.P – C.O.G forecast models' (document 1624).

²⁴⁶ See the email from [GSK's Vice President Pharma Patents] to [GSK's Patent Attorney] dated 13 May 1999 (document 0116), stating that they had *'been approached by Norton (a UK generic) who want to talk about a non-infringing form of paroxetine which they allegedly have developed'*. See also the fax from Knoll AG to Norton dated 8 February 2000 (document 1673), which refers to earlier correspondence between Knoll and Norton in 1999.

²⁴⁷ See Witness statement of [IVAX's Head of New Business Development], dated 13 February 2013 ('[REDACTED]WS') (document 2333), paragraph 3.4.

²⁴⁸ See witness statement of [IVAX's Commercial Director], dated 2 December 2012 ('[REDACTED]WS') (document 2332), paragraph 3.3: *'IVAX wanted to be seen by its customers to be the company that launched first. Being first to market in any market normally brings significant commercial upside.'* See also Witness statement of [IVAX's Managing Director], dated 18 January 2013 ('[REDACTED]WS') (document 2334), paragraph 3.1 and [REDACTED]WS (document 2333), paragraph 3.1. See further email from [IVAX's Head of Intellectual Property] to [BASF employee] dated 10 March 2000 (document 1686). See also the email from [IVAX's Sales and Marketing Manager] to [IVAX employee] dated 30 November 2001 (document 1746) stating: *'First to market launch secures a higher revenue and profit return for IVAX and provides a solid base for our market share when our competitors enter the market.'*

produce the anhydrate form of paroxetine without it converting to hemihydrate form and thereby infringing the Hemihydrate Patent. However the note also recorded that IVAX was investigating whether it was possible to make an anhydrate form of paroxetine that could be proven not to convert.²⁴⁹

- 3.169 The note also recorded IVAX's awareness that there were several other generic suppliers who were trying to produce paroxetine anhydrate, including Hexal, GUK, Apotex, Synthon, BASF and Sumika.²⁵⁰
- 3.170 That note canvassed a range of options open to IVAX at the time, including: (i) launching in Ireland with IVAX's own product (from a BASF source) and then getting mutual recognition of IVAX's MA to launch elsewhere; (ii) entering into a 'supply agreement' with GSK; or (iii) partnering with another supplier (a 'Partner of choice in UK').²⁵¹
- 3.171 According to [REDACTED], a former employee (and Head of New Business Development) of IVAX, Ireland was selected for the MA application rather than the UK because Ireland had a shorter period of data exclusivity in 2001²⁵² and therefore provided the '*quickest way for IVAX to access the UK market*'.²⁵³
- 3.172 In response to concerns within IVAX that its product may potentially infringe GSK's Hemihydrate Patent, IVAX considered introducing a low humidity manufacturing suite, which would reduce the risk of conversion. This was referred to in the notes of the paroxetine team meeting of 14 August 2001 ('*There are [...] talks about a climate-protected packing line*'), with one of the actions from that meeting being for [IVAX employee] to *check on status of ANDA and packing line upgrade and report back to the group on feasibility of IVAX manufacture and packaging*'.²⁵⁴ This possibility is also referred to in [IVAX's Head of New Business Development's] witness statement where he stated:²⁵⁵

²⁴⁹ IVAX internal document entitled 'Serostat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699). See also [REDACTED]WS (document 2334), paragraph 3.4.

²⁵⁰ Hexal, Apotex, BASF and Sumika (in conjunction with GUK) were all producing versions of paroxetine anhydrate. BASF and Sumika were suppliers of bulk paroxetine API, rather than paroxetine tablets. BASF supplied bulk paroxetine to Hexal and IVAX. Sumika supplied bulk paroxetine to GUK. Synthon was in fact attempting to produce a different salt version of paroxetine called paroxetine mesylate. It was subsequently involved in protracted litigation with GSK. Apotex was supplied by another bulk supplier of paroxetine from the US, Brantford Chemicals.

²⁵¹ IVAX internal document entitled 'Serostat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699).

²⁵² [REDACTED]WS (document 2333) at paragraph 4.7. Although [REDACTED]WS refers to a data exclusivity period of 10 years in the UK in 2001, the 10 year period for data exclusivity for Serostat expired in December 2000.

²⁵³ [REDACTED]WS (document 2333), paragraph 4.7.

²⁵⁴ Minutes from IVAX paroxetine team meeting on 14 August 2001 (document 1709).

²⁵⁵ [REDACTED]WS (document 2333), paragraph 4.19.

'At the time, the paroxetine team had identified ways to reduce but not to eliminate the risk of conversion. One possible method was to install a low humidity manufacturing suite which would reduce humidity in the manufacturing process and therefore reduce the risk of conversion.'

3.173 The note recognised that if IVAX pursued the option of launching with its own product, it would need to 'scale up' its facilities at Waterford, which was at that stage 'not currently possible as no capital investment to control humidity'. The note estimated that the capital investment required would be 'c.£50k', which [IVAX's Head of New Business Development] considered 'was not a hugely significant amount for a company like IVAX'.²⁵⁶ In July 2003, when considering the launch of its paroxetine product in France, IVAX considered that temperature and humidity controls would be required during manufacturing to 'prevent the conversion from anhydrous to hemihydrate', suggesting that changes to manufacturing processes remained a feasible approach.²⁵⁷

3.174 [IVAX's Managing Director's] note identified the key advantages for IVAX of entering into a supply agreement with GSK rather than launching IVAX's own product. In particular, the note highlighted the delay that it would cause to other potential generic entrants that could otherwise have benefited from action by IVAX to challenge the paroxetine patents held by GSK.²⁵⁸

3.175 Under a supply agreement, according to [IVAX's Head of New Business Development], IVAX's commercial proposition to GSK was as follows:²⁵⁹

'IVAX could say: "we have a product and we are about to come to the market. We have on average 25 % market share. If you don't want to lose most of your market share – which you will when generic companies will eventually come onto the market, then we can be the

²⁵⁶ See IVAX internal document entitled 'Seroxat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699) and [X]WS (document 2333), paragraph 4.19. The CMA also notes that £50,000 is not a large figure when compared to the profit that IVAX would likely receive in return for this investment. Although IVAX's documents did not contain a figure setting out its expected profit from independent entry with its own generic product, the CMA notes that in an email dated 31 December 2001, [GUK's General Manager] commented that the offer that GSK had made to GUK would enable it to earn profits that were comparable with those that it expected to earn by entering the UK paroxetine market independently of GSK. [GUK's General Manager] noted that the GSK offer 'would deliver a similar bottom line (£5.6m v's £6m)'. Email chain between [Merck's Head of Patents and Raw Material Support Group], [the Chief Executive of Merck Generics Group], [GUK's General Manager], [GUK's Head of Research and Development], [Head of Merck Operation in Canada], [the Head of Merck Operation in Australia] and [GUK's Managing Director] dated 31 December 2001 (document 0955).

²⁵⁷ See email from [X] (Regulatory Affairs, IVAX) to [IVAX Head of Operations, Ireland] dated 23 September 2003 (document 1869).

²⁵⁸ IVAX internal document entitled 'Seroxat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699).

²⁵⁹ [X]WS (document 2333), paragraph 6.6.

best commercial partner for you to sell a generic version of your product.”

- 3.176 The supply agreement route had previously been used between GSK and IVAX in 1998 in relation to GSK’s branded medicine, named ‘Augmentin’.²⁶⁰ Under the Augmentin supply agreement, GSK supplied IVAX with GSK’s product Augmentin which allowed IVAX to supply a smaller share of the market whilst GSK retained the remaining larger share of the market.²⁶¹
- 3.177 Other internal IVAX documents expanded on the idea of sourcing finished product from competitors in the supply of generic medicines (the third option canvassed in [IVAX’s Managing Director’s] note).²⁶² [IVAX’s Managing Director] informed the OFT that IVAX decided to consider third party options given that it had identified potential patent infringement concerns with respect to its own paroxetine product, principally concerns associated with the possible conversion of IVAX’s anhydrate product to a hemihydrate product which potentially infringed the Hemihydrate Patent.²⁶³ Teva confirmed that:²⁶⁴

‘Teva UK understands that IVAX also had some discussions in 2000 and 2001 with various other suppliers - GUK, Tillomed - to see if it could obtain supply from them.’

- 3.178 In summary, therefore, prior to entering into the IVAX-GSK Agreement, IVAX had three main options to supply paroxetine in the UK:
- Option one: to develop IVAX’s own version of paroxetine;
 - Option two: to source finished product paroxetine from another generic medicine supplier; and
 - Option three: to enter into a supply agreement with GSK.

²⁶⁰ See document entitled ‘Augmentin, Late Stage Life Cycle Management’ (document 1648). The agreement had an initial term of three years and was open ended. IVAX was appointed as GSK’s exclusive distributor with rights to appoint sub distributors. IVAX appointed two sub distributors. The arrangement, reconciled quarterly, involved GSK charging a transfer price for all liveries and then receiving a profit share of IVAX’s margin. The transfer price to sub distributors by IVAX varied depending on the average retail price within the market. See also part two of the response (dated 20 July 2012) to the Section 26 Notice dated 12 June 2012 sent to Teva (document 2124), Tables 1 and 2. Note that Tables 1 and 2 refer to Co-Amoxiclav which are active ingredients of Augmentin. Augmentin is the brand name for Co-Amoxiclav.

²⁶¹ Document entitled ‘Augmentin, Late Stage Life Cycle Management’ (document 1648). See also part two of the response (dated 20 July 2012) to the Section 26 Notice dated 12 June 2012 sent to Teva (document 2124), Tables 1 and 2.

²⁶² See for example the Minutes from IVAX paroxetine team meeting on 14 August 2001 (document 1709).

²⁶³ See [redacted]WS (document 2334), paragraph 3.8.

²⁶⁴ Part one of the response dated 30 April 2012 to the Section 26 Notice dated 23 March 2012 sent to Teva, added to on 26 March 2012 and 5 April 2012 (‘Teva Second Section 26 Notice’) (document 2043), question 4.

Further details of IVAX's exploration of those options are set out in turn below.

b) Option one: to develop IVAX's own version of paroxetine

- 3.179 By June 2000, IVAX had successfully developed a paroxetine product in tablet form and applied for an MA in Ireland. The product which was the subject of that application was based on the API that IVAX had obtained from BASF.
- 3.180 During the course of 2001, IVAX agreed in principle to become the exclusive purchaser of BASF's API in the UK.²⁶⁵
- 3.181 Minutes from an internal IVAX paroxetine team meeting on 14 August 2001 report the progress made on the various work strands associated with the development of IVAX's own product and, in particular, on the MA (also referred to as a 'licence'):²⁶⁶

'Registration status: Medical assessment completed and returned. IMB [Irish Medicines Board] due to review on 24 August. If no more outstanding issues, licence expected to be issued then. MR [mutual recognition] strategy yet to be developed.'

Manufacturing: There are plans to upgrade the ANDA [Abbreviated New Drug Application] suite and talks about a climate-protected packing line. These would be essential for in-house development and packing of full-scale paroxetine.'

API source: It was noted that IVAX are currently using BASF generics. Other possible source is Sumika (being used by IPI [Ivax Pharmaceuticals Incorporated]).'

- 3.182 The minutes make clear that at that stage, IVAX had not yet reached a concluded view on the 'feasibility of IVAX manufacture and packaging' of its own product. The issue appears to have been whether IVAX could or would upgrade its facilities to provide a manufacturing environment that could ensure that the anhydrate product would not convert to hemihydrate form.²⁶⁷

²⁶⁵ IVAX also considered sourcing paroxetine from Sumika but preferred the BASF product because it was likely to be cheaper. See Minutes from the paroxetine team meeting on 11 September 2001 (document 1714).

²⁶⁶ Minutes from IVAX paroxetine team meeting on 14 August 2001 (document 1709).

²⁶⁷ See [REDACTED]WS (document 2333), paragraphs 4.14–4.21. See also [REDACTED]WS (document 2334), paragraph 3.3 and [REDACTED]WS (document 2332), paragraphs 4.13–4.14.

- 3.183 The same minutes also note that IVAX was also continuing to explore the option of entering into a supply agreement with GSK in parallel with considering the possibility of launching on an independent basis.
- 3.184 The MA in Ireland was granted on 7 September 2001.²⁶⁸
- 3.185 Having been successful in gaining an MA in Ireland, IVAX was then in a position to apply for an MA in the UK under the EU rules on mutual recognition.²⁶⁹ Upon approval under the mutual recognition procedure by the then UK MCA (which is now the MHRA), IVAX would then have been able to sell its own generic paroxetine product in the UK (subject to any patent infringement proceedings initiated by GSK). Teva and IVAX employees submitted that the mutual recognition process usually took around 7 to 12 months to complete, but could sometimes take longer.²⁷⁰ Teva has estimated that, had IVAX applied for mutual recognition, *'a formal MA would have been issued to IVAX in late September 2002.'*²⁷¹
- 3.186 At a meeting held on 11 September 2001, it was reported that IVAX had decided that it would nevertheless source paroxetine product from a third party for supply in the UK:²⁷²

'UK Launch status: [REDACTED] [IVAX's Head of New Business Development] informed the group that the decision had been taken to launch in the UK with a 3rd party product. Discussions are ongoing with two parties and are being managed by [IVAX's Managing Director] and [IVAX's Commercial Director]. It is possible that one of the options will involve IVAX having to arrange it's [sic] own packing from bulk product...'

- 3.187 Although there is some evidence to suggest that, subsequent to entering into the IVAX-GSK Agreement, IVAX intended to continue developing its in-house product²⁷³ and gave some further consideration to developing its paroxetine

²⁶⁸ This was reported in Minutes from the paroxetine team meeting on 11 September 2001 (document 1714): *'Regulatory status: The product finally received its Product Licence from the IMB on 7th September. The team congratulated [Regulatory Affairs, IVAX] on the productivity of her hard work. Once the assessors report is complete, the product will be ready to submit for mutual recognition.'*

²⁶⁹ See [REDACTED]WS (document 2332), paragraph 4.6 and Teva submission to the OFT dated 24 September 2012, 'Mutual recognition timeline' (document 2154).

²⁷⁰ See [REDACTED]WS1 (GUK) (document 0885), paragraph 7.7, [REDACTED]WS (document 2332), paragraph 4.8, [REDACTED]WS (document 2333), paragraphs 4.10–4.11. [IVAX's Commercial Director] indicated that the process could take longer if IVAX had needed to make changes to the API used (See [REDACTED]WS (document 2332) at paragraphs 4.8 and 4.9).

²⁷¹ See Teva submission to the OFT dated 24 September 2012, 'Mutual recognition timeline' (document 2154).

²⁷² Minutes from the paroxetine team meeting on 11 September 2001 (document 1714).

²⁷³ Document entitled 'New Product Delivery (In House Development & Licensed In) Monthly Report – October 2001' (document 1719), page 9, document entitled 'New Product Delivery (In House Development & Licensed In) Monthly Report – September 2001' (document 1711) which states *'in house development project is to continue in order to support the product in the longer term'*.

product in terms of obtaining an MA in the UK,²⁷⁴ it did not subsequently obtain an MA for its anhydrous product in the UK or any other EU countries (except Ireland).²⁷⁵ Moreover, there is no other evidence from internal IVAX documents at the time or from OFT and CMA interviews with former IVAX employees that IVAX carried out further development of its anhydrous product.²⁷⁶ Additionally, [IVAX's Managing Director] and [IVAX's Head of New Business Development] could not recall any development work taking place on IVAX's own product after the IVAX-GSK Agreement was entered into. Indeed, [IVAX's Head of New Business Development], in an email to colleagues in IVAX France on 7 June 2004 stated that '*the decision was taken to discontinue with the project*'.²⁷⁷

c) Option two: to source paroxetine product from a third party

3.188 As mentioned at paragraph 3.177, IVAX had discussions with companies other than BASF, including GUK and Tillomed, in order to explore the possibility of obtaining from them supply of finished paroxetine product.²⁷⁸ Such arrangements between pharmaceutical suppliers (known as in-licensing arrangements) were common during this period (and subsequently) and enabled the recipient companies to expand their respective product portfolios.²⁷⁹ For example, the CMA understands that IVAX obtained a supply of a different pharmaceutical product, omeprazole, from GUK in January 2002.²⁸⁰

²⁷⁴ IVAX documents show that IVAX considered whether it should apply for an MA in the UK and other European countries. In particular, email chain between [REDACTED] (Regulatory Affairs, IVAX), [IVAX's Head of New Business Development], [IVAX's Head of Intellectual Property] dated 7 March 2002 (document 1763), email chain between [IVAX's Sales and Marketing Manager], [IVAX employee, Sweden], [IVAX's Commercial Director], [Regulatory Affairs, IVAX], [IVAX's Head of New Business Development], [IVAX's Head of Regulatory Affairs], and [IVAX's Research & Development Director] dated 9 April to 6 May 2002 (document 1773) in which IVAX suggests submitting an MA in the UK as 'back-up', and email chain between [Head of Project Management, IVAX], [Licensing Manager, IVAX], [IVAX's Head of New Business Development], [other IVAX employees], [IVAX's Sales and Marketing Manager], [IVAX's Commercial Director], [IVAX's Product Manager], and [Medical Director, Teva UK Ltd] dated 2 October 2003 (document 1818).

²⁷⁵ Email from [IVAX's Head of New Business Development] to [IVAX employee, Sweden] and [IVAX employee, France] dated 18 July 2003 (document 1869). [IVAX's Head of New Business Development] explains why IVAX never submitted an MA in other EU states, referring to the uncertain launch situation due to GSK's patent.

²⁷⁶ Minutes from the paroxetine team meeting on 11 September 2001 (document 1714). [REDACTED]WS (document 2333). Document entitled 'New Product Delivery (In House Development & License In)' (document 1650).

²⁷⁷ Email from [IVAX employee] to [IVAX's Regulatory Affairs Manager] dated 21 June 2004 forwarding an email from [IVAX's Head of New Business Development] to [IVAX Legal Counsel, France] dated 7 June 2004 (document 1930). See also Minutes of API Working Team 2 Meeting dated 27 January 2004 (document A0040R), which states that an in-house paroxetine project was discontinued after results from BASF showed the samples provided were mostly hemihydrate.

²⁷⁸ Part one of the response dated 30 April 2012 to the Teva Second Section 26 Notice, (document 2043), question 4. For further information on Tillomed, see <http://www.tillomed.com/company/the-history/>

²⁷⁹ See [REDACTED]WS (document 2333), paragraph 1.3.

²⁸⁰ See [REDACTED]WS (document 2333), paragraph 7.6. As a result of negotiations between [IVAX's Head of New Business Development] and [GUK's General Manager], IVAX and GUK entered into an in-licensing agreement dated 28 January 2002 for omeprazole (10mg, 20mg and 40mg capsules) for a term of two years. Omeprazole

- 3.189 In an interview with the OFT, [IVAX's Commercial Director] stated that IVAX was exploring a range of sources in relation to the supply of paroxetine in 2001. [IVAX's Commercial Director] described the paroxetine landscape as a 'moving feast' which IVAX was continually monitoring to identify who would be launching, and who would be a possible source of, paroxetine in the UK.²⁸¹
- 3.190 In his witness statement, [IVAX's Managing Director] refers to two main options (other than GSK) for IVAX to obtain paroxetine. These were either from GUK or Tillomed.²⁸² Negotiations took place with both of these companies about obtaining a supply of paroxetine as described below.

Negotiations with GUK

- 3.191 By 2001, IVAX knew that GUK was developing a paroxetine product. In his notes of 14 March 2001, [IVAX's Managing Director] listed GUK as one of IVAX's competitors in relation to paroxetine. In addition, IVAX was aware that GUK was sourcing the API for its paroxetine from a company named Sumika in Japan. Indeed, IVAX's parent company in the US, IVAX Pharmaceuticals Incorporated, was also sourcing paroxetine API from Sumika.²⁸³
- 3.192 During the course of 2001, several discussions took place between individuals at IVAX and GUK about the possible supply of paroxetine from GUK to IVAX, as well as discussions regarding the potential supply of paroxetine from IVAX to GUK.²⁸⁴
- 3.193 In his witness statement, [IVAX's Managing Director] recalled that he had some discussions with [GUK's Managing Director] regarding possible supply of paroxetine from GUK. However, he recalled that he left GUK's offer 'on the table' and did not respond to GUK immediately while he negotiated terms with Tillomed and GSK. [IVAX's Managing Director] believed that Tillomed and

subsequently became one of IVAX's top 10 selling formulations in 2002-03 (see also part two of the response (dated 20 July 2012) to the Section 26 Notice dated 12 June 2012 sent to Teva (document 2124), page 6).

²⁸¹ Transcript of interview with [IVAX's Commercial Director] on 18 May 2012, dated 9 August 2012. (document 2143), page 17.

²⁸² [REDACTED]WS (document 2334), sections 4 and 5.

²⁸³ Minutes from the paroxetine team meeting on 11 September 2001 (document 1714), report that: '*IPI source: It was noted that IPI [IVAX Pharmaceuticals Incorporated] use the same source as GUK – Sumika from Japan. [REDACTED] [IVAX's Head of New Business Development] suggested that it might be suitable to source this product if GUK win their case against GSK after they launch, as long as they don't have exclusivity. [REDACTED] [IVAX's Head of Intellectual Property] noted that GUK did not have exclusive rights to the Sumika source, but that the source was probably irrelevant to the patent situation anyway. If Sumika source is OK, then BASF source is likely to be OK. The main point of contention is with the formulation patent (hemihydrate). BASF source also likely to be cheaper than Sumika.*'

²⁸⁴ Reference to these discussions is provided in [REDACTED]WS2 (GUK) Exhibit [REDACTED]5 (document 0888), paragraph 1.1 and [REDACTED]WS (document 0901) and [REDACTED]WS (document 2333) and [REDACTED]WS (document 2332) in particular, paragraphs 5.4–5.10.

GSK were more credible options than GUK.²⁸⁵ [IVAX's Managing Director] stated:²⁸⁶

'At the time, I recall that I was sceptical about [GUK's Managing Director's] claims because GUK often overstated its ability to supply certain products. [GUK's Managing Director] was a very successful man in the generics industry and to be successful in the generics industry requires a certain amount of "bluff".'

3.194 In an interview with the OFT, [IVAX's Commercial Director] stated that he recalled that GUK was *'an option'* but he did not believe GUK had a viable product because GUK did not have an MA in the UK in September 2001 when negotiations were taking place between IVAX and both GUK and GSK.²⁸⁷

3.195 It appears that throughout September 2001 discussions between IVAX and GUK continued. In early September 2001, IVAX had told GSK that it was considering its options and that a decision would be taken at the end of September 2001.²⁸⁸ In addition, according to [GSK's Finance Director A], [the Managing Director] of IVAX told him that GUK was offering IVAX an indemnity over any issues relating to patent infringement.²⁸⁹ In a subsequent witness statement, [GSK's Finance Director A], in reference to the negotiations, said it was:²⁹⁰

'touch and go which option Norton would choose right up to the time when the major terms were finalised between SB [SmithKline Beecham] and Norton on Friday 28 September.'

3.196 On 3 October 2001, [IVAX's Sales and Marketing Manager] telephoned [GUK's General Manager] to say that IVAX had decided to take supply from GSK.²⁹¹ In an email to other IVAX employees, [IVAX's Head of New Business Development] reported:²⁹²

'Apparently, [GUK's Managing Director] is v. pissed off that we have gone to GSK. He seems to think that he and [IVAX's Managing Director] had some sort of [sic – of] "gentleman's agreement" not to do so, and that we would go with GUK. I told him that I was never aware

²⁸⁵ [REDACTED]WS (document 2334), paragraph 4.4: *'I do not recall considering GUK to be a serious option at the time'*.

²⁸⁶ [REDACTED]WS (document 2334), paragraph 4.2.

²⁸⁷ [REDACTED]WS (document 2332), paragraphs 5.4–5.10.

²⁸⁸ [REDACTED]WS2 (GUK) Exhibit [REDACTED]5 (document 0888), paragraph 1.1.

²⁸⁹ [REDACTED]WS2 (GUK) Exhibit [REDACTED]5 (document 0888), paragraph 1.1.

²⁹⁰ [REDACTED]WS2 (GUK) Exhibit [REDACTED]5 (document 0888).

²⁹¹ See [REDACTED]WS (document 0901), paragraph 22.

²⁹² Email from [IVAX's Head of New Business Development] to [IVAX's Commercial Director] dated 10 October 2001 (document 1795).

that we had ever agreed anything but that discussions had certainly taken place – perhaps [GUK's Managing Director] misinterpreted something?? Not sure what effect this may have on our other "discussions" with GUK. Whether he misinterpreted or not, [GUK's General Manager] is making out that [GUK's Managing Director's] upset with us anyway.'

3.197 When interviewed by the OFT, [IVAX's Managing Director] said that he did not consider that IVAX had a 'gentleman's agreement' with GUK. He recalled that there had been discussions with GUK about GUK supplying IVAX with paroxetine but that nothing had been agreed and that [IVAX's Managing Director] had, as described above, left this 'on the table'.²⁹³

Negotiations with Tillomed

3.198 In addition to GUK, IVAX also had engaged in negotiations with Tillomed about Tillomed supplying paroxetine to IVAX.²⁹⁴

3.199 In 2001, Tillomed was 50% owned by the German company, Hexal, (referred to at paragraph 3.13), that had been granted an MA in Denmark for a generic version of paroxetine anhydrate.²⁹⁵ Hexal was sourcing the API for its paroxetine product from BASF.²⁹⁶ Hexal, through its subsidiary GEA, had subsequently entered the Danish market with its paroxetine product in February 2001.²⁹⁷

²⁹³ [REDACTED]WS (document 2334), paragraph 4.2.

²⁹⁴ There is also evidence to suggest that IVAX had offered to supply Tillomed with paroxetine before concluding the IVAX-GSK Agreement. In the GUK Litigation, GUK's Sales and Marketing Director, [REDACTED], stated in his witness statement that [REDACTED], Managing Director of Tillomed, had informed him in a telephone conversation which took place between mid-August and mid-September 2001 that Tillomed would take supply from IVAX between mid-August and mid-September 2001 (see [REDACTED]WS (document 0901), paragraph 25). In GSK's response to this witness statement, GSK's Finance Director [A], [REDACTED], confirmed that no agreement on paroxetine had been reached between GSK and IVAX until 3 October 2001 although negotiations were ongoing and he speculated that IVAX may have 'thought that it was desirable to have its prospective sub-distributors lined up in advance and was promoting to other generic companies the idea that they should wait for the hoped-for agreement with SB rather than launching their own generic product.' (See [REDACTED]WS2 (GUK) Exhibit [REDACTED]5 (document 0888), paragraph 1.3).

²⁹⁵ IVAX internal document entitled 'Seroxat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699). See also GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100) and [REDACTED]WS (document 0150).

²⁹⁶ Email chain between [Sumitomo employee] and [Merck's Strategic Sourcing Specialist] dated 23 May 2001 (document 0848). See also IVAX internal document entitled 'Seroxat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699).

²⁹⁷ IVAX internal document entitled 'Seroxat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699). GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100) and [REDACTED]WS (document 0150), paragraph 4.8.

- 3.200 In a note from March 2001, [IVAX's Managing Director] wrote that Hexal had recently launched paroxetine in Denmark.²⁹⁸
- 3.201 In his witness statement, [IVAX's Managing Director] stated that he later had discussions with Tillomed's Managing Director, [REDACTED]²⁹⁹ (one of which he recalled taking place in his office) about Tillomed supplying IVAX with the Hexal product.³⁰⁰
- 3.202 There is evidence to suggest that Hexal had withdrawn the product from Denmark in June 2001.³⁰¹ Whilst [IVAX's Managing Director] suspected that he was not '*free of doubt*' regarding the status of the Tillomed product, he recalls thinking that Tillomed was a '*strong option*' from which to obtain supply of paroxetine. In particular, he does not recall being aware of any intellectual property or patent infringement concerns.³⁰²
- 3.203 In response to a formal information request from the OFT, Tillomed stated that [Tillomed's Managing Director] recalled that the discussions related to supply from Tillomed to IVAX of the paroxetine product from the Hexal Group. Tillomed confirmed that, before it entered into a heads of agreement with IVAX, Tillomed had been intending to launch that paroxetine product once it had received its UK MA, provided supplies were forthcoming from Hexal's group.³⁰³
- 3.204 Following the discussions referred to at paragraph 3.201, IVAX and Tillomed entered into a heads of agreement on 4 October 2001 (the 'IVAX-Tillomed Heads of Agreement') – that is, one day after the IVAX-GSK Agreement was signed by [IVAX's Managing Director] on behalf of IVAX, in which IVAX and

²⁹⁸ IVAX internal document entitled 'Seroxat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699). See also [REDACTED]WS (document 2334), paragraph 3.4.

²⁹⁹ The OFT requested documents relating to these discussions from IVAX and Tillomed. IVAX was unable to produce any emails from [IVAX's Managing Director] and Teva's representatives have stated that Teva no longer retains [IVAX's Managing Director's] email account (document 2551). Similarly, Tillomed has no record of any emails or notes of meetings between [Tillomed's Managing Director] and [IVAX's Managing Director]. In relation to Tillomed, the OFT requested a voluntary interview with [Tillomed's Managing Director] but this request was declined: see email from [Tillomed's Company Secretary] to the OFT dated 12 September 2012 (document 2305).

³⁰⁰ [IVAX's Managing Director] noted that his recall in relation to Tillomed was initially very limited: '*I did not recall the involvement of Tillomed in this matter at all until I reviewed the relevant documents provided to me by the OFT. I had completely forgotten about Tillomed.*' See [REDACTED]WS (document 2334), paragraph 5.1.

³⁰¹ See GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100) and [REDACTED]WS (document 0150). See also [REDACTED]WS2 (GUK) Exhibit [REDACTED]5 (document 0888).

³⁰² See [REDACTED]WS (document 2334), paragraphs 5.3 and 5.7.

³⁰³ See Tillomed response dated 4 December 2012 to the Section 26 Notice dated 14 November 2012 (document 2337).

Tillomed agreed to use reasonable endeavours to enter into an agreement by 31 October 2001.³⁰⁴

- 3.205 In his witness statement, [IVAX's Managing Director] recalled that the IVAX-Tillomed Heads of Agreement was a form of '*insurance*' in case the IVAX-GSK Agreement could not be finalised.³⁰⁵ In his recollection, the dates provided in the documents are inaccurate and he recalls signing the IVAX-Tillomed Heads of Agreement before signing the IVAX-GSK Agreement. This may have been due to the documents being dated incorrectly or due to logistical reasons associated with the provision of the documents for signature.³⁰⁶
- 3.206 After it entered into the IVAX-GSK Agreement, IVAX no longer needed to take supply from Tillomed in the short term. For this reason, [IVAX's Managing Director] stated that he agreed to '*flip*' the proposed deal with Tillomed to instead involve the supply of paroxetine product sourced from GSK (the GSK Product) by IVAX to Tillomed rather than for Tillomed to supply IVAX with the Tillomed paroxetine product.³⁰⁷
- 3.207 To implement the IVAX-Tillomed Heads of Agreement, on 11 December 2001, IVAX and Tillomed entered into an agreement (the 'IVAX-Tillomed Supply Agreement')³⁰⁸ which provided that IVAX would acquire the exclusive rights to the Tillomed MA for paroxetine. In consideration, IVAX agreed to pay Tillomed a royalty of 50% of the net profit IVAX made from the sale of paroxetine in the UK (including from the sale of GSK's paroxetine).
- 3.208 In addition to the IVAX-Tillomed Supply Agreement, on the same day, 11 December 2001, a supplemental letter was sent by IVAX to Tillomed, which stated that IVAX agreed that it would supply Tillomed with limited quantities of paroxetine '*free of charge*' and deduct any sales from the sums that IVAX owed to Tillomed under the clause relating to royalty payments in the IVAX-Tillomed Supply Agreement.³⁰⁹ The combined royalty payments and the value of product transferred to Tillomed by IVAX during the IVAX-Tillomed Supply

³⁰⁴ The heads of agreement between IVAX and Tillomed dated 4 October 2001 ('IVAX-Tillomed Heads of Agreement') (document 1725).

³⁰⁵ [REDACTED]WS (document 2334), paragraphs 5.3 and 5.5.

³⁰⁶ [REDACTED]WS (document 2334), paragraph 5.10.

³⁰⁷ [REDACTED]WS (document 2334), paragraph 7.2.

³⁰⁸ The supply agreement between IVAX and Tillomed dated 11 December 2001 (and supplemental letter, where appropriate) ('IVAX-Tillomed Supply Agreement') (document 1751).

³⁰⁹ Letter supplementing the IVAX-Tillomed Supply Agreement dated 11 December 2001 (document 1752).

Agreement was considerable, amounting to some £2.85 million between 2001 and 2004.³¹⁰

3.209 In his witness statement, [IVAX's Managing Director] stated that the rationale for the IVAX-Tillomed Supply Agreement was also to act as a back-up deal given the risk that GSK might refuse to supply IVAX at some time in the future. [IVAX's Managing Director] believed that this was desirable for IVAX, since the term of the IVAX-GSK Agreement was only initially one year.³¹¹

d) Option three: to enter into a supply agreement with GSK

3.210 IVAX first approached GSK in 1999 to discuss the option of entering into a supply agreement.³¹²

3.211 In June 2000, GSK became aware that IVAX had filed for an MA in Ireland to launch generic paroxetine. Internal GSK documents confirm that '*Norton have submitted a file for generic paroxetine, however they remain open to discussions.*'³¹³ In this context, IVAX informed GSK that it would '*be ready to launch Europe-wide in September [2001]*'.³¹⁴

3.212 In July 2000, GSK scheduled an internal conference call to discuss the specific threat from IVAX in the UK.³¹⁵

3.213 In a GSK presentation dated 5 February 2001, [GSK's Head of Regulatory Affairs] and [GSK's Finance Director A] considered the 'Seroxat Patent Challenge'. The presentation stated that:³¹⁶

'Norton may have filed in 2000 [in Ireland] – approval may be expected any time.'

3.214 The presentation concluded that, in response to Norton having filed for regulatory approval of a paroxetine anhydrate product, GSK should carry out tests to ensure that there was no patent infringement. The presentation

³¹⁰ Based on the calculations by the CMA, using data submitted by IVAX and Tillomed.

³¹¹ See [REDACTED]WS (document 2334), paragraph 5.5.

³¹² Email from [GSK's Vice President Pharma Patents] to [GSK's Patent Attorney] dated 13 May 1999 (document 0116). In [GSK's Finance Director A's] recollection, IVAX approached GSK in mid-2000 (see [REDACTED]WS1 (Alpharma) (document 0241), paragraph 6.1 and [REDACTED]WS2 (GUK) Exhibit [REDACTED]5 (document 0888), paragraph 1.1).

³¹³ See email from [GSK's Marketing Director for Seroxat] to [GSK's Patent Attorney] and others dated 21 June 2000 (document 0120).

³¹⁴ Email from [GSK's Patent Attorney] to [GSK's Senior Vice President Patents & Trademarks] and others dated 6 March 2001 (document 0127).

³¹⁵ Email from [GSK's Marketing Director for Seroxat] to [GSK's Vice President – R&D Legal Operations], [GSK President (Pharmaceuticals International)], [GSK's Chief Executive Officer] and other GSK employees dated 21 July 2000 (document 0121) entitled '*Paroxetine anhydrate telecon – 28th July*'.

³¹⁶ GSK presentation entitled 'Seroxat Patent Challenge' dated 5 February 2001 (document 0123), page 3.

recommended entering into a supply agreement that would enable IVAX to sell paroxetine at around 75% of the market supply price ('MSP'),³¹⁷ that being the price Seroxat was sold at by GSK:³¹⁸

- Norton Healthcare have confirmed source of anhydrous salt*
- Test required to ensure no patent infringement*
- Recommend establishment of supply agreement*
- Commence mid 2001 (in 2001 Op Plan)*
- Take-up molecule 10%, 20% 30% years 1-3*
- Generic price 75% MSP to compete with PI [Parallel Imports]*
- Supply price (per Augmentin model) 47% MSP*
- Sales/profit impact £2.3m/£7.4m/£13.2m/£16.8m'*

3.215 This presentation appears to have been an early indication of the types of terms that GSK was considering offering to IVAX. GSK explained that the reference to a "supply price 47% MSP" was consistent with the supply price of £8.45 that was included in the IVAX-GSK Agreement, which is 47.6% of the then Seroxat list price of £17.76 and therefore very close to the level envisaged.³¹⁹ Having entered into the IVAX-GSK Agreement, GSK continued to anticipate that IVAX would sell the product at around the same price as parallel importers, as explained by [GSK's Finance Director A] in his witness statement in the GUK Litigation in October 2001.³²⁰

'In essence, Norton will want to maximise its return on the price which it pays to SB [SmithKline Beecham], and so is unlikely to want to undercut the existing prices paid by customers. SB therefore expects that Norton would probably be selling at a similar price to that charged by the parallel importers [...]

3.216 By August 2001, it appears that IVAX began to contact other generic competitors to see if they would be interested in taking supply of paroxetine from IVAX, which would be sourced from GSK. In a witness statement in the

³¹⁷ In GSK Third Response (document 0750), GSK indicates that that 'MSP' referred to the list price at the time of £17.76.

³¹⁸ GSK presentation entitled 'Seroxat Patent Challenge' dated 5 February 2001 (document 0123).

³¹⁹ GSK Third Response (document 0750).

³²⁰ See [X]WS2 (GUK) (document 0182), paragraph 2.6.

GUK Litigation, [REDACTED], GUK's Sales & Marketing Director, explained that IVAX was already offering to supply GUK with paroxetine in August 2001, and that his impression was that an agreement had already been reached between IVAX and GSK:³²¹

'I am told by [REDACTED], who is Managing Director of GUK and a regional European Director of the Merck Generics Group, that he had a telephone conversation with [REDACTED], Managing Director of Norton Healthcare, on 17 August this year. In the course of that conversation, [IVAX's Managing Director] said that SB had agreed to supply Norton with paroxetine under licence, and that Norton would be SB's "broker". Prices for the supply of paroxetine from Norton to GUK were discussed. During the course of these discussions, it was recognised by both [IVAX's Managing Director] and [GUK's Managing Director] that the selling price for generic paroxetine to wholesalers would be in the same ball park as the parallel import price for Seroxat, which was £11 per pack. On that basis [IVAX's Managing Director] indicated that Norton would offer the product to GUK at approximately £8 - £9 per pack. [GUK's Managing Director] told [IVAX's Managing Director] that Norton's proposals were not of interest to GUK.'

3.217 In September 2001, negotiations continued between GSK and IVAX in relation to a supply agreement, which was yet to be finalised. In a witness statement given by [GSK's Finance Director A] in the GUK Litigation in October 2001, [GSK's Finance Director A] provided his account of the negotiations with IVAX:³²²

'Norton first approached SB well over a year ago, and has discussed some sort of supply agreement with us off and on since then. We thought that we were close to agreement in late July, but final agreement could not be reached and the discussions were broken off. At about the time when discussions were restarted in early September [2001], [IVAX's Managing Director] and [IVAX's Commercial Director] [sic] of Norton told me that they were in active negotiations with GUK about the possible supply of generic paroxetine by GUK to Norton. They were seriously considering three options: to source their product themselves, from GUK (which was offering, I understand an indemnity

³²¹ [REDACTED]WS (document 0901), paragraph 19.

³²² [REDACTED]WS2 (GUK) Exhibit [REDACTED]5 (document 0888), paragraph 1.1. [GSK's Finance Director A] refers to discussions breaking off in late July and restarting in September 2001. However, the Minutes from IVAX paroxetine team meeting on 14 August 2001 (document 1709), indicate that [IVAX's Managing Director] was having discussions with GSK at that time. They also suggest these discussions would be strengthened once the Irish MA was granted.

in respect of patent infringement), or from SB, and they told me that they would make their decision at the end of September. It was touch and go which option Norton would choose right up to the time when the major terms were finalised between SB and Norton on Friday 28 September. [...] The agreement was not signed until 03 October 2001. When I signed my first statement [25 September 2001], the agreement with Norton had not been finalised and I did not know whether agreement would be reached.'

3.218 On 3 October 2001, GSK and IVAX entered into the IVAX-GSK Agreement.³²³ The IVAX-GSK Agreement was signed by [GSK's Finance Director A] on behalf of GSK and by [IVAX's Managing Director] on behalf of IVAX. The terms of, and the rationales of GSK and IVAX for entering into, the IVAX-GSK Agreement are set out in paragraphs 3.219 to 3.248.

iii) The IVAX-GSK Agreement

a) The operation of the IVAX-GSK Agreement

The terms of the IVAX-GSK Agreement

3.219 The IVAX-GSK Agreement (and relevant addenda) included the following relevant obligations:

- GSK shall supply IVAX with paroxetine, and appoint IVAX as sole distributor for the product in the UK, for 12 months from 1 December 2001.³²⁴
- Product: GSK shall supply packs containing 30 tablets of 20mg each with paroxetine hydrochloride as its active substance.³²⁵
- Duration: the IVAX-GSK Agreement became effective on 1 December 2001 and was agreed for 12 months, subject to IVAX's right to terminate that Agreement at any time upon one month's notice. Subsequently, the term was extended: (i) until 1 December 2004 under the first addendum dated 15 February 2002 to amend the IVAX-GSK Agreement (the 'First Addendum'); and (ii) until 13 March 2005 under the second addendum dated 12 September 2002 to amend the IVAX-GSK Agreement (the

³²³ IVAX-GSK Agreement (document 0168).

³²⁴ IVAX-GSK Agreement (document 0168), clauses 2.1 and 3.1.

³²⁵ IVAX-GSK Agreement (document 0168), Schedule 1.

'Second Addendum'). However, the IVAX-GSK Agreement was finally terminated on 29 June 2004.³²⁶

- Supply price: *'The PRODUCT shall be supplied to IVAX by SB ... at the SUPPLY PRICE in Schedule II [£8.45]'*.³²⁷
- IVAX sale price: *'The prices at which IVAX shall sell the PRODUCT to third parties and any discounts to be allowed to third parties shall be set by IVAX'*.³²⁸
- Price review: *'The SUPPLY PRICE shall remain fixed for the twelve month period of this Agreement. Should the Agreement continue after expiry of the initial twelve month period, SB and IVAX shall review the SUPPLY PRICE in conjunction with the volume forecast and agree a new SUPPLY PRICE if appropriate'*.³²⁹ The effective supply price was maintained at £8.45 until the IVAX-GSK Agreement was terminated on 29 June 2004.³³⁰
- Early termination clause: *'At any time during the term of this Agreement should the average price offered by any party to retail pharmacists over an average period of three (3) consecutive days for a generic product (other than Seroxat or the PRODUCT) having paroxetine hydrochloride as its active substance reach £8.45 per PACK or below IVAX shall have the option to terminate this Agreement forthwith.'*³³¹
- Promotional allowance: *'SB shall pay to IVAX a promotional allowance of £3.2 million in recognition of its promotional activities required to support the distribution and marketing of the PRODUCT. [...] In the event that this Agreement terminates before the twelve month period has expired other than by SB pursuant to clauses 3.3 or 3.4, then all outstanding instalments shall remain payable for the remaining months during that twelve month period.'*³³² Pursuant to the fourth addendum dated 28 February 2003 to amend the IVAX-GSK Agreement (the 'Fourth Addendum'), the

³²⁶ IVAX-GSK Agreement (document 0168), clauses 3.1 and 3.2. See also the letter providing for the final termination of the IVAX-GSK Agreement dated 29 June 2004 (document 0495).

³²⁷ IVAX-GSK Agreement (document 0168), clause 4.1.

³²⁸ IVAX-GSK Agreement (document 0168), clause 4.2.

³²⁹ IVAX-GSK Agreement (document 0168), clause 4.1.

³³⁰ The CMA notes that although the supply price to IVAX was subsequently revised in the Heads of Agreement and Second Addendum (Heads of Agreement between GSK and IVAX dated 14 March 2002 (document 0217), clause 3 and Second Addendum (document 0318), clause 2.9), this was to reflect the fact that IVAX was receiving product as bulk rather than packaged supply and as such it did not comprise additional margin available to IVAX. Therefore the CMA has treated the supply price as £8.45 throughout this Decision.

³³¹ IVAX-GSK Agreement (document 0168), clause 3.2.

³³² IVAX-GSK Agreement (document 0168), clause 5.

promotional allowance was £3.45 million for the second year of the operation of the IVAX-GSK Agreement and £3.5 million for the other years.

- Volume provisions: IVAX shall send to GSK its twelve month forecast of its likely sale volume requirements and its monthly orders of the product to GSK. *'For technical reasons the quantities of the PRODUCT to be supplied to IVAX during the twelve month term of this Agreement shall not exceed seven hundred and seventy thousand (770,000) PACKS of the PRODUCT unless otherwise agreed.'*³³³
- Right to appoint sub-distributors: IVAX is granted the right to appoint third party sub-distributors.³³⁴

The Side Letter

3.220 On 3 October 2001, as part of the IVAX-GSK Agreement, IVAX and GSK also entered into the 'Side Letter',³³⁵ which provided IVAX with certain assurances in relation to GSK's conduct of the GUK Litigation (discussed in more detail in paragraphs 3.265 to 3.280), and as to IVAX's rights following the termination of that litigation, as follows:

- GSK agreed to diligently prosecute the action, and to provide IVAX with full disclosure of any terms of settlement of the action;
- in the event of GSK obtaining judgment against GUK, GSK agreed to pay IVAX any damages recovered from GUK, up to an amount not exceeding £3.2 million; and
- in the event of GSK settling with GUK, GSK agreed to pay IVAX any sum it received pursuant to the settlement, up to an amount not exceeding £3.2 million.

3.221 In its response to the SSO, GSK said the following about the Side Letter:³³⁶

'GSK did not seek it; IVAX did, and for understandable reasons. For GSK it was a meaningless concession. The letter adds nothing of any substance to what GSK was already going to do.'

³³³ IVAX-GSK Agreement (document 0168), clauses 7.1 and 7.3.

³³⁴ IVAX-GSK Agreement (document 0168), clause 2.2.

³³⁵ Side Letter (document 0167).

³³⁶ See GSK written response dated 2 December 2014 to the SSO (document 3668), paragraph 3.31.

3.222 During interviews with the OFT and CMA, [IVAX's Commercial Director] and [IVAX's Sales and Marketing Manager] were unable to recall participating in negotiations regarding the terms of the Side Letter.³³⁷ Additionally, neither of them recalls the reasoning behind the drafting of the Side Letter or the basis for its terms.³³⁸ [IVAX's Head of New Business Development] also confirmed that he had no recollection of the Side Letter.³³⁹ Further, Teva UK has not identified any additional information to explain the content of the Side Letter.³⁴⁰

The addenda to the IVAX-GSK Agreement and the operation of the IVAX-GSK Agreement

3.223 On 15 February 2002, GSK and IVAX entered into the First Addendum.³⁴¹ The primary purpose of the First Addendum was to extend the period of the IVAX-GSK Agreement for a further two years. The First Addendum became effective on 1 December 2002 and was scheduled to end in December 2004 subject to IVAX's right to terminate the IVAX-GSK Agreement at any time upon one month's notice.³⁴²

3.224 On 14 March 2002, GSK and IVAX entered into a Heads of Agreement, in which (a) IVAX agreed to add GUK as a sub-distributor, and (b) GSK agreed to provide IVAX with additional paroxetine in order to supply GUK. IVAX and GSK also agreed to enter into a Second Addendum at a later stage which would incorporate the formal terms of supply to GUK as set out in the Heads of Agreement.³⁴³

3.225 Under the Second Addendum made on 12 September 2002, GSK and IVAX added GUK as a sub-distributor and provided that IVAX would be supplied with the product in bulk form. To account for the allocation to GUK, GSK

³³⁷ See part one of the response (dated 6 July 2012) to the Section 26 Notice dated 12 June 2012 sent to Teva (document 2105), question 1. In an interview with the CMA, [IVAX's Sales and Marketing Manager] confirmed that he had no recollection of having seen the Side Letter before the Investigation: witness statement of [IVAX's Sales and Marketing Manager], signed 16 August 2014 (document 3235R), paragraph 12.11. [IVAX's Managing Director], in response to a Section 26 Notice issued to him on 16 January 2015, confirmed that he had no recollection of the Side Letter (The response 2 February 2015 to the Section 26 Notice dated 16 January 2015 (document 3800)).

³³⁸ Witness statement of [IVAX's Sales and Marketing Manager], signed 16 August 2014 (document 3235R, paragraph 12.11). [IVAX's Managing Director], in response to a Section 26 Notice issued to him on 16 January 2015, confirmed that he had no recollection of the Side Letter (The response 2 February 2015 to the Section 26 Notice dated 16 January 2015 (document 3800)).

³³⁹ [§]WS (document 2333), paragraph 9.28.

³⁴⁰ See part one of the response (dated 6 July 2012) to the Section 26 Notice dated 12 June 2012 sent to Teva (document 2105), question 1.

³⁴¹ First Addendum (document 0205).

³⁴² First Addendum (document 0205), clause 2.1.

³⁴³ Heads of Agreement between GSK and IVAX dated 14 March 2002 (document 0217).

agreed to increase the volume of product to IVAX to enable it to supply 1,520,000 packs in each contract year.³⁴⁴

3.226 Under the third addendum dated 20 November 2002 to amend the IVAX-GSK Agreement (the 'Third Addendum'), GSK and IVAX added Alpharma as a sub-distributor. To account for the allocation to Alpharma, GSK agreed to increase the volume of product to IVAX to enable it to supply 2,020,000 packs in each contract year.³⁴⁵

3.227 Under the Fourth Addendum, GSK agreed to increase the promotional allowance paid to IVAX to £3.45 million for the second contract year and £3.5 million for the third contract year.³⁴⁶ In addition, GSK agreed to increase the volume of product to IVAX to enable it to supply 2,370,000 packs in each contract year to account for the allocation to [X].³⁴⁷

The Termination of the IVAX-GSK Agreement

3.228 IVAX considered during the term of the IVAX-GSK Agreement that it would become unsustainable in the event that GSK was not able to maintain the Anhydrate Patent in the face of litigation.

3.229 In December 2003, when IVAX was considering the implications of the High Court's invalidation of the Anhydrate Patent (as explained above), but before Neolab and Waymade had begun to supply paroxetine in the UK independently of GSK, [IVAX's Sales and Marketing Manager] wrote that:

'Under this scenario [where GSK lose an appeal against the High Court's judgment] Neolab/Waymade will launch immediately and the price will almost certainly drop to below £8.45 (the market is already over supplied).

This will require a raft of actions from IVAX

[.....]

³⁴⁴ Second Addendum (document 0318).

³⁴⁵ Third Addendum (document 0359).

³⁴⁶ Fourth Addendum (document 0384), clause 2.4.

³⁴⁷ Fourth Addendum (document 0384), clause 2.6. Additionally, [X] was added as a sub-distributor under this addendum, with a consequent increase in the volume of packs supplied from GSK to IVAX to 2,370,000: Fourth Addendum (document 0384), clauses 2.2, 2.3 and 2.9.

1. [W]e cancel orders (thus terminating our agreement) for IVAX bulk supply (unless we are able to negotiate a new price with GSK)' ³⁴⁸

3.230 Subsequent to that, the IVAX-GSK Agreement was finally terminated by agreement on 29 June 2004.³⁴⁹ GSK agreed to pay IVAX an amount of £2.362 million at termination³⁵⁰ to reflect the outstanding value transfers under the promotional allowance at that time. In total, GSK agreed to pay IVAX £10.2 million through promotional allowances during the period of the IVAX-GSK Agreement.³⁵¹

3.231 In addition to the IVAX-GSK Agreement – and subsequently the First Addendum, the Second Addendum, the Third Addendum and the Fourth Addendum (together, the 'Addenda') – IVAX also entered into separate sub-distribution agreements with each appointed distributor, that is, GUK,³⁵² Alpha³⁵³ and [X].³⁵⁴

Sub-distribution agreements between IVAX and other generic companies

3.232 On 11 December 2001, IVAX appointed Tillomed as a sub-distributor to the IVAX-GSK Agreement (the IVAX-Tillomed Supply Agreement). Under the IVAX-Tillomed Supply Agreement, IVAX agreed to acquire exclusive rights to the Tillomed MA for paroxetine. In return, IVAX agreed to pay a royalty to Tillomed based on IVAX's sales of paroxetine in the UK and also agreed to supply Tillomed with a supply of the paroxetine sourced from GSK.³⁵⁵

3.233 The IVAX-Tillomed Supply Agreement led to IVAX making considerable value transfers to Tillomed of some £2.85 million between 2001 and 2004.³⁵⁶ [IVAX's Head of New Business Development], in a witness statement he provided to the OFT, considered this arrangement to be '*unusual*'. He said that, based on his experience, for IVAX to have been willing to enter an agreement in which it paid 50% of its net profit on paroxetine to Tillomed, he

³⁴⁸ Email from [IVAX's Sales and Marketing Manager] to [Medical Director, Teva UK Ltd] dated 16 December 2003 (document 1888), entitled 'Paroxetine – Update'.

³⁴⁹ See letter providing for the final termination of the IVAX-GSK Agreement dated 29 June 2004 (document 0495).

³⁵⁰ When the IVAX-GSK Agreement was terminated in July 2004, GSK was liable to IVAX for the promotional payments until the end of November 2004 as set out in of the Fourth Addendum (document 0384), clause 2.4.

³⁵¹ This is made up of £3.2 million in 2001-02, £3.45 million in 2002-03 and £3.5 million in 2003-04 (exclusive of VAT). See the IVAX-GSK Agreement (document 0168), clause 5 and the Fourth Addendum (document 0384), clause 2.4.

³⁵² GUK-IVAX Agreement (document 1003).

³⁵³ Alpha-IVAX Agreement (document 1806).

³⁵⁴ The Agreement between IVAX and [X] dated 19 February 2003 (document 1823).

³⁵⁵ IVAX-Tillomed Supply Agreement (document 1751).

³⁵⁶ Based on the calculations of the CMA, using data submitted by IVAX and Tillomed.

would have expected that Tillomed had a viable product that, absent the agreement, it would have been able to launch, in competition with IVAX:³⁵⁷

'In order to reach this agreement with Tillomed, I expect that IVAX considered that Tillomed must have had a viable product otherwise IVAX would not have done a deal. Presumably IVAX felt there was sufficient validity in Tillomed's claims to make it worthy of IVAX paying Tillomed 50 per cent of its profit. However, this is conjecture on my part. I cannot recall whether this was the case or not.

If IVAX had thought the Tillomed product was definitely not viable, it is highly likely that it would have told Tillomed that there was no deal on the table, unless there were other "trade offs" under discussion. However, in the absence of any trade-offs, it is my assumption that there must have been an element of belief between IVAX and GSK that Tillomed had a product that it could potentially bring to market notwithstanding the withdrawal of the Gea product from Denmark. ... However, there will probably have been a belief that Tillomed could potentially come to the market with a product that might not infringe the GSK product. Therefore, it was probably in IVAX's interests to consider doing a deal with Tillomed.'

b) The rationales of GSK and IVAX for entering into the IVAX-GSK Agreement

GSK's rationale

3.234 GSK's rationale for the IVAX-GSK Agreement was explained by [GSK's Finance Director A] in witness evidence dated 20 October 2001 given in the GUK Litigation. [GSK's Finance Director A] understood that, in the absence of the IVAX-GSK Agreement, IVAX would have launched a paroxetine product independently of GSK. On this basis, [GSK's Finance Director A] considered that the advantages of the IVAX-GSK Agreement included the avoidance of risks and costs associated with litigation, the prevention of the financial loss that would have been associated with any generic paroxetine entry, and the ability to instead maintain a profit on sales to IVAX at levels that could be forecasted with some certainty:³⁵⁸

'In my discussions with Norton, my belief, based on what Norton told me in confidence, was that, in the absence of an agreement, they

³⁵⁷ [REDACTED]WS (document 2333), paragraphs 8.5 and 8.6.

³⁵⁸ See [REDACTED]WS2 (GUK) (document 0182), paragraphs 2.3 and 2.4.

would launch their own generic paroxetine. Indeed they could still do this. It was likely that this material would infringe one of [GSK]'s patents, and, if we had evidence that Norton was infringing, or was about to infringe, we would commence proceedings and apply for an interim injunction.

In assessing this situation, we recognised that there will be a financial loss from any generic entry into the paroxetine market. Through a supply agreement we could obtain a profit on the supply price. The primary objective becomes certainty of profits (although at a reduced level) as an alternative to losing sales to Norton and making no return on them at all. In addition, it might help avoid the adverse effects referred to in my first statement.³⁵⁹

3.235 On entering into the IVAX-GSK Agreement, GSK's expectation was that, as a consequence of the level of the supply price charged by GSK to IVAX, IVAX would be unlikely to be incentivised to charge prices that were significantly below those being offered by suppliers of parallel imported paroxetine and by GSK itself, such that the financial impact on GSK would be minimised:³⁶⁰

'In essence, Norton will want to maximise its return on the price which it pays to [GSK], and so is unlikely to want to undercut the existing prices paid by customers. [GSK] therefore expects that Norton would probably be selling at a similar price to that charged by the parallel importers, and this is confirmed by what [GUK's General Manager] says that Norton has told his colleagues at GUK, that "the selling price for generic paroxetine to wholesalers would be in the same ballpark as the parallel import price for Seroxat...". This is a price to which [GSK] is already discounting a number of existing brand equalisation deals'.

3.236 GSK also considered that, to the extent that other generic suppliers were appointed as sub-distributors to IVAX, the pricing terms would be such that the sub-distributors would be unlikely to greatly undercut the IVAX price, such that the impact on GSK would continue to be 'minimised':³⁶¹

'We [GSK] appreciate that other generic companies would also want to distribute paroxetine under similar arrangements. Accordingly, the agreement gives Norton the right to appoint sub-distributors. Whom

³⁵⁹ Indeed, GSK considered that if the IVAX-GSK Agreement and GUK-GSK Agreement were not maintained there would be a considerable margin erosion of some £10m. See GSK UK Pharmaceuticals Operating Unit – 2003 plan (document D 004)

³⁶⁰ [REDACTED]WS2 (GUK) (document 0182), paragraph 2.6.

³⁶¹ [REDACTED]WS2 (GUK) (document 0182), paragraph 2.7.

Norton appoints and on what commercial terms is entirely up to Norton. Since Norton's selling price to its sub-distributors is likely to be above the price which it pays to [GSK], their prices to their customers are unlikely to greatly undercut Norton's.'

- 3.237 This is consistent with GSK's consideration that the IVAX-GSK Agreement (and the subsequent GUK-GSK Agreement and the Alpharma-GSK Agreement) was 'a key strategy to maintain market stability for Seroxat across the Plan period'.³⁶²
- 3.238 [GSK's Finance Director A] indicated in a witness statement that prices had not fallen after IVAX, GUK and Tillomed had begun to supply paroxetine as GSK sub-distributors.³⁶³ *'I believe the current situation, therefore, is that the price at which both Ivax and its sub-distributors sell Distributed Paroxetine has remained stable since the coming into effect of the Ivax Agreement.'*
- 3.239 The alternative situation, as [GSK's Finance Director A] stated in his witness statement, was that if a generic supplier such as IVAX launched paroxetine products, he would have expected GSK to lose around 40-60% of Seroxat sales.³⁶⁴ [GSK's Finance Director A] said that the total loss to GSK would be unquantifiable given that GSK's loss would not only include the loss of sales but also lower prices, as the entry of subsequent generic suppliers would lead to a downward spiral in the price of paroxetine.³⁶⁵
- 3.240 In later handwritten manuscript notes from around August or September 2003, [X], GSK's Finance Director [B] in 2003, made notes regarding GSK's Agreements with the Generic Companies. The notes specifically refer to the IVAX-GSK Agreement and the GUK-GSK Agreement. They state that a deal with IVAX 'just had to be done' and that the Agreements were 'mechanisms for paying a certain amt' and that GSK 'devised mechanisms'. The document states that GSK recognised that it had 'no real strengths' in its negotiating position and that the Agreements related to a 'wk. patent' and 'stopped [the generics] entering the market'.³⁶⁶ [GSK's Finance Director B] has explained

³⁶² GSK UK Pharmaceuticals Operating Unit – 2003 plan (document D 004)

³⁶³ Witness statement of [GSK's Finance Director A] in the litigation between GSK and the Apotex Parties, dated 22 October 2002 ('[X]WS1 (Apotex)') (document 0333), paragraph 6.7.

³⁶⁴ [X]WS1 (GUK) (document 0885), paragraph 8.2.

³⁶⁵ [X]WS1 (GUK) (document 0885), paragraph 9.4.

³⁶⁶ [GSK's Finance Director B's] electronic transcribed note and handwritten original note contained in 'Non-confidential 3rd questionnaire response - seroxat financial information' undated (document 0081). GSK estimates that the second manuscript note was written 'a few weeks after taking up her role [...] in August 2003'; GSK Third Response (document 0750), paragraph 12.1. This was clarified by [GSK's Finance Director B] in a witness statement provided to the CMA dated 23 July 2014 ('[X]WS2', document 3180), at paragraph 4.2: 'I recall that page 3 of the Handwritten Notes was written within a few weeks or months of becoming GSK Finance Director in

that although she was not personally involved in the Agreements, she wrote this note following a call with GSK's in-house lawyer shortly after becoming GSK's Finance Director.³⁶⁷ The note recorded [GSK's Finance Director B's] own '*attempt to try to crystallise, in perhaps slightly rough and ready lay person's terms, a summary of what [GSK's in-house lawyer] might have explained to me over a long discussion, providing me with more detail than I needed*'.³⁶⁸

3.241 An internal IVAX presentation states that IVAX's understanding of GSK's rationale was to secure volumes and value within the generics markets and to avoid the loss of its intellectual property:³⁶⁹

- *Secured volume and value within the generics market*
- *Out of court settlement avoided loss of all intellectual property*
- *Enabled continued promotion & growth of brand*'.

IVAX's rationale

3.242 In his witness statement, [IVAX's Commercial Director] stated that IVAX's commercial goal in relation to paroxetine was to be the first generic supplier to launch a generic paroxetine product in the UK. [IVAX's Commercial Director] stated that by accomplishing this goal, IVAX would be able to: (i) improve its reputation with customers; and (ii) secure significant commercial advantages.³⁷⁰

3.243 Entering into the IVAX-GSK Agreement would also avoid any patent infringement concerns arising from its own product. This is highlighted by an undated IVAX internal document which discussed the rationale for entering into a supply agreement with the 'originator' (GSK) rather than a supplier of generic medicines.³⁷¹

3.244 IVAX considered that a supply agreement with GSK would keep the paroxetine market '*strong*'.³⁷² It would also delay other generics who were

2003, so fairly soon into the new role.' The manuscript note and the witness statement of [GSK's Finance Director B] are addressed further at paragraphs 6.134, E.19 and F.17–F.20.

³⁶⁷ [REDACTED]WS2 (document 3180), paragraph 4.2. The manuscript note and the witness statement of [GSK's Finance Director B] are addressed further at paragraphs 6.134, E.19 and F.17–F.20.

³⁶⁸ [REDACTED]WS2 (document 3180), paragraph 4.4.

³⁶⁹ See IVAX presentation, 'Augmentin Late Stage Life Cycle Management' (document 1648), page 6.

³⁷⁰ [REDACTED]WS (document 2332), paragraphs 3.3 and 6.9.

³⁷¹ See IVAX presentation, 'Augmentin Late Stage Life Cycle Management' (document 1648), page 4.

³⁷² See IVAX internal document entitled 'Seroxat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699), page 4.

seeking to launch generic paroxetine products because IVAX realised that if it decided to challenge GSK, *'testing the patent clears the way for other manufacturers.'*³⁷³ IVAX therefore decided to sign what one of its employees later referred to as a *'lucrative'* agreement with GSK.³⁷⁴

3.245 [IVAX's Commercial Director] has explained the pricing proposal within the IVAX-GSK Agreement as follows:³⁷⁵

'I recall that the pricing proposal came from GSK. My preferred option was for a lower cost of goods [supply price] than the agreed £8.45 per pack of 20mg paroxetine. [...] Although it was not my preferred option, which would have been simply a lower cost of goods, I consulted with IVAX's internal finance team and it confirmed that I could base my own profit margins as if the lower cost of goods of around £3-4 per pack applied.'

3.246 [IVAX's Commercial Director] went on to explain that the marketing contribution and supply price were considered together during negotiations:³⁷⁶

'Had GSK offered purely an £8.45 supply price, without a marketing contribution, that would not have been acceptable to IVAX because the supply price was too high. IVAX was very much aware of the risk of buying the product at too high a price and then not being able to sell the product if other generic companies entered. The risk of being caught with a cost of goods that was higher than the market price was extremely high.'

3.247 Shortly after entering into the IVAX-GSK Agreement, IVAX provided a presentation to its US parent on the benefits of adopting an approach of cooperating with originator companies such as GSK. In the presentation, IVAX stated that *'companies can work together to improve product value'* and that *'higher market prices are often maintained'*. In addition, sourcing product from the originator would offer IVAX *'a secure supply of product'* whilst providing the originator *'a share of the generic market (spreads risk)'*.³⁷⁷

³⁷³ IVAX internal document entitled 'Seroxat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699), page 2.

³⁷⁴ See email from [IVAX's Head of New Business Development] to [IVAX employee, Sweden], [IVAX employee, France], [IVAX Head of Operations, Ireland], and [REDACTED] and [other IVAX employees] dated 18 July 2003 (document 1858), entitled 'Paroxetine Hydrochloride'

³⁷⁵ [REDACTED]WS (document 2332), paragraphs 6.15–6.16.

³⁷⁶ [REDACTED]WS (document 2332), paragraph 6.18.

³⁷⁷ Teva presentation entitled 'IVAX UK In-Licensing presentation to IVAX US' dated 23 January 2002 (document 1760), page 9. In an interview with the OFT, [IVAX's Head of New Business Development] indicated that the presentation was used to promote the idea of using supply agreements to IVAX's US parent company; see

3.248 In his witness statement, [IVAX's Head of New Business Development]³⁷⁸ explains that the expected impact of the restricted volumes available was price stabilisation:

'The impact of IVAX selling additional packs of course would be price destabilisation, because you are potentially providing more than what is required by the market and competing to make sales, unless GSK reduced their own volume of sales. I expect that is why GSK would not agree to additional packs being sold by IVAX. To this extent, the clause probably had the effect of stabilising prices, at least to some degree.'

iv) The GSK-GUK Agreement

a) The background to the GUK-GSK Agreement

3.249 As early as February 1997, GUK started to investigate developing, and obtaining regulatory approval for, its own paroxetine product for supply across a variety of markets (including the UK).³⁷⁹ GUK focussed on producing a generic anhydrate version of paroxetine.³⁸⁰

3.250 Like IVAX, GUK's commercial goal was for it to be the first generic supplier to launch a generic paroxetine product in the UK.³⁸¹

b) GUK's commercial position in relation to paroxetine

3.251 This sub-section considers GUK's commercial position, focussing on the steps that GUK took in 2001 to develop a paroxetine product for launch in the UK. It will set out the facts in relation to the following issues:

- GUK's UK MA;
- the development of a GUK paroxetine product; and
- the patent issues relating to the GUK paroxetine product.

transcript of first interview with [IVAX's Head of New Business Development] on 28 June 2012, dated 14 September 2012 (document 2231), pages 19–20: '[...] there would have been political sensitivities around this internally that we wouldn't want to necessarily tell our US fathers that we develop products that infringe [...]'].

³⁷⁸ [REDACTED]WS (document 2333), paragraph 9.15.

³⁷⁹ See [REDACTED]WS (document 0901), paragraphs 14 and 15 and [REDACTED]WS, Exhibit [REDACTED]1 (document 0796), Tab 2, 'Paroxetine 20mg Tablets Timeline'.

³⁸⁰ Minutes of meeting between GUK and the OFT on 7 February 2012 (document 1210), paragraph 5.

³⁸¹ See also, for example, GUK submission to the OFT dated 22 February 2012 (document 1214), paragraph 2.1: 'GUK intended to be the first to launch a generic version of paroxetine in the UK and [...] made considerable efforts and investments and took significant risks in order to achieve its commercial objectives'.

GUK's UK MA

- 3.252 GUK had set an initial target date of June 1998 for the first submission of a regulatory filing in relation to its paroxetine product. However, additional time was required to resolve raw material and product issues and to prepare an appropriate regulatory dossier. GUK was therefore only in a position to submit a regulatory filing in Denmark³⁸² in May 2000.³⁸³
- 3.253 The Danish Medicines Agency commenced its assessment of GUK's regulatory filing on 18 May 2000. Following a period of consideration of additional information requested by the Danish Medicines Agency, GUK subsequently obtained an MA in Denmark in April 2001.³⁸⁴ In May 2001, GUK submitted mutual recognition applications in 17 Member States, including the UK.³⁸⁵
- 3.254 GUK was subsequently granted an MA in the UK for its paroxetine 20mg product on 29 October 2001.³⁸⁶

The development of a GUK paroxetine product

- 3.255 GUK had negotiated an agreement to source the API for its paroxetine product from Sumika Fine Chemicals Corporation (a subsidiary of Sumitomo Chemicals) in Japan.³⁸⁷ GUK planned for the product to be tableted in

³⁸² GUK chose Denmark for its filing as the data exclusivity period ended earlier than in the UK.

³⁸³ See [REDACTED]WS, Exhibit [REDACTED]1 (document 0796), Tab 2, 'Paroxetine 20mg Tablets Timeline'.

³⁸⁴ Note: the regulatory approval was obtained in Denmark by Scand Pharm, a GUK sister company: see [REDACTED]WS, Exhibit [REDACTED]1 (document 0796), Tab 2.

³⁸⁵ [REDACTED]WS, Exhibit [REDACTED]1 (document 0796), Tab 2, 'Paroxetine 20mg Tablets Timeline' sets out the various steps and actions that GUK took to achieve its various MAs for paroxetine.

³⁸⁶ GUK submission to the OFT dated 22 February 2012 (document 1214), paragraph 2.1, footnote 1. The MHRA has also informed the CMA that the MA was granted to GUK on 29 October 2001. See MHRA list of product licences containing paroxetine hydrochloride granted between 1999 and 2005 dated 11 June 2012 (document 2590).

³⁸⁷ See email from [Sumitomo employee] to [the Chief Executive of Merck Generics Group] dated 30 May 2001 (document 0851) which refers to an agreement relating to the purchase of 1,500kg of API by GUK from Sumika. See also witness statement of [Merck's Head of Patents and Raw Material Support Group] in the GUK Litigation, dated 15 October 2001 (document 0900), paragraph 16.

Australia by GUK's sister company, Alphapharm PTY Limited,³⁸⁸ before being shipped to Germany in preparation for launch in the UK.³⁸⁹

3.256 GUK and the Merck Generics Group had purchased a large amount of API for the development and launch of its paroxetine product in a number of countries, including the UK – around 1,000kg – and had committed itself to significant further purchases to satisfy expected demand for generic paroxetine – around 500kg.³⁹⁰ Stock had been built up ready for launch in the UK.³⁹¹

3.257 Details of the Merck Generics Group's investment in raw material for the development and launch of its paroxetine product, and the significant amount of expenditure on the launch of its product in the UK, were also provided in a witness statement from [GUK's General Manager], in the GUK Litigation:³⁹²

'To date, the Merck Group has spent almost \$8 million on raw material for development and product launch; of this sum, over \$6 million has been invested in the UK exercise alone, a cost which GUK has borne. [...] The cost of the initial raw material acquired for testing purposes alone exceeded \$300,000. We have since acquired a further \$7.5 million worth of raw material, of which \$3 million worth is destined solely for the UK launch. A further \$3 million worth has been earmarked to supply the UK market in the first year, although it is impossible to say with accuracy whether this amount will be sufficient.'

3.258 As well as its investments in API and its preparations for tableting that raw material, GUK gave active consideration to its volume requirements both in

³⁸⁸ See, for example, witness statement of [Merck's Head of Patents and Raw Material Support Group] in the GUK Litigation, dated 15 October 2001 (document 0900), paragraph 16. See various actions involving Alphapharm from December 1999 onwards referred to in [redacted]WS, Exhibit [redacted]1 (document 0796), Tab 2, 'Paroxetine 20mg Tablets Timeline'. See also, for example, email from [a GUK Sales and Marketing employee] to [a GUK Special Projects Manager], [GUK's General Manager], [GUK's Sales and Marketing Director] and [GUK's Head of Contract Sales] dated 1 November 2001 (document 0927). See also, for example, reference to Alphapharm being source of the product which GUK intended to sell in the SB Skeleton Argument in support of the GUK Interim Injunction (document 0910), paragraph 15.

³⁸⁹ GUK had also made preparations to launch elsewhere in Europe. See email from [Merck's Head of Patents and Raw Material Support Group] to [the Chief Executive of Merck Generics Group] dated 27 March 2002 (documents 1029 and 1030).

³⁹⁰ See, for example, email chain between [the Chief Executive of Merck Generics Group], [GUK's Commercial Director] and others dated 12 April 2002 (document 1040). See also email from [Merck's Strategic Sourcing Specialist] to [Sumitomo employee] dated 23 May 2001 (documents 0848 and 0847), enclosing paroxetine forecasts for the Merck Generics Group, including 1,010kg for the UK; email from [Merck's Head of Patents and Raw Material Support Group] to [the Chief Executive of Merck Generics Group] and others dated 5 April 2002 (document 1038); and [redacted]WS (document 0901), paragraphs 14 and 42.

³⁹¹ Paroxetine from Alphapharm was delivered to GUK in October 2001 – see email chain between [GUK's General Manager], [the Chief Executive of Merck Generics Group], [GUK's Finance Director B] and [a GUK Special Projects Manager] dated 12 March 2002 (document 0991).

³⁹² See [redacted]WS (document 0901), paragraph 14.

order to launch its paroxetine product in the UK and following launch.³⁹³ For example, an internal GUK email sent by [GUK's Managing Director] to [the Chief Executive of Merck Generics Group] on 8 August 2001, set out GUK's initial launch quantity order:³⁹⁴

'I have already communicated with [the Head of Merck Operation in Australia] on GUK requirements. GUK have placed initial launch quantity orders for 16 million tablets bulk. [...] These are required for the anticipated launch date of 15 October [2001] [GUK's Head of Research and Development] is trying to bring this forward with the MCA - but chances are slim'.³⁹⁵ This GUK launch quantity is not expected to last beyond the end of November therefore it [is] essential to have follow up supplies by early December.'

3.259 In a later email on 29 October 2001, [a GUK Sales and Marketing employee] set out GUK's initial stock requirements: *'750k (3.75 months stock at 57% of generic market) then 200k per month (57% of generic market) to be monitored and adjusted as necessary after launch'*.³⁹⁶ [GUK's General Manager] replied on the same day, proposing that:³⁹⁷

'We should aim to take 50-55% of the generic market (OLS included)

- This is expensive stock and I do not want to be left with it if Norton etc undermine the market

[...]

³⁹³ Although GUK initially focussed on launching its paroxetine 20mg, there is also evidence that it intended to launch a 30mg product shortly thereafter, and it had taken steps to do so. See spreadsheet entitled 'Product Development List', dated 8 January 2001 (document 0836), which includes an estimated launch date of April 2002 for 30mg paroxetine (September 2001 for 20mg) and an estimated '*submission*' date of October 2001, which the CMA understands to refer to the date for submission of an MA application. Further, GUK had engaged in discussions with Sumika about ordering API for both 20mg and 30mg in UK. See email from [Merck's Strategic Sourcing Specialist] to [Sumitomo employee] dated 23 May 2001 (documents 0848 and 0847) enclosing paroxetine forecasts for the Merck Generics Group, including for the UK.

³⁹⁴ See email from [GUK's Managing Director] to [the Chief Executive of Merck Generics Group] dated 8 August 2001 (document 0863).

³⁹⁵ Some of the authors of GUK's documents frequently used square brackets and ellipses (...). In the Decision, the square brackets and/or ellipses that were in the original document have been kept in italics, for example, [*original text*], while the CMA's insertions are non-italicised, for example, [*added text*].

³⁹⁶ See email chain between [a GUK Sales and Marketing employee], [GUK's General Manager], [GUK's Sales and Marketing Director] [and other GUK employees] dated 25 October 2001 and 30 October 2001 (document 0923).

³⁹⁷ Email chain between [a GUK Sales and Marketing employee], [GUK's General Manager], [GUK's Sales and Marketing Director] [and other GUK employees] dated between 25 October 2001 and 30 October 2001 (document 0923).

- I would guess we should sell 160k/month all labels with a 700k launch volume.'

3.260 GUK had planned to launch its paroxetine product in the UK in early November 2001.³⁹⁸ GUK had taken advanced orders of its paroxetine product ahead of its launch in the UK. GUK started to approach customers about its paroxetine product in September 2001 and customers began to place orders immediately. Between 7 and 21 September 2001 GUK had received orders for 492,800 packs of paroxetine, which would have amounted to approximately £5.5 million in sales for the month of October 2001,³⁹⁹ and would have equated to an average sales price of about £11.16 per pack.⁴⁰⁰ In a witness statement in which [GUK's General Manager] was describing the losses that GUK would suffer as a consequence of an injunction, [GUK's General Manager] stated that some customers had also indicated their estimated monthly requirements for the next six months which in total represented approximately £35 million in potential sales.⁴⁰¹ Further, GUK was prepared to and, in fact did, provide '*certain indemnities*' to its customers.⁴⁰²

3.261 GUK also engaged in discussions with a number of other generic suppliers about GUK supplying its paroxetine product to them:

- IVAX (as discussed at paragraphs 3.191 to 3.197): in an email to [the Chief Executive of Merck Generics Group] on 8 August 2001, [GUK's Managing Director] explained that he was '*negotiating with Norton & Hexal to supply*

³⁹⁸ See GUK's Skeleton Argument in the GUK Litigation for the hearing on 23 October 2001 (document 0907), paragraph 4. See also Spreadsheet entitled 'Paroxetine – Launch analysis' dated 11 June 2001 (document 0855), recording the '*Earliest est. launch for 20mg strength paroxetine in the UK as September 2001*'.

³⁹⁹ [REDACTED]WS (document 0901), paragraph 17. This would have accounted for approximately 10% of all paroxetine 20mg sales (by volume) in the UK in 2001 (based on a total market size of around 49 million packs of 30 paroxetine 20mg tablets).

⁴⁰⁰ £5,500,000 divided by 492,800.

⁴⁰¹ See [REDACTED]WS (document 0901), paragraph 17, and [REDACTED]WS, Exhibit [REDACTED]1 (document 0174), Tab 3, 'Order notes for purchase of paroxetine'.

⁴⁰² In an email from [Merck's Head of Patents and Raw Material Support Group] to [GUK's Head of Research and Development], [Commercial Director of Merck Generics] and [another Merck employee] dated 14 February 2001 (document 0837), [Merck's Head of Patents and Raw Material Support Group] stated that '*we are prepared to give certain indemnities along the lines of we supply the product and we control all the litigation and no liability falls on the customer*'; in an email chain between [GUK's Head of Research and Development], [GUK's Managing Director], [the Chief Executive of Merck Generics Group], [GUK's General Manager] and [Merck's Head of Patents and Raw Material Support Group], [Commercial Director of Merck Generics] and [the Head of Merck Operation in Australia] dated 12 March 2002 (document 0990), [the Chief Executive of Merck Generics Group] stated that '*I think we [GUK] did underwrite that we did not infringe*'; in an email chain between [Commercial Director of Merck Generics], [the Chief Executive of Merck Generics Group], [GUK's Managing Director], [Merck's Head of Patents and Raw Material Support Group], [GUK's General Manager] and [GUK's Head of Research and Development] dated 12 March 2002 (document 1002), [Commercial Director of Merck Generics] explained that GUK '*indemnified Ratio and Novartis so we would have to conduct any legal activity. We did not guarantee that we would fight, but obviously they would be very upset if we do a deal and do not include them in some way*'; in [REDACTED]WS2 (GUK) Exhibit [REDACTED]5 (document 0888), at paragraph 1.1, [GSK's Finance Director A] stated that GUK '*was offering, I understand, an indemnity in respect of patent infringement*' to IVAX.

them in the UK and that *'Norton is keen with anticipated volume of +/- 10mio tablets a year'*.⁴⁰³ Further evidence shows that GUK was in discussion with IVAX about GUK supplying its paroxetine product to IVAX:

- In an exhibit to his witness statement in the GUK Litigation, [GSK's Finance Director A] explained that *'in early September [2001], [IVAX's Managing Director] , and [IVAX's Commercial Director] [sic] of Norton told me that they were in active negotiations with GUK about the possible supply of generic paroxetine by GUK to Norton.'*⁴⁰⁴
- In an internal IVAX email on 11 October 2001, there is a reference to a *'gentleman's agreement'* for the supply of paroxetine from GUK to IVAX.⁴⁰⁵ This is discussed at paragraph 3.196.
- Hexal: as with IVAX, GUK offered its product to Hexal in August 2001.⁴⁰⁶
- Novartis and Ratiopharm: GUK entered into a non-exclusive distribution agreement with Novartis (on 28 June 2001) and Ratiopharm (on 20 August 2001) in relation to the supply of GUK's paroxetine product within Europe.⁴⁰⁷ In an email to [the Chief Executive of Merck Generics Group] on 8 August 2001, [GUK's Managing Director] explained that Novartis' and Ratiopharm's volume estimates were *'expected to be significant'*.⁴⁰⁸
- GUK also considered out-licensing its paroxetine product to a number of other generic suppliers.⁴⁰⁹

⁴⁰³ See email from [GUK's Managing Director] to [the Chief Executive of Merck Generics Group] and others dated 8 August 2001 (document 0863).

⁴⁰⁴ See [X]WS2 (GUK) Exhibit [X]5 (document 0888), paragraph 1.1

⁴⁰⁵ Email from [IVAX's Commercial Director] to [IVAX's Head of New Business Development] dated 11 October 2001 (document 1795), forwarding an e-mail from [IVAX's Head of New Business Development] to [IVAX's Commercial Director], [IVAX's Sales and Marketing Manager] and others dated 10 October 2001 which refers to a *'gentleman's agreement'*.

⁴⁰⁶ See email from [GUK's Managing Director] to [the Chief Executive of Merck Generics Group] and others dated 8 August 2001 (document 0863).

⁴⁰⁷ See email from [Commercial Director of Merck Generics] to [a Merck employee] dated 19 April 2002 (document 1049), distribution agreement between GUK and Ratiopharm dated 28 June 2001 (unsigned) (document 0856) and distribution agreement between GUK and Biochemie dated 20 August 2001 (unsigned) (document 0864). See also email from [GUK's Head of Research and Development] to [GUK's Managing Director] and [the Chief Executive of Merck Generics Group] dated 12 March 2002 (document 1002), explaining that *'Ratio and Novartis... both signed contracts with obligations'*.

⁴⁰⁸ See email from [GUK's Managing Director] to [the Chief Executive of Merck Generics Group] and others dated 8 August 2001 (document 0863).

⁴⁰⁹ See email from [GUK's Head of Contract Sales] to [a GUK Special Projects Manager] dated 25 October 2001 (document 0923) and email from [GUK's Head of Contract Sales] to [a GUK Special Projects Manager] dated 8 November 2001 (document 0927).

Patent issues prior to the GUK Litigation

3.262 In addition to the requirement for regulatory approval needed to launch a paroxetine product in the UK, GUK also expected that it would be subject to litigation proceedings by GSK regarding the patent situation. As early as December 2000, in an email to [Merck Generics' Head of Corporate Business Development], [the Chief Executive of Merck Generics Group] explained that GUK anticipated that such litigation might delay the launch of its paroxetine product.⁴¹⁰

'[...] litigation is virtually unavoidable with SKB on paroxetine - given that we are registering in various countries a generic [with non-infringing process].'

3.263 Similarly, in a separate email to [Merck Generics' Finance Director] on 15 December 2000, [a Research and Development employee of Merck Generics] set out the following in respect of GUK's paroxetine product:⁴¹¹

'G[UK]

Of the products listed for launch in 2001, the following will not be launched in 2001:

Paroxetine tablets - this will be subject to litigation with SmithKline - hence, even though the regulatory approval should be received in 2001, there will be no effective launch until the litigation has been completed'.

3.264 Internal GUK correspondence during 2001 indicates that although there was the prospect of patent litigation, in 2001 GUK took the decision to launch its paroxetine product in Australia and Europe. In an email sent on 29 May 2001 to [Merck's Chairman of the Executive Board], [the Chief Executive of Merck Generics Group] explained that:⁴¹²

'Just to let you know that discussions with GSK re paroxetine were fruitless. I have taken the decision to proceed with launch in Australia

⁴¹⁰ See email from [the Chief Executive of Merck Generics Group] to [Merck Generics' Head of Corporate Business Development] dated 1 December 2000 (document 0832).

⁴¹¹ See email from [a Research and Development employee of Merck Generics] to [Merck Generics' Finance Director], [GUK's Head of Research and Development] and [the Chief Executive of Merck Generics Group] dated 15 December 2000 (document 0835).

⁴¹² See email from [the Chief Executive of Merck Generics Group] to [Merck's Chairman of the Executive Board] dated 29 May 2001 (document 0850). See also email from [Merck's Head of Patents and Raw Material Support Group] to [a Merck employee] dated 14 February 2001 (document 0837). See also email from [Merck's Head of Patents and Raw Material Support Group] to [a GUK-Merck Senior Registration Officer] and others dated 23 April 2001 (document 0843).

and Europe - working on the basis that GSK has an invalid patent and we do not infringe.'

c) The GUK Litigation

- 3.265 GSK initiated patent infringement proceedings alleging infringement of the Anhydrate Patent by GUK in the UK High Court, Chancery Division (Patents Court), on 18 September 2001.
- 3.266 Prior to those proceedings, [GSK's external lawyers], wrote to GUK on 8 August 2001 to *'bring to [GUK's] attention that the importation into the UK for disposal either of tablets containing paroxetine hydrochloride anhydrate or of the bulk material from which they are made, would constitute an infringement'* of the Anhydrate Patent.⁴¹³ That letter also explained that if GUK was to import such a product without GSK's consent then GSK would begin proceedings *'without delay to seek the immediate restraint of such activity'*.⁴¹⁴
- 3.267 GUK responded on 9 August 2001, explaining that GSK *'can be assured that we will not infringe any valid patents'*.⁴¹⁵
- 3.268 Further correspondence on this issue was exchanged on 21 August 2001 and on 5, 10 and 14 September 2001. In particular:⁴¹⁶
- on 5 September 2001, GSK explained that it had tested product from GUK's sister company (Alphapharm) and considered that it fell within the scope of at least the Anhydrate Patent; and
 - on 14 September 2001, GUK set out its position that GUK had *'no intention of infringing'* the Anhydrate Patent and that the Anhydrate Patent was *'invalid in that it is, inter alia, neither novel nor inventive'*.

The GUK Interim Injunction

- 3.269 On 21 September 2001, GSK sought an interim injunction to restrain GUK from selling its generic paroxetine in the UK claiming infringement of the Anhydrate Patent. Following a hearing on 23 October 2001, Mr Justice Jacob, decided to grant the GUK Interim Injunction requested by GSK on the same

⁴¹³ See exhibit [REDACTED]4 referred to in the statement of [GSK's Patent Attorney] dated September 2001 (document 0871).

⁴¹⁴ Exhibit [REDACTED]4 referred to in the statement of [GSK's Patent Attorney] dated September 2001 (document 0871).

⁴¹⁵ Exhibit [REDACTED]4 referred to in the statement of [GSK's Patent Attorney] dated September 2001 (document 0871).

⁴¹⁶ Exhibit [REDACTED]4 referred to in the statement of [GSK's Patent Attorney] dated September 2001 (document 0871).

date.⁴¹⁷ That injunction restrained GUK from '*disposing of or offering to dispose of any pharmaceutical preparation containing paroxetine hydrochloride*' and provided for GSK to give a cross-undertaking in damages pursuant to which GSK would be liable to pay GUK compensation for any losses suffered, in the event that the court subsequently found that the injunction was wrongfully granted.⁴¹⁸

3.270 In his witness statement in the GUK Litigation, [GUK's General Manager] commented on GSK's decision to enter into a supply agreement with IVAX a full five years before patent expiry. [GUK's General Manager] considered that this was, in his experience, highly unusual and was most likely to be explained by GSK's view that generic suppliers would be able to bring to market a product which did not infringe valid claims in GSK's patents:⁴¹⁹

*'In my experience of the generics market, **no pharmaceutical company has ever attempted** to join forces with a generics company to supply a version of its product 5 years prior to the [Hemihydrate] patent on the branded product expiring. Yet that is precisely the position here, which begs the question why is SB [SmithKline Beecham] doing this? There are only two possible reasons that I can think of. **The first and most likely is that it is a reflection of SB's views on the strength of its anhydrate patent, which was granted as recent as 1997. That is to say, the reason that SB is going to start selling generic paroxetine is that it can see that generic competitors will shortly be entering the market in any event, either because the anhydrate patent is invalid or because the competitors have a non-infringing product. The only other possible reason I can think of is the impending genericisation of Cipramil [...]**' (emphasis added).⁴²⁰*

3.271 On the IVAX-GSK Agreement, GSK argued in its skeleton argument that:⁴²¹

'it is clear [...] that [IVAX] is willing for GUK to be a sub-distributor. This would enable GUK to mitigate its loss by selling paroxetine at the

⁴¹⁷ *SmithKline Beecham Plc v Generics (UK) Ltd*, transcript of hearing before Jacob J dated 23 October 2001 (document 0911).

⁴¹⁸ GUK Interim Injunction (document 0909).

⁴¹⁹ [REDACTED]WS (document 0901), paragraph 37.

⁴²⁰ Additionally, in an interview with the OFT [Merck's Head of Patents and Raw Material Support Group] explained '*... if an innovator is willing to settle then they must have to a certain extent a feeling ... as much as we had, you know, not necessarily a hundred percent of winning, they would have the same viewpoint, they may not have a hundred percent chance of winning, so there's a certain amount of 'leverage', so they must feel as unsecure as we feel insecure, so having got to that position where there's an insecurity on the other side, let's lever it for as much as possible'*, transcript of interview with [Merck's Head of Patents and Raw Material Support Group] on 25 May 2012, dated 13 November 2012 ('[REDACTED]1') (document 2330), pages 41-42.

⁴²¹ SB Skeleton Argument in support of the GUK Interim Injunction (document 0910), paragraph 54.

parallel import price. It would not enable it to severely undercut this price and de-stabilize the market.'

- 3.272 In granting the GUK Interim Injunction, Mr Justice Jacob observed that there was '*perhaps... some force*' to the argument advanced by GUK's Counsel that GSK would never have entered into the IVAX-GSK Agreement if GSK considered its patent position to be '*impregnable*', whilst also noting that there were '*other possible motives*' for GSK entering into the IVAX-GSK Agreement and that GSK's patent protection was not unlimited in relation to the active ingredient in the product.⁴²²
- 3.273 In relation to the parties' substantive arguments, Mr Justice Jacob explained that he had '*come to the clear conclusion that I am quite unable to decide the relative strengths of the parties' contentions*'.⁴²³
- 3.274 On the adequacy of damages as a remedy, Mr Justice Jacob set out his understanding that if GUK was not enjoined (and therefore launched a generic paroxetine product in the UK, independently of GSK) GSK '*will very probably suffer price loss and loss of market share*' and that '*the amounts involved will be very substantial sums indeed*',⁴²⁴ and observed, in particular, that '[t]he only thing I think I can say with some certainty is that the order of damage to the claimant is likely to be a good deal greater than that to the defendants [GUK]' and that '*the claimant's [GSK] damage is more unquantifiable than that of the defendant's [GUK] but both are unquantifiable*'.⁴²⁵
- 3.275 In his consideration of whether an injunction should be granted, Mr Justice Jacob observed that a relevant factor was that GUK had '*known for a long time about this patent*'⁴²⁶ and could have taken steps to clear any dispute out

⁴²² *SmithKline Beecham Plc v Generics (UK) Limited*, transcript of hearing before Jacob J, dated 23 October 2001 (document 0911), pages 2–3.

⁴²³ In a similar vein, Mr Justice Jacob also observed at page 5 that '[t]here is nothing to tip the balance of probability one way or the other' and at page 6 that '*I really cannot decide one way or the other on the information I have*': see *SmithKline Beecham Plc v Generics (UK) Limited*, transcript of hearing before Jacob J, dated 23 October 2001 (document 0911), pages 4–5.

⁴²⁴ *SmithKline Beecham Plc v Generics (UK) Limited*, transcript of hearing before Jacob J, dated 23 October 2001 (document 0911), page 9, lines 15–17.

⁴²⁵ *SmithKline Beecham Plc v Generics (UK) Limited*, transcript of hearing before Jacob J, dated 23 October 2001 (document 0911), pages 10–11.

⁴²⁶ *SmithKline Beecham Plc v Generics (UK) Limited*, transcript of hearing before Jacob J, dated 23 October 2001 (document 0911) page 11

of the way, as soon as GUK was settled on the product that it was intending to sell, by causing the litigation to start.⁴²⁷ He concluded that:⁴²⁸

'I see no question of principle involved here of any sort. It is purely commercial common sense. If there may be an obstacle in your way, clear it out. To my mind, this is a case where the retention of the status quo is a rational thing to do. It was something that could have been avoided by the defendants; they chose not to do it.'

3.276 On the day that the GUK Interim Injunction was granted, 23 October 2001), [GUK's Managing Director] sent an email to others in GUK and the Merck Generics Group updating on the situation and explaining that '[u]nfortunately injunctions "come with the territory"'.⁴²⁹

3.277 In an internal GUK email sent on 24 October 2001, the day after the GUK Interim Injunction, [GUK's Managing Director] indicated that GUK was 'confident' that its product did not infringe the Anhydrate Patent.⁴³⁰ In that email, [GUK's Managing Director] also considered the potential for a supply agreement between IVAX and GSK and explained that IVAX had offered to 'sub-licence' GUK but that 'frankly the terms are not interesting to us'. Instead, he suggested that 'they could well play into our hands' and that 'it will be patently clear to our customers that Norton again are the generic spoilers in this regard' and were 'preventing true generic competition'.⁴³¹

'You will by now no doubt have heard about the court's decision yesterday to injunct GUK against selling Paroxetine before the actual infringement case now scheduled for March next year. The court's reason for this centred around the judge's inability to decide whether our product did indeed infringe GSK's patent. ... We are confident that we do not infringe and will therefore be able to launch next year AND claim substantial damages from GSK. This information is for you only and should not be discussed with customers at this stage. We will discuss further at the next sales meeting.'

⁴²⁷ *SmithKline Beecham Plc v Generics (UK) Limited*, transcript of hearing before Jacob J, dated 23 October 2001 (document 0911) pages 11–12.

⁴²⁸ *SmithKline Beecham Plc v Generics (UK) Limited*, transcript of hearing before Jacob J, dated 23 October 2001 (document 0911) page 13.

⁴²⁹ Email from [GUK's Managing Director] to [GUK's Operations Director] and others dated 23 October 2001 (document 0908).

⁴³⁰ Email from [GUK's Managing Director] to [GUK's Sales and Marketing Director] and others dated 24 October 2001 (document 0913). See also email from [a GUK Sales and Marketing employee] to [GUK's General Manager] dated 26 October 2001 (document 0917).

⁴³¹ Email from [GUK's Managing Director] to [GUK's Sales and Marketing Director] and others dated 24 October 2001 (document 0913).

Going forward you may also be aware that Norton have signed an agreement with GSK to launch the GSK "generic" version of this product. We are not fully informed as to the nature of this agreement but it is very likely that Norton will be heavily controlled by GSK in the amount of product they can sell and the price they sell it at - probably a penny or two under the PI [parallel import price]. Also, Norton are free to sub-licence the product to other generic players. We have been offered this deal but frankly the terms are not interesting to us. In fact, they could well play into our hands. Assuming Norton launch limited quantities into the market in December [the earliest date we have heard] we will only have to wait a further three months to launch our own product which we know will be much more competitive than Norton.

Additionally, it will be patently clear to our customers that Norton again are the generic spoilers in this regard in aiding and abetting a multinational company by preventing true generic competition and artificially managing the situation which can only harm the short-liners. This point should be clearly stressed.

It is obvious for us that this is not the ideal situation but I firmly believe that we can turn it around to our advantage in 2002.'

3.278 Following the GUK Interim Injunction, GUK also contacted a number of its customers to provide some reassurance in relation to the supply of its paroxetine product. In a letter sent to all of GUK's wholesalers on 29 October 2001, GUK said that:⁴³²

'With regard to Paroxetine as you may be aware we are still fighting to bring this product to the market as quickly as possible. We are confident that we have a non-infringing product and will win our legal case. It is my greatest wish to be able to supply you and break GSK's dominance and manipulation of the product via other 3rd parties.'

3.279 In interviews with the OFT on 25 May 2012, [Merck's Head of Patents and Raw Material Support Group] stated that the GUK Interim Injunction was 'a big shock' and that 'he did not expect [GUK] to be injuncted.'⁴³³ He explained that it was 'a landmark injunction' and that there had 'never been an injunction

⁴³² Email from [a GUK Marketing Assistant] to [GUK's General Manager] and others dated 29 October 2001 (document 0922) attaching letter to wholesalers dated 29 October 2001 (document 0921).

⁴³³ [redacted]1 (document 2330), pages 28–29. A similar view '...losing the injunction had knocked GUK' was expressed by GUK in a meeting with the OFT on 7 February 2012 (Minutes of meeting between GUK and the OFT on 7 February 2012 (document 1210), paragraph 13).

*in the United Kingdom for the previous ten years... [i]t was the first pharmaceutical injunction I think that had happened'. He also said that the Court found that GUK could have gone ahead and 'cleared the undergrowth' by clearing 'the patent out of the way.'*⁴³⁴ Separately, in an interview with the OFT on 25 May 2012, [the Chief Executive of Merck Generics Group] explained that *'[t]he minute you get an injunction it does sort of make you think, hold on a second, maybe we don't have such a strong case. It probably did, it probably did have some effect on it' and that 'an injunction definitely would have had a negative consequence and made us ... made me more risk averse'. His 'summation' of the GUK Interim Injunction was that GUK's 'case is weaker than I first thought'.*⁴³⁵

GSK's action against GUK in relation to the Hemihydrate Patent

3.280 As described at paragraph 3.128, in November 2001 GSK made an application to add, to the proceedings against GUK invoking the Anhydrate Patent, an action against GUK for infringement of the Hemihydrate Patent; that application was rejected on 30 November 2001. GSK then brought a separate action against GUK for infringement of the Hemihydrate Patent, which was stayed, pending a decision on the Anhydrate Patent.

d) Negotiation of the GUK-GSK Agreement

Discussions between GSK and GUK prior to the GUK Litigation

3.281 Prior to the GUK Litigation, GUK countenanced the possibility of discussions with GSK regarding paroxetine as far back as December 2000. For example, in an email to [Merck Generics' Head of Corporate Business Development] on 1 December 2000, [the Chief Executive of Merck Generics Group] asked:⁴³⁶

'what scope would there be for "discussions" on this and for some sort of collaboration? Seems to me that this should be raised at the earliest opportunity and at a relatively senior level.'

⁴³⁴ 1 (document 2330), pages 28–29. See also GSK Second Response, Part Two (document 0734), paragraph 4.20, in which GSK explained that at the relevant time *'injunctions in pharmaceutical patent disputes were rare (GSK's subsequent successful injunction against GUK was one of the first against a generic company for about ten years)'*.

⁴³⁵ Transcript of interview with [the Chief Executive of Merck Generics Group] on 25 May 2012, dated 17 December 2012 ('MU1') (document 2335), pages 21–22.

⁴³⁶ Email from [the Chief Executive of Merck Generics Group] to [Merck Generics' Head of Corporate Business Development] dated 1 December 2000 (document 0832).

3.282 The earliest evidence of discussions between GUK and GSK is from May 2001, prior to the GUK Litigation. Internal GUK documents show that GUK and GSK had discussed entering into an agreement in relation to the supply of paroxetine. In an internal GUK email to [the Head of Merck Operation in Australia], [GUK's Head of Research and Development], [Merck's Head of Patents and Raw Material Support Group], and [Commercial Director of Merck Generics] on 21 May 2001, [the Chief Executive of Merck Generics Group] explained that:⁴³⁷

'For information re the big "P".⁴³⁸

Discussions with our friends⁴³⁹ are essentially inconclusive. They [at this point] are not interested in a global deal. They appear happy to look at this market by market ...but for UK they want Norton; Germany - Hexal; France maybe with us; maybe Hollandno interest in US; maybe Australia [with settlement - which would be a problem re supply to Europe and elsewhere - unless we could produce somewhere else ... but it starts getting complicated, I think] - which all adds up to an unacceptable situation right now.

They will think once more about a global situation [sic] and may revert tomorrow - but it is not looking positive right now - given the number of generic competitors per our friends; and the fact that they want dominant partners in every market

I believe it is going to amount to delaying tactics ...and that we need to press ahead.

[...]

Pity - because API is so expensivebut we are working on this ...'

⁴³⁷ Email from [the Chief Executive of Merck Generics Group] to [the Head of Merck Operation in Australia] and others dated 21 May 2001 (document 0846). See also email from [Merck's Head of Patents and Raw Material Support Group] to [GUK employee] and others dated 26 October 2001 (document 0918), explaining that *'Hexal have done a deal with GSK in Germany which we think extends elsewhere but have no confirmation. GSK seem to be trying to do deals piecemeal i.e. Hexal in Germany, Norton/Ivax in UK and presumably others elsewhere.'* The CMA notes that at paragraph 1.4 of his witness statement in the GUK Litigation in 2001 ([§]WS2 (GUK) Exhibit [§]5 (document 0888)), [GSK's Finance Director A] explained that *'I did not approach GUK until 1 October [...]. This was an attempt to reach a commercially sensible arrangement whereby litigation could be avoided.'* This is not necessarily inconsistent with GSK holding discussions with GUK in May 2001, for example, GUK may have approached GSK about those earlier discussions.

⁴³⁸ The CMA has inferred that *'the big "P"'* was a reference to paroxetine.

⁴³⁹ Given the context, the CMA has inferred that *'our friends'* is a reference to GSK. See also email from [the Chief Executive of Merck Generics Group] to [Merck's Chairman of the Executive Board] dated 29 May 2001 (document 0850), referring to *'discussions with GSK re paroxetine'*.

3.283 On 29 May 2001, [the Chief Executive of Merck Generics Group] explained to [Merck's Chairman of the Executive Board] that those discussions were ultimately '*fruitless*' and that he had '*taken the decision to proceed with launch in Australia and Europe - working on the basis that GSK has an invalid patent and we do not infringe*'.⁴⁴⁰

3.284 GSK made a further offer to GUK prior to the GUK Litigation. In an email to [the Head of Merck Operation in Australia], on 26 July 2001,⁴⁴¹ [the Chief Executive of Merck Generics Group] asked if there was '[a]ny news re *paroxetine proposals*' and explained that the '[p]robability is that we will reject the UK offer'.⁴⁴² Later on the next day (27 July 2001), [the Chief Executive of Merck Generics Group] set out what GSK's '*UK offer*' was:⁴⁴³

'The UK deal was simply an offer to license GUK to give a reasonable returnbut not good enough for us to avoid the patent risks and launch ...'

Discussions between GSK and GUK once the GUK Litigation had commenced

3.285 Following the application for the GUK Interim Injunction,⁴⁴⁴ GUK had further discussions with IVAX and GSK in which GSK offered to supply GUK with paroxetine, via IVAX. GUK then indicated that it might be interested in obtaining paroxetine directly from GSK, as set out in the witness statement of [GUK's General Manager]. In particular:

- On 1 October 2001 [GUK's Managing Director] met with [GSK's Finance Director A] and GSK offered to supply paroxetine to GUK via IVAX. GUK's

⁴⁴⁰ See email from [the Chief Executive of Merck Generics Group] to [Merck's Chairman of the Executive Board] dated 29 May 2001 (document 0850).

⁴⁴¹ Email chain between [the Chief Executive of Merck Generics Group] and [the Head of Merck Operation in Australia] dated 26–27 July 2001 (document 0859). GSK was also involved in a negotiation with Alphapharm about reaching a settlement agreement in Australia (same email refers). This is consistent with an email from [GSK's Senior Vice President Patents & Trademarks] to [GSK's Patent Attorney], and other GSK employees dated 20 July 2001 (document 0139) in which it is recorded that (GSK's General Manager of Australia) '*is in fairly advanced talks with Alphapharm*'.

⁴⁴² Email chain between [the Chief Executive of Merck Generics Group] and [the Head of Merck Operation in Australia] dated 26–27 July 2001 (document 0859). [the Head of Merck Operation in Australia] replied on 27 July 2001, setting out details of the offer that GSK had made to Alphapharm: '*GSK appears more keen to do a deal although they could well be playing games...after several rounds the offer is for them to supply our brand of paroxetine at a 40% margin, with no restrictions on our exports (initially they wanted restrictions then dropped that condition) but a non-exclusive agreement so they can do deals with Arrow (they have the Synthon product) etc. They also wanted us not to launch until September which they then relaxed to a "soft" launch. We responded to them today that we wanted a 50% margin on an exclusive deal with a launch Aug 1 as planned.*'

⁴⁴³ Email chain between [the Chief Executive of Merck Generics Group] and [the Head of Merck Operation in Australia] dated 26–27 July 2001 (document 0859).

⁴⁴⁴ See GSK's Claim Form in the GUK Litigation dated 18 September 2001 (document 0146).

response at the time was to reject this offer but suggested that GUK may be interested in supply directly from GSK (consistent with GUK's discussions with GSK in May 2001, see paragraphs 3.282 to 3.283 and GUK's internal consideration in December 2000, see paragraph 3.281).

- On 3 October 2001, [IVAX's Sales and Marketing Manager] spoke with [GUK's General Manager] on the telephone, during which IVAX offered to supply GUK with paroxetine sourced from GSK.
- On 8 October 2001, [GUK's Managing Director] met with [GSK's Finance Director A] during which GSK explained that it could not supply paroxetine directly to GUK but only via IVAX. GUK's response in that meeting was that it would *'launch its own product'*:⁴⁴⁵

'I am also informed by [GUK's Managing Director] that he had a meeting with [Finance Director A] of SB, on Monday 1 October. I am told by [GUK's Managing Director] that he was approached by [GSK's Finance Director A] who was offering GUK paroxetine to be supplied via Norton (under licence from SB). Again, these proposals were not of interest to GUK. [GUK's Managing Director] did however say to [GSK's Finance Director A] that GUK might be more interested in taking a supply directly from SB, if this could be arranged.

[X], one of the Marketing Managers of Norton Healthcare, telephoned me on Wednesday 3 October. The purpose of his call was to inform me that Norton planned to launch a paroxetine product with effect from 1 December and to propose a commercial arrangement between Norton and GUK for the supply to GUK by Norton of paroxetine. [IVAX's Sales and Marketing Manager] stated that Norton's paroxetine supply would be obtained under licence from SB.

I am also told by [GUK's Managing Director] that he had a further meeting with [GSK's Finance Director A] on 8 October 2001 at which time [GUK's Managing Director] conveyed to [GUK's Managing Director] that his company's lawyers had advised him that SB could not do a deal with GUK directly but that any deal to supply GUK should come through Norton. [GUK's Managing Director] therefore advised [GSK's Finance Director A] that GUK would launch its own product. [GSK's Finance Director A] also advised that SB was "too far down the road with Norton" to enable it to conclude a deal directly with GUK.'

⁴⁴⁵ [X]WS (document 0901), paragraphs 21–23.

3.286 Following the GUK Interim Injunction and before the GUK-GSK Agreement, GSK made a number of offers to GUK with a view to settling the GUK Litigation. Table 3.2 below summarises certain of the various offers that were made to GUK that are recorded on the CMA's file.⁴⁴⁶

Table 3.2: Summary of terms offered by GSK

Date	Summary of terms offered by GSK ⁴⁴⁷
21 November 2001 ⁴⁴⁸	<p>GSK offered to supply GUK at £8.45 per pack. Two options were suggested by GSK:</p> <ul style="list-style-type: none"> • 385,000 packs per annum, contribution to sales/marketing costs by a product support payment of £900,000 per year (paid monthly) • 513,000 packs per annum without sales and marketing support.
23-26 November 2001 ⁴⁴⁹	<p>GSK offered to supply 520,000 packs at a supply price of £8.45 per pack plus £1 million per annum for 'marketing support'. According to GUK calculations, this offer equated to £6.53 per pack).</p>
27 November 2001 ⁴⁵⁰	<p>GSK offered to supply GUK on the following terms:</p> <ul style="list-style-type: none"> • Year 1: 520,000 packs at £8.25 + £1.5 million marketing payment • Year 2: 520,000 packs + £1 million marketing payment • Year 3: 520,000 packs + £1 million marketing payment

⁴⁴⁶ Another offer is reported by [GUK's Managing Director] on 24 October 2001 (email from [GUK's Managing Director] to [GUK's Sales and Marketing Director] and others dated 24 October 2001 (document 0913)). This has not been included in the table as specific details of it are not reported.

⁴⁴⁷ The offers were made variously by IVAX and GSK. However, as [GUK's General Manager] states (in a letter from [GUK's General Manager] to [IVAX's Commercial Director] dated 24 January 2002 (document 0965) this involved GSK making certain offers 'through yourselves [IVAX]'.
⁴⁴⁸ Email chain between [IVAX's Sales and Marketing Manager], [GUK's General Manager], [IVAX's Commercial Director], [IVAX's Head of New Business Development], [GUK's external lawyer] of [external law firm], [GUK's Managing Director], [Merck's Head of Patents and Raw Material Support Group], [the Chief Executive of Merck Generics Group] dated 21 November 2001 (document 0932).

⁴⁴⁹ Email chain between [GUK's General Manager], [GUK's Managing Director], [GUK's external lawyer] of [external law firm], [the Chief Executive of Merck Generics Group] and [Merck's Head of Patents and Raw Material Support Group] dated 26 November 2001 (document 0936).

⁴⁵⁰ Email chain between [GUK's General Manager], [GUK's Managing Director], [the Chief Executive of Merck Generics Group], [Merck's Head of Patents and Raw Material Support Group] dated 27 November 2001 (document 0938).

Date	Summary of terms offered by GSK ⁴⁴⁷
22 December 2001 ⁴⁵¹	<p>GSK offered to supply GUK on the following terms:</p> <ul style="list-style-type: none"> • Year 1: 520,000 packs at a supply price of £8.85 + £4 million marketing payment • Year 2: 520,000 packs at a supply price of £8.85 + £1 million + £2 million (if no European agreement) • Year 3: £1 million +stock as above.
24 January 2002 ⁴⁵²	GSK offers 550,000 packs per annum. ⁴⁵³
12 March 2002 ⁴⁵⁴	<p>Summary of the heads of agreements ('so far') provided for:</p> <p>GUK/GSK: GSK agreed to purchase GUK's paroxetine stock for \$12.5million, payable quarterly over three years. £1.65 million would be paid annually over three years (reasons for payment not specified). In Year 1 – £250,000 would be paid on a quarterly basis to cover court costs (refundable if agreement terminated during three year term).</p> <p>GUK/IVAX: Three year term – 750,000 packs per annum + a supply price of £8.45 per pack. If GUK could not achieve a sales price over £12.20, GSK agreed to pay a rebate to reach the agreed profit figure – guaranteed for Years 1 & 2. Year 3 – margin guaranteed if selling price greater than £8.45.</p>

3.287 The first of the offers following the commencement of the GUK Litigation, was referred to in an internal email exchange dated 23 to 26 November 2001 between [GUK's Managing Director], [GUK's General Manager], and [the Chief Executive of Merck Generics Group], and [GUK's external lawyer]

⁴⁵¹ Email from [GUK's General Manager] to [the Chief Executive of Merck Generics Group] and [GUK's Managing Director] dated 22 December 2001 (document 0953).

⁴⁵² Letter from [GUK's General Manager] to [IVAX's Commercial Director] dated 24 January 2002 (document 0965).

⁴⁵³ There are no details of the other terms offered by GSK in this correspondence.

⁴⁵⁴ Email chain between [the Chief Executive of Merck Generics Group], [GUK's Managing Director] and [GUK's General Manager] dated 12 March 2002 (document 0989).

of[external law firm]. This provides details of discussions with GSK (and IVAX, as GSK's distributor) at that point.⁴⁵⁵

[GUK's Managing Director]

FYI

Ivax have come back with an improved offer:-

520k packs PA @ £8.45/pack + £1m PA for "marketing support".

This would give us gross sales of £6.5m with a £3m profit. In return for this they (Glaxo) want a side letter (Tomlin order ?) to the effect that we would withdraw our case.

[...]

[GUK's General Manager],

We obviously need to keep the process going. This offer equates to £6.53 per pack - still short of my £6.00 target for 600,000 packs. [...]

3.288 By 27 November 2001, the offer to GUK had improved to 520,000 packs at £8.25 plus a £1.5 million marketing payment in the first year of that proposed agreement.⁴⁵⁶

3.289 An internal GUK email on 29 November 2001 shows that GSK had sent GUK a draft agreement but that GUK was considering suggesting to GSK that they could still sell Sumika product, as follows:⁴⁵⁷

'The draft UK (only) GSK agreement has just appeared and I have not read it yet but can we consider the following

[...]

Question: What are the best settlement terms to be based on?

Suggestions

⁴⁵⁵ Email chain between [GUK's General Manager], [GUK's Managing Director], [GUK's external lawyer] of [external law firm], [the Chief Executive of Merck Generics Group] and [Merck's Head of Patents and Raw Material Support Group] dated 26 November 2001 (document 0936), entitled 'Improved Glaxo offer'.

⁴⁵⁶ Email from [GUK's General Manager] to [GUK's Managing Director] dated 27 November 2001 (document 0937).

⁴⁵⁷ Email from [Merck's Head of Patents and Raw Material Support Group] to [the Chief Executive of Merck Generics Group] and others dated 29 November 2001 (document 0940).

GSK allow us to sell our anhydrate product from Sumika without any patent litigation fears, where we pay a (small/reasonable) royalty from our profits in Europe (to include Israel) for non-exclusive patent rights/licence. [...] If we win in the USA then all our royalty payments cease [...]

Advantage is that Sumika is happy and we can control (to some extent) our base costs.

Disadvantage to GSK, they lose volume and control. (I suppose we could agree to maximum volumes, if needed, to assist a settlement?)'

3.290 An internal email dated 22 December 2001 from [GUK's General Manager] to [GUK's Managing Director] and [the Chief Executive of Merck Generics Group] set out the terms of GSK's latest offer, including further increases.⁴⁵⁸

'As agreed yesterday here is a summary of what is on offer:-

Year 1

£4m (Marketing Payments)

+

520k Packs at £8.85 cogs (this will give gross sales of £6.2m and nett profit of £1.63m)

Year 2

£1 m + £2m (if no European agreement has been made)

+

520k packs @ £8.85

Year 3

£1m + stock as above.

In summary over a 3 year term they [are] guaranteeing [...]

Gross sales:£18.6m

Profit £12.89m

Nett less active costs @ £8.3m =£4.6m

+ any other deal done in Europe.

⁴⁵⁸ Email from [GUK's General Manager] to [the Chief Executive of Merck Generics Group] and [GUK's Managing Director] dated 22 December 2001 (document 0953).

Having slept on this I am inclined to agree with your view that this is a poor return given the level of investment. That said I would like to be confident that we will win in march.'

3.291 An internal email exchange between [the Chief Executive of Merck Generics Group], [Merck's Head of Patents and Raw Material Support Group], [GUK's General Manager] and others in GUK on 29 and 31 December 2001 indicates that although negotiations with GSK continued, GUK continued to consider it could successfully challenge the Anhydrate Patent. In particular, [the Chief Executive of Merck Generics Group] said:⁴⁵⁹

[GUK's General Manager]and I were taking [GSK's] offers until the last minute before Christmasbut their final offer was still not acceptable. [...]

[A]s long as you remain confident of winning [although there are no guarantees] we must push for the best deal we can [...] otherwise we should puch [sic] on with the case for ultimate launch.'

3.292 In the same email exchange, [GUK's General Manager] responded to [the Chief Executive of Merck Generics Group] by saying:⁴⁶⁰

'Provide that we confident [sic] that we can win the case and seek damages on the 18th of March then we should go ahead on our own.

Although GSK's offer would deliver a similar bottom line (£5.6m v's £6m) this does not include recovery of active and any damage such an action may have with Sumika. Also we would also expect to recover substantial damages from GSK.'

3.293 Again, in the same email exchange, [✂], GUK's Head of Research and Development, responded:⁴⁶¹

⁴⁵⁹ Email chain between [Merck's Head of Patents and Raw Material Support Group], [the Chief Executive of Merck Generics Group], [GUK's General Manager], [GUK's Head of Research and Development], [Head of Merck Operation in Canada] and [the Head of Merck Operation in Australia] dated 31 December 2001 (document 0954).

⁴⁶⁰ Email chain between [Merck's Head of Patents and Raw Material Support Group], [the Chief Executive of Merck Generics Group], [GUK's General Manager], [GUK's Head of Research and Development], [Head of Merck Operation in Canada], [the Head of Merck Operation in Australia] and [GUK's Managing Director] dated 31 December 2001 (document 0955).

⁴⁶¹ Email chain between [Merck's Head of Patents and Raw Material Support Group], [the Chief Executive of Merck Generics Group], [GUK's General Manager], [GUK's Head of Research and Development], [Head of Merck Operation in Canada], [the Head of Merck Operation in Australia] and [GUK's Managing Director] dated 2 January 2002 (document 0959).

'court cases are a bit of a lottery..... I am 110 % confident that we will present the best case....there is always a small chance that despite the evidence the court decides against us.'

3.294 Following this internal GUK consideration of GSK's settlement offer, [GUK's General Manager] contacted [GSK's Finance Director A] on 2 January 2002, rejecting GSK's December 2001 offer, as recorded in an email from [GSK's Finance Director A] to others from GSK:⁴⁶²

'I have received confirmation from [GUK's General Manager] this afternoon saying that Merck Generics have rejected the offer of a commercial settlement for Paroxetine. They are clearly only interested in a European deal. I could not negotiate away their requirement for assurances of further European deals.

As they have now rejected our final offer they will now go to court.

[✂], [GSK's Financial Director (Europe)] - I will call you on Monday to discuss possible financial implications.'

3.295 In an internal GUK email dated 2 January 2002 sent to [the Chief Executive of Merck Generics Group], [Merck's Head of Patents and Raw Material Support Group] provided his view on the likelihood of winning the litigation with GSK and raised the possibility of further discussions with GSK in relation to a licensing agreement:⁴⁶³

'Whilst I am confident of winning [sic] in the long run...that is the operative word...long. GSK will delay, if thay [sic] can, when it suits them and alternatively push for deadlines to give us pressure. Obviously we will have to cope with all of this...and ultimately we will win:-

*a) the anhydrate patent is invalid, we can prove that now
b) the tablet patent is invalid or could be restricted to hemihydrate only.
c) the hemihydrate patent is more difficult to knock out, but possible. If GSK argue that there are traces of hemihydrate in our product, whilst again I think we can win it could take a long time going through appeals etc. to get the landmark ruling that something less than 1% is irrelevant....in each country.*

⁴⁶² Email from [GSK's Finance Director A] to [GSK's Financial Director (Europe)] and others dated 2 January 2002 (document 0196).

⁴⁶³ Email from [Merck's Head of Patents and Raw Material Support Group] to [the Chief Executive of Merck Generics Group] dated 2 January 2002 (document 0958).

Now, we are quite prepared to do this [...] but it would be nicer to get a world settlement along the "licence" idea, where we sell ours and theirs until the USA is resolved. Is it possible to have this discusson [sic] with GSK?'

3.296 Although GUK had rejected GSK's previous offers, an internal GUK email on 8 February 2002 from [the General Manager for Merck Generics] to [Merck's Head of Patents and Raw Material Support Group] and [GUK's Senior Patents Manager] suggests that GSK continued to be interested in negotiating a settlement with GUK.⁴⁶⁴ In that email, [the General Manager for Merck Generics] explained that Merck had been in discussion with GSK about a settlement in the Netherlands and that GSK had '*mentioned that a kind of settlement (with Hexal) was in preparation*'. He explained that '*during the meeting with Hexal as a representative of GSK in the NL,*⁴⁶⁵ *the person from Hexal mentioned again that GSK is strongly in favour of a settlement with MG in the UK*'. By 12 March 2002, discussions between GSK and GUK regarding paroxetine had restarted.⁴⁶⁶

3.297 One issue that arose in the negotiations from GUK's perspective was the need to compensate GUK's suppliers and others for their losses that would arise from GUK abandoning its plan to launch on an independent basis. That issue was debated in an internal GUK email exchange on 12 March 2002. First, in an email from [GUK's Head of Research and Development] to [GUK's Managing Director] and [the Chief Executive of Merck Generics Group], [GUK's Head of Research and Development] said:⁴⁶⁷

'Guys....can I raise once again the issue of Sumika.....my view is that we cannot let them go away empty handedyes I know they got the purchase price of the first lots of material but they had an expectation of ongoing business.....they are a very good technical partner and we will need them again.....we have to keep them in the loop.'

⁴⁶⁴ See email from [the General Manager for Merck Generics] to [Merck's Head of Patents and Raw Material Support Group] and [GUK's Senior Patents Manager] dated 8 February 2002 (document 0974).

⁴⁶⁵ In that email, Hexal holding discussions with Merck as '*a representative of GSK in the NL*' is consistent with GUK's discussions with IVAX as GSK's exclusive distributor in the UK, see paragraphs 3.285–3.286.

⁴⁶⁶ Email chain between [GUK's Head of Research and Development], [GUK's Managing Director], [the Chief Executive of Merck Generics Group], [GUK's General Manager], [Merck's Head of Patents and Raw Material Support Group], [Commercial Director of Merck Generics], [the Head of Merck Operation in Australia] dated 12 March 2002 (document 0990).

⁴⁶⁷ Email from [GUK's Head of Research and Development] to [GUK's Managing Director] and [the Chief Executive of Merck Generics Group] dated 12 March 2002 (document 1002).

3.298 [The Chief Executive of Merck Generics Group] forwarded [GUK's Head of Research and Development's] email to [GUK's General Manager], copying [GUK's Head of Research and Development] and others and said:⁴⁶⁸

[GUK's General Manager],

For information.

Sumika ... my view is that we need to work out the period to which the purchases of API relate.... Sumika clearly will benefit from our purchases for this notional period. So – what is required is a notional launch date [and this one I would not launch at risk] ... so - speak to [Merck's Head of Patents and Raw Material Support Group] – but I think earliest would have been December 2002 – and then work out the expected offtake in API i.e. at what point would we have needed a new shipment.

Beyond that point, we need to contemplate some form of compensation

... Bear in mind that the only reason we are contemplating a distribution agreement with GSK is because there is a real chance we may not prevail in the courts ... and Sumika need to understand this very clearly. If we did not prevail, then we would not be buying [sic] any API in the short term. And, Syumika [sic] have not been very flexible on the price and /or quantities [sic] i.e. they have forced us to go out at risk on the API [which in turn has influenced our position with GSK to a significant extent]...'

3.299 [The Chief Executive of Merck Generics Group] then forwarded that email chain to [the Head of Merck Operation in Australia] and added that:⁴⁶⁹

'In case nobody else has been keeping you informed, discussions with GSK have restarted re the above [paroxetine].

We have a real concern that we may not prevail in the patent case - so a settlement and local distribution agreement seem to be the best way to go - provided the numbers are right.

⁴⁶⁸ Email from [the Chief Executive of Merck Generics Group] to [GUK's General Manager] and others dated 12 March 2002 (document 1002).

⁴⁶⁹ Email chain between [GUK's Head of Research and Development], [GUK's Managing Director], [the Chief Executive of Merck Generics Group], [GUK's General Manager], [Merck's Head of Patents and Raw Material Support Group], [Commercial Director of Merck Generics] and [the Head of Merck Operation in Australia] dated 12 March 2002 (document 0990).

What will this do to your sales/OR for 2002?

What progress have you managed to make regarding the termination of legal action on Australia ... seems to make little sense to continue [providing your distribution agreement is sound]?'

3.300 Although in those emails [the Chief Executive of Merck Generics Group] referred to what he characterised as '*a real chance we may not prevail in the Courts*', that characterisation needs to be understood in the context of [the Chief Executive of Merck Generics Group's] discussion of the need to justify GUK's actions to Sumika (GUK's supplier of the API) and GUK's Australian affiliate (who was manufacturing the product for GUK). The CMA finds that [the Chief Executive of Merck Generics Group's] characterisation of the risks of litigation in these emails was affected by his desire to put GUK's actions in a favourable light. On any view, however, [the Chief Executive of Merck Generics Group] did not suggest that GUK's case in the litigation would have been hopeless or that GUK would have abandoned the litigation in the absence of the lucrative deal that GSK was offering.

3.301 Another internal GUK email chain dated 12 March 2002, discussed the latest terms offered by GSK and suggested that GUK may be able to obtain an improved offer from GSK:⁴⁷⁰

'I thought the deal totalled £15mio but [GUK's General Manager] assures me that this is correct [and maybe we can pick up some of my mental shortfall as below !]

Let's get the RM [Raw Material] quantity clear and defined in the agreement - I feel that we can pick up at least another \$5mio "profit" here.'

3.302 Although negotiations with GSK were ongoing, an internal GUK email sent by [GUK's Head of Research and Development] on the same day (12 March 2002) referred to its continued view that it had a '*good case*' in the patent litigation with GSK in which it was arguing that (i) the relevant patent claims were invalid; and (ii) that its product was non-infringing even if the relevant patent claims were upheld:⁴⁷¹

⁴⁷⁰ Email from [GUK's Managing Director] to [the Chief Executive of Merck Generics Group] and [GUK's General Manager] dated 12 March 2002 (document 0989).

⁴⁷¹ Email from [GUK's Head of Research and Development] to [the Chief Executive of Merck Generics Group] and others dated 12 March 2002 (document 0994).

'we have a good case and will argue for non infringement and invalidity....

-we can then launch at risk,.....they will try to injunct on the basis of the hemihydrate patent.....we think they will not succeed as we will argue that they should have gone fro [sic] this action long before May.....ie when they are likely to try for an injunction based upon loosing [sic] the anhydrate case'

3.303 In another email on the following day (the day on which GUK settled the litigation), [GUK's Head of Research and Development] said:⁴⁷²

'the first strage [sic] of the case is no issue.....ie anhydrate....think we can win this part ... hemihydrate is a bit more tricky because we know that under certain circumstances or [sic] product can contain hemihydrate.....think it is winnable but it is a bit more uncertain'.

3.304 The GUK-GSK Settlement Agreement and the GUK-IVAX Agreement were entered into on 13 and 14 March 2002 respectively. The terms of these agreements are set out in paragraphs 3.305 to 3.310.

e) The GUK-GSK Agreement

3.305 The GUK-GSK Settlement Agreement was entered into between SmithKline Beecham Plc, Beecham Group Plc and GUK, and was recorded in a letter dated 13 March 2002, the day before the substantive hearing on the patent infringement was due to commence.⁴⁷³

3.306 The GUK-GSK Settlement Agreement was signed by [GSK's Finance Director A] on behalf of GSK, and by [the Chief Executive of Merck Generics Group] on behalf of GUK.⁴⁷⁴

3.307 Under the GUK-GSK Settlement Agreement, GUK and GSK agreed to a Consent Order that the GUK Litigation be stayed, and the GUK Interim Injunction (and GSK's cross undertaking in damages) be discharged.⁴⁷⁵

⁴⁷² Email from [GUK's Head of Research and Development] to [the Chief Executive of Merck Generics Group] dated 13 March 2002 (document 0997).

⁴⁷³ See GUK-GSK Settlement Agreement (document 0995, signed by both Parties, and document 0996, signed and initialled by both Parties).

⁴⁷⁴ Merck was updated about the GUK-GSK Settlement Agreement at the time of its execution. Indeed, [the Chief Executive of Merck Generics Group] discussed the communications strategy in relation to that agreement with [Merck's Chairman of the Executive Board] around 14 March 2002. See email chain between [the Chief Executive of Merck Generics Group] and [and another Merck employee] dated 14 March 2002 (document 1011).

⁴⁷⁵ GUK-GSK Settlement Agreement (document 0995), draft Minutes of Order.

3.308 The GUK-GSK Settlement Agreement also included the following provisions:

- Stock purchase: GSK agreed to purchase GUK's stock of paroxetine hydrochloride anhydrate for US\$12.5 million, payable on a quarterly basis over three years.⁴⁷⁶
- Marketing allowance: GSK agreed to pay GUK an annual '*marketing allowance*' of £1.65 million for three years, commencing in March 2002.⁴⁷⁷
- As a condition precedent, GUK agreed to enter into the GUK-IVAX Agreement.⁴⁷⁸
- Legal costs: GSK agreed to pay 50% of GUK's legal costs incurred in the litigation (whether billed or unbilled), up to a maximum of £500,000 payable on 31 March 2002.⁴⁷⁹
- IVAX obligations: if the IVAX-GSK Agreement was terminated, GSK agreed to perform certain of IVAX's obligations, namely the delivery of paroxetine to GUK and the obligations to maintain '*GUK's minimum level of profit over the term of the*' GUK-IVAX Agreement, as if those obligations were imposed directly on GSK.⁴⁸⁰ If IVAX was unable to fulfil its obligations under the GUK-IVAX Agreement, GSK agreed to guarantee those of IVAX's obligations set out above.⁴⁸¹
- Restriction on entry: during the term of the GUK-IVAX Agreement, GUK agreed that neither it (nor any member of the Merck Generics Group) would '*make, import, supply or offer to supply paroxetine hydrochloride in*

⁴⁷⁶ GUK-GSK Settlement Agreement (document 0995), clause 1. For internal discussions regarding the paroxetine stock to be sold, see email chain between [GUK's General Manager], [a GUK Special Projects Manager], [the Chief Executive of Merck Generics Group] and [GUK's Finance Director B] dated 12 March 2002 (document 0991); letter from [GUK's General Manager] to [GSK's Finance Director A] dated 26 March 2002 (document 1004); email from [GUK's Commercial Director] to [GUK's Materials Manager], [a GUK Special Projects Manager] and [GUK's Finance Director B] dated 27 March 2002 (document 1028); email chain between [a GUK Special Projects Manager], [GUK's Commercial Director], [and other GSK employees] dated 28 March 2002 (document 1031); and email from [a GUK Special Projects Manager] to [GUK's Materials Manager], [GUK's Commercial Director] and [and other GUK employees] dated 24 May 2002 (document 1070).

⁴⁷⁷ GUK-GSK Settlement Agreement (document 0995), clause 2.

⁴⁷⁸ GUK-GSK Settlement Agreement (document 0995), clause 4.

⁴⁷⁹ GUK-GSK Settlement Agreement (document 0995), clause 3. [GUK's external law firm's] fees for the action are set out in an email from [GUK's external lawyer] of [external law firm] to [GUK's Commercial Director] dated 26 March 2002 (document 1024). At the time, unbilled and billed fees for the anhydrate action were £1.033 million and for the hemihydrate action were £87,000. An internal GUK document dated February 2002 shows legal fees of £609,330.55 and disbursements of £138,296.73 (GUK internal document entitled 'Schedule of Generics (UK) Limited Paroxetine Legal costs to date end – February 2002' (document 1020)), although note that an email from [GUK's Finance Director B] to [GUK's Commercial Director] dated 26 March 2002 (document 1023) comments that there '*must be some bills yet to come through*' as GUK are expecting to reach a total of £1.033 million.

⁴⁸⁰ GUK-GSK Settlement Agreement (document 0995), clause 5.1.

⁴⁸¹ GUK-GSK Settlement Agreement (document 0995), clause 5.2.

the United Kingdom', save as purchased from IVAX or otherwise manufactured or marketed by GSK or with GSK's consent.⁴⁸²

- GUK agreed not to assign or transfer its MA for three years.⁴⁸³
- Other markets: GUK and GSK agreed to discuss the supply by GSK of paroxetine to GUK/Merck Generics Group in other European markets.⁴⁸⁴
- On termination of the GUK-IVAX Agreement (set out below) whether by effluxion of time or otherwise, both GSK and GUK were at liberty to restore the GUK Litigation.⁴⁸⁵

3.309 As a condition precedent to the GUK-GSK Settlement Agreement,⁴⁸⁶ a sub-distribution agreement between GUK and IVAX, the GUK-IVAX Agreement, was entered into on 14 March 2002. This was reflected in the Second Addendum to IVAX's supply agreement with GSK, which amended the original IVAX-GSK Agreement as necessary (see paragraph 3.224).⁴⁸⁷ Both the GUK-GSK Settlement Agreement and the GUK-IVAX Agreement were to be for three years, save as set out below. The GUK-IVAX Agreement included the following other relevant obligations:

- Restriction on entry: GUK agreed not to '*manufacture, import or distribute*' paroxetine hydrochloride in Great Britain, Northern Ireland, the Channel Islands and the Isle of Man during the term of the GUK-IVAX Agreement.⁴⁸⁸
- Product: the product was defined as paroxetine hydrochloride 20mg tablets. '*Packs*' were defined as 30 x 20mg patient packs, with paroxetine hydrochloride as the active substance.⁴⁸⁹
- IVAX appointed GUK as a non-exclusive sub-distributor for paroxetine hydrochloride for Great Britain, Northern Ireland, the Channel Islands and the Isle of Man.⁴⁹⁰

⁴⁸² GUK-GSK Settlement Agreement (document 0995), clauses 8(i) and (ii).

⁴⁸³ GUK-GSK Settlement Agreement (document 0995), clause 8(iii).

⁴⁸⁴ GUK-GSK Settlement Agreement (document 0995), clause 9.

⁴⁸⁵ GUK-GSK Settlement Agreement (document 0995), clause 11.

⁴⁸⁶ GUK-GSK Settlement Agreement (document 0995), clause 4.

⁴⁸⁷ GUK-IVAX Agreement (documents 1003 and 1765). See also Heads of Agreement between GSK and IVAX dated 14 March 2002 (document 0217) and Second Addendum (document 0318).

⁴⁸⁸ GUK-IVAX Agreement (documents 1003 and 1765), clause 2.2. This clause replicated an equivalent clause in the GUK-GSK Settlement Agreement.

⁴⁸⁹ GUK-IVAX Agreement (documents 1003 and 1765), clause 1.1.

⁴⁹⁰ GUK-IVAX Agreement (documents 1003 and 1765), clause 1.1.

- Volume: 'GUK shall order and IVAX shall supply' 750,000 packs for each year of the agreement; This volume was subject to a clause stating that 'GUK shall be entitled to vary quantities ordered', subject to providing IVAX with a lead time of at least 12 weeks.⁴⁹¹ GUK's ability to vary the quantities it ordered did not, however, oblige IVAX to fulfil any orders in excess of 750,000 packs. Although IVAX would '*where requested, use reasonable endeavours to comply with any order for such excess*', it was under no obligation to do so.⁴⁹² In short, GUK was not obliged to order its full quantity (750,000 packs) and IVAX was not obliged to supply any quantities in excess of that set out in the agreement.
- Initial delivery: Clause 3.1 recognised that for '*regulatory reasons*' IVAX may face an initial delay in supplying product to GUK. Accordingly, it allowed for IVAX, in lieu of supply in the first two months of the GUK-IVAX Agreement, to pay GUK £237,500 (excluding VAT) per month. This clause was, in fact, invoked.⁴⁹³
- Duration and termination: the GUK-IVAX Agreement was specified as being for three years, but could be terminated if the Market Price per pack fell below £8.45 for at least three consecutive months in the third year of the contract, or any time after that.⁴⁹⁴
- Profit Guarantee: should the average selling price of a pack of 30 tablets fall below £12.25 per pack, IVAX provided GUK a profit guarantee, agreeing to pay GUK the shortfall, to ensure that GUK's profits would not fall below £2.85 million per year (excluding VAT) (clause 4.3). £2.85 million was the amount that GUK would make if it sold all its allocated packs of paroxetine (750,000) at £12.25 less the cost of the packs at £8.45 per pack. The profit guarantee therefore only covered the loss of profit incurred between £12.25 and £8.45 (that is, £3.80 per pack) and not any losses generally incurred by GUK for selling below the supply price of £8.45.⁴⁹⁵

⁴⁹¹ GUK-IVAX Agreement (documents 1003 and 1765), clauses 3.1 and 3.3.

⁴⁹² Indeed, to do so, IVAX would need to obtain additional supplies from GSK (or otherwise supply less paroxetine itself). Additional supply from GSK would have been inconsistent with the Second Addendum (document 0318), clause 2.6.

⁴⁹³ See email from [a GUK Sales and Marketing employee] to [IVAX's Sales and Marketing Manager] dated 6 March 2003 (document 1112) entitled 'Paroxetine yr 1 reconciliation [sic]' attaching spreadsheet entitled 'Norton/GUK Paroxetine Deal 2002/3' (document 1108). See also email from [X] of IVAX to [X] of IVAX dated 13 May 2002 (document 1774).

⁴⁹⁴ GUK-IVAX Agreement (documents 1003 and 1765), clauses 11.1 and 4.4.

⁴⁹⁵ GUK invoked this clause in both 2002 and 2003. In relation to 2002, see email from [a GUK Sales and Marketing employee] to [IVAX's Sales and Marketing Manager] dated 6 March 2003 (document 1112) entitled 'Paroxetine yr 1 reconciliation [sic]' attaching spreadsheet entitled 'Norton/GUK Paroxetine Deal 2002/3' (document 1108). In relation to 2003, see email from [a GUK Sales and Marketing employee] to [IVAX's Sales and Marketing Manager] dated 16 March 2004 (document 1130) entitled 'Paroxetine reconciliation [sic]' attaching spreadsheet entitled 'Norton/GUK Paroxetine Deal 2003/4' (document 1129) (a revised version of the relevant

The text of clause 4.3 was as follows: *'In the event that the Average Selling Price in any Contract Year falls below £12.25 per Pack, IVAX shall pay (within 30 days of the end of the relevant Contract Year of this Agreement) such sum as shall ensure (by making up any shortfall) that GUK's Profit in that Contract Year does not fall below £2.85million (excluding VAT) provided that, if this Agreement is terminated under clause 4.4 such amount shall be pro-rated accordingly'*.

- Price: the price for the product per pack was £8.45.⁴⁹⁶

3.310 The GUK-GSK Settlement Agreement was terminated with effect from 1 July 2004. At around the same time, namely on 25 June 2004, the associated GUK-IVAX Agreement was terminated.⁴⁹⁷ Reflecting GSK's role as guarantor of the GUK-IVAX Agreement, GSK made, under clause 5.1 of the GUK-GSK Settlement Agreement, a full and final settlement payment of £1,107,278.20 relating to the profit guarantee clause,⁴⁹⁸ as discussed above.

f) The Parties' rationale for entering into the GUK-GSK Agreement

3.311 GSK's rationale for the 'settlement' (and associated supply) agreements is set out at paragraphs 3.234 to 3.241.

3.312 As appears from the internal GUK emails discussing the negotiations with GSK set out above, for GUK the 'settlement' was a commercial decision taken after weighing the profitability of the agreement against the profitability and likelihood of successful independent entry through litigation.

3.313 In addition to the internal emails within GUK set out above, that balancing is also clear from an explanation given by GUK to its supplier, Sumika, by email dated 20 March 2002:⁴⁹⁹

spreadsheet was emailed to IVAX on 21 May 2004 which provided revised selling prices for January and February 2004, see email from [GUK's Head of Marketing] to [IVAX's Sales and Marketing Manager] dated 21 May 2004 (document 1137) attaching spreadsheets entitled 'Norton/GUK Paroxetine Deal 2002/3' and 'Norton/GUK Paroxetine Deal 2003/4' (document 1136).

⁴⁹⁶ GUK-IVAX Agreement (documents 1003 and 1765), clause 4.1. This price is then consistently shown in GUK internal documents: see internal reconciliations, spreadsheet entitled 'Norton/ GUK Paroxetine Deal 2002/3' (document 1109) and spreadsheet entitled 'Norton/ GUK Paroxetine Deal 2003/4' (document 1136).

⁴⁹⁷ Letter of termination of GUK-GSK Settlement Agreement dated 25 June 2004 (document 1147). See also email from [GUK's Head of Marketing] to [GUK's General Manager] and [a GUK Sales and Marketing employee] dated 25 June 2004 (document 1146) updating [GUK's General Manager] and [a GUK Sales and Marketing employee] on what had happened that day, including that GUK had *'Terminated Paroxetine with IVAX via emails, agreed fees with GSK, and received fax confirming protection of all monies.'*

⁴⁹⁸ Termination letter from GSK to GUK dated 20 December 2004 (document 0518 and 1174). Letter of termination of GUK-GSK Settlement Agreement dated 25 June 2004 (document 1147).

⁴⁹⁹ Email from [Merck's Head of Patents and Raw Material Support Group] to [Sumika employee] and [Sumitomo employee] dated 20 March 2002 (document 1017).

'We have not agreed to anything as regards validity or otherwise of any of the patents. The litigation is only stayed and can restart potentially at any time, but we don't expect that to happen in the short term. The decision to agree to a settlement after negotiations was taken by our commercial section which balanced the proposal against, amongst other things, the likelihood of an early launch given the legal uncertainties about the pending hemihydrate trial and the timing of any resulting appeal hearing.

BASF are continuing to challenge the anhydrate patent.'

3.314 Similarly, in an email dated 17 April 2002, [Merck's Head of Patents and Raw Material Support Group] explained the position to [✂] (a Merck employee in Vienna) in the following terms:⁵⁰⁰

'We settled in the UK for commercial reasons with no decision on patents. BASF continued with invalidation attempt on the anhydrate patent and the result is expected in about a month. (We would have done a better job!!)

The settlement was not really satisfactory from the legal point of view because it did not settle anything. We will have to continue litigation in 3 years time (I expect). It also did not take into account our "responsibilities" towards the supplier of the active in the medium and long term.

You may be approached by GSK with an offer to sell their product. If the offer is of interest to you, before you commit to anything, please can we have a discussion and be involved in the proposed terms. We may have to insist on extra terms (which GSK might not like).'

3.315 An internal GUK document entitled 'Strategic Plan 2002-2005', attached to an email dated 21 June 2002, sent by [GUK's R&D Financial Controller], to [GUK's Managing Director], [the Head of Merck Operation in Australia] and [Head of Merck Operation in Canada], stated that GUK is 'currently benefiting from successfully working with branded manufacturers in a variety

⁵⁰⁰ Email chain between [a Merck employee in Vienna], [GUK's Senior Patents Manager], [Merck's Head of Patents and Raw Material Support Group] [and other Merck employees] dated 17 April 2002 (document 1044). See also email from [Merck's Head of Patents and Raw Material Support Group] to [Sumika employee] dated 26 March 2002 (document 1022).

of ways that are mutually beneficial' and referred to the GUK-GSK Settlement Agreement and the GUK-IVAX Agreement:⁵⁰¹

'Paroxetine is a three year deal and this has been built in for the period. This will generate £9m in annualised sales and £2.8m profit. There will also be £1.6m in NTR and \$12.5m in raw material sales with an attendant cost of \$5.0m over the next three years.'

3.316 In an interview at the OFT on 25 May 2012, [the Chief Executive of Merck Generics Group] explained his recollection of why GUK entered into the GUK-GSK Settlement Agreement and the GUK-IVAX Agreement:⁵⁰²

'Well, at that point we were enjoined so we couldn't get into the market. I was concerned; I think we were all concerned, I was certainly concerned that we might not win the litigation. We had spent a lot of money, a lot of time on trying to get a product to market and it seemed that due to the injunction and the possibility of losing the litigation that we might not get one until very late in the day. So one way to monetise this opportunity was to consider this proposition.'

3.317 In taking the decision to settle, GUK recognised the GUK-GSK Settlement Agreement only stayed the GUK Litigation, rather than reaching a conclusion regarding the infringement claims. In an internal GUK email chain dated 12 April 2002, [Merck's Head of Patents and Raw Material Support Group] wrote:⁵⁰³

'No, we can't launch unless someone else has cleared the undergrowth. The fact that we didn't complete all the litigation or ensured the agreement continued until 10/2006 (when the hemihydrate expires) means we have to go through all of this again in 3 years time.'

⁵⁰¹ Email from [GUK's R&D Financial Controller] to [GUK's Managing Director], [Head of Merck Operation in Canada] and [the Head of Merck Operation in Australia] dated 21 June 2002 (document 1079), and GUK report entitled 'Strategic plan 2002-2005' dated 21 June 2002 (document 1078), page 3.

⁵⁰² [redacted]1 (document 2335), page 35.

⁵⁰³ Email chain between [the Chief Executive of Merck Generics Group], [GUK's Commercial Director] and others dated 12 April 2002 (document 1040). See also email from [Merck's Head of Patents and Raw Material Support Group] to [the Chief Executive of Merck Generics Group] and others dated 5 April 2002 (document 1036) and email chain between [a Merck employee in Vienna], [GUK's Senior Patents Manager], [Merck's Head of Patents and Raw Material Support Group] [and other Merck employees] dated 17 April 2002 (document 1044): 'The settlement was not really satisfactory from the legal point of view because it did not settle anything. We will have to continue litigation in 3 years time (I expect).' See also email from [Merck's Head of Patents and Raw Material Support Group] to [GUK's Commercial Director] and others dated 16 March 2002 (document 1009): 'Even though the action is stayed it has not gone away permanently (in 3 years time it could be back)'.

3.318 Accordingly, GUK subsequently retained an interest in GSK's patent litigation with other generic suppliers.⁵⁰⁴

v) The Alparma-GSK Agreement

a) Alparma's commercial position in relation to paroxetine

3.319 Alparma began preparing to launch generic paroxetine as early as 2000 when it identified an appropriate supplier of paroxetine. As described in paragraph 3.323, according to a witness statement of [Alparma Ltd's Director of Sales and Marketing] in the Alparma Litigation, Alparma intended to launch a paroxetine product as soon as the outcome of the BASF Litigation was known.⁵⁰⁵ As with IVAX and GUK, Alparma focussed on producing an anhydrate version of paroxetine.⁵⁰⁶

3.320 The business case for Alparma's entry into the UK paroxetine market is set out in a witness statement of [Alparma Ltd's Director of Sales and Marketing] in the Alparma Litigation:⁵⁰⁷

'Paroxetine offers a good income stream with a good enough margin to repay all the development costs associated with it as well as being able to support other business initiatives. The impact of obtaining first mover status in the generic field should not be underestimated. Although Generics UK and Ivax are already on the market, everyone is aware that their product is in fact sourced from GSK and is therefore not a true developed generic product. Our proposed product is and that is important to market perception. The market will be aware that there are constraints imposed by GSK on Ivax and Generics UK relating to their supply of paroxetine. Being truly independent will mean that Alparma's product will be viewed to be a true alternative to Seroxat, which will help us not only to enter the market but also to maintain our usual market share. The same rule as to the reluctance of doctors and patients to move brands applies to us. If we are able to establish

⁵⁰⁴ See, for example, email chain between [GUK's Senior Patents Manager], [the Chief Executive of Merck Generics Group], [GUK's Head of Research and Development], [GUK's Managing Director], [GUK's General Manager], [a GUK Sales and Marketing employee] and [Merck's Head of Patents and Raw Material Support Group] dated 12 to 16 July 2002 (document 1083) regarding the BASF litigation.

⁵⁰⁵ Draft witness statement of [Alparma Ltd's Director of Sales and Marketing] in the Alparma Litigation, dated July 2002 ('[redacted]WS1 (draft)') (document 1318), paragraph 7.

⁵⁰⁶ Minutes of meeting between Actavis and the OFT on 25 January 2012 (document 1513), paragraph 6: [Director of IP for Actavis UK Limited] indicated that 'he anticipated Alparma would have gone out to a number of vendors and considered a range of factors (e.g. reputation) before reaching a decision on [the source of the product]'.

⁵⁰⁷ Second witness statement of [Alparma Ltd's Director of Sales and Marketing] in the Alparma Litigation, dated 24 July 2002 ('[redacted]WS2') (document 1325), paragraph 37.

Alpharma's paroxetine as a true alternative before others come on to the market, we will have built up a position that is difficult to assail.'

3.321 In terms of Alpharma's consideration of the impact of generic entry, the evidence indicates that Alpharma expected prices to decline following independent entry by itself, and others, to supply paroxetine in the UK:

- [Alpharma Ltd's Director of Sales and Marketing] confirmed that Alpharma's independent entry would be likely to introduce price competition in the supply of paroxetine in the UK;⁵⁰⁸
- An internal Alpharma document prepared in August 2002⁵⁰⁹ noted that:

'As always the more players the more aggressive and rapid the price decline. If Alpharma launches as GSK's only rival for the next 6-12 months the impact on GSK could be: 20mg - 22% and 30mg -30% loss in volume and 20mg & 30mg circa 20% price erosion.'

- In an internal email dated 2 September 2002,⁵¹⁰ [redacted], Alpharma [Ltd]'s Marketing Manager, set out forecasts of generic price erosion of 45% in the first six months after launch (described as *'cautious'*) followed by price erosion of 70% in the second six months for both paroxetine 20mg and paroxetine 30mg. The email noted that if Alpharma remained the *'only true generic distributor for some time'* [Alpharma Ltd's Marketing Manager] would hope to see less price erosion.

3.322 The next sub-section considers Alpharma's commercial position regarding paroxetine, focussing on the steps that it took in 2001-2002 to launch a generic paroxetine product in the UK. It will set out the facts in relation to the following issues which are relevant to a UK launch of the product:

- Alpharma's UK MA;
- the development of an Alpharma paroxetine product; and
- the patent issues relating to the Alpharma paroxetine product prior to the Alpharma Litigation.

⁵⁰⁸ [redacted]WS2 (document 1325), paragraph 3.

⁵⁰⁹ Spreadsheet entitled 'Current GSK annual sales and market share in paroxetine' dated 1 August 2002 (document 1330).

⁵¹⁰ Email from [Alpharma Ltd's Marketing Manager] to [Alpharma ApS's patent attorney] and [other Alpharma employee] dated 2 September 2002 (document 1338).

Alpharma's UK MA

3.323 Alpharma submitted an application for MAs for both paroxetine 20mg and paroxetine 30mg tablets on 30 May 2001.⁵¹¹ These MAs were granted on 29 April 2002,⁵¹² after the MCA notified this fact to Alpharma on 27 April 2002, as discussed in a witness statement of [Alpharma Ltd's Director of Sales and Marketing] in the Alpharma Litigation.⁵¹³

'Once we had obtained a produce licence from the Medicines Control Agency ("MCA") it was Alpharma's intention to launch a paroxetine product as soon as the BASF decision (which I understand was the decision challenging the main patent covering paroxetine) was known. MCA notification came through on 27 April 2002.'

The development of an Alpharma paroxetine product

3.324 In 2000, Alpharma identified an appropriate supplier of paroxetine: Medis, the distributor for and subsidiary of Delta, which manufactured a paroxetine hydrochloride product using API sourced from BASF.⁵¹⁴ In March 2000, Alpharma entered into a non-exclusive supply agreement with Medis in relation to the Delta-manufactured paroxetine hydrochloride product (the 'Alpharma Product').⁵¹⁵ Alpharma later obtained UK regulatory approval for the licensed-in Alpharma Product.⁵¹⁶

3.325 Alpharma had made substantial commercial preparations for market entry between 2000–2002, including ordering significant quantities of the Alpharma Product to meet customer demand, preparing and agreeing artwork for packaging,⁵¹⁷ establishing expected prices, agreeing prices and volumes with at least two significant customers and providing two wholesalers with the pack

⁵¹¹ MHRA list of product licences containing paroxetine hydrochloride granted between 1999 and 2005 dated 11 June 2012 (document 2590).

⁵¹² MHRA list of product licences containing paroxetine hydrochloride granted between 1999 and 2005 dated 11 June 2012 (document 2590).

⁵¹³ [REDACTED]WS1 (draft) (document 1318), paragraph 7.

⁵¹⁴ See Actavis Response dated 2 August 2013 to the SO ('Actavis SO Written Response') (document 2754), paragraph 2.5.

⁵¹⁵ License & Supply Agreement dated 30 March 2000 between Medis Ltd., its affiliate SEQ Ltd and Alpharma AS (document D 190) This supply agreement was later amended by the General Amendment dated 26 March 2002 between Medis Ltd and Alpharma AS (document D 191). This amendment was later cancelled, by means of the Cancellation Agreement dated 29 October 2002 between Medis ehf. and Alpharma AS (document D 189)

⁵¹⁶ As set out in paragraph 3.323. See also witness statement of [Alpharma ApS's Director of Intellectual Property and Technology Affairs] in the Alpharma Litigation, dated 21 June 2002 ('[REDACTED]WS') (document 1315), paragraph 4.

⁵¹⁷ Document entitled 'New Product Team Report' dated 28 May 2002 (document 1313).

details for the Alparma Product, in order to allow the wholesalers time to adjust their distribution facilities:⁵¹⁸

- On 29 April 2002 [Alparma ApS's Director of Intellectual Property and Technology Affairs], following discussions with [Alparma ApS's Sales and Marketing Director], agreed to Alparma ordering some 360,000 packs of paroxetine 20mg and some 138,000 packs of paroxetine 30mg, at a cost to Alparma of some £3.5 million.⁵¹⁹ [Alparma Ltd's Marketing Manager], in an interview with the OFT has confirmed that expenditure of that magnitude was:⁵²⁰

'a significant amount for Alparma to pay for stock, given that Alparma had total annual revenues of £80 million'.

- According to an internal Alparma email dated 21 May 2002 sent by [Alparma Ltd's Director of Sales and Marketing], Alparma had agreed an initial purchase price of £6.39 with Delta for the 20mg x 30 pack, and was planning to sell paroxetine 20mg x 30 packs for £12.07 to wholesalers, with an expected retail price of £14.20.⁵²¹
- [Alparma Ltd's Director of Sales and Marketing] explained in a draft witness statement in the Alparma Litigation that:⁵²²

'As the major wholesalers, AAH and Unichem require that they are notified some 4-6 weeks before actual launch so they can prepare for the product, we took the decision to give them the relevant notification. For instance, they need to allocate computer codes to assist in pricing and ordering. They also need to know the pack sizes and dimensions as they have an automated picking line for packing. We normally notify

⁵¹⁸ Email chain between [Moss Pharmacy employees], [Alparma's National Account Manager], [Alparma Ltd's Director of Sales and Marketing], [Alparma's Distribution Manager] and [Alparma Ltd's Marketing Manager] dated 21 May 2002, (document 1312).

⁵¹⁹ Email from [Alparma ApS's Director of Intellectual Property and Technology Affairs] to [Alparma Ltd's Marketing Manager] and others dated 29 April 2002 (document 1309). See also email chain between [Alparma Ltd's Marketing Manager], [Alparma Ltd's Director of Sales and Marketing] and others dated 25 April 2002 (document 1308).

⁵²⁰ Witness statement of [Alparma Ltd's Marketing Manager], dated 28 September 2012 ('[redacted]WS') (document 1587), paragraph 3.9.

⁵²¹ Email from [Alparma Ltd's Director of Sales and Marketing] to [Alparma's National Account Manager] and [Alparma Ltd's Marketing Manager] dated 21 May 2002, (document 1312). This price is also confirmed in [redacted]WS2 (document 1325), paragraph 22.

⁵²² See [redacted]WS1 (draft) (document 1318), paragraph 7.

*them by way of an Application for Product Listing, which we know as a Proforma. A Proforma was submitted to AAH on 1 May 2002.*⁵²³

- Furthermore, according to [GSK's Finance Director A's] witness statement in the Alpharma Litigation, Alpharma had made an offer to AAH Pharmaceuticals to supply them with generic paroxetine commencing on 1 June 2002:⁵²⁴

'On Wednesday 22 May 2002, I received two telephone calls; one from [Commercial Director] of Ivax and one from [GUK's General Manager]. [GUK's General Manager] and [IVAX's Commercial Director] each told me that he had been contacted by a representative of AAH. AAH plc is one of the UK's largest wholesalers of pharmaceutical products and is the wholly owned subsidiary of GeHe AG, the second largest such wholesaler in Germany.

That representative had, I was told by both [GUK's General Manager] and [IVAX's Commercial Director], asked for a quotation for the supply of generic paroxetine to compare with a quotation given to AAH by the Defendant [Alpharma] for supply from 01 June 2002 onwards. After the matter had been investigated as far as possible internally at GSK, [GSK's external lawyers] were instructed to send a warning letter to Alpharma, which was sent on 27 May 2002.'

- The warning letter which GSK's lawyers sent to Alpharma on 27 May 2002 noted that GSK expected Alpharma to launch on 1 June 2002:

'Our clients understand that, with effect from 01 June 2002, you plan to launch for sale generic paroxetine tablets in this country. Further, our clients understand that the tablets in question will be manufactured by Delta of Iceland.

*Our clients' concern is that previous tests they have carried out on material produced in Iceland indicated that the material infringed both of the patents referred to above.*⁵²⁵

⁵²³ Witness evidence from [GSK's Finance Director A] in the Alpharma Litigation indicates that GSK was aware that Alpharma had provided AAH Pharmaceuticals with this quotation in May 2002 ([§]WS1 (Alpharma) (document 0241), paragraphs 7.1–7.2).

⁵²⁴ [§]WS1 (Alpharma) (document 0241), paragraphs 7.1–7.2.

⁵²⁵ Letter from [GSK's external lawyers] to the Directors of Alpharma Limited dated 27 May 2002 (documents D185, D186 and D187). The patents referred to in this document are the Hemihydrate Patent and the Anhydrate Patent.

b) The Alparma Litigation

3.326 Alparma considered it likely that GSK would challenge its launch of generic paroxetine by claiming that the Alparma Product infringed relevant claims in GSK's patents. An internal email from [Alparma ApS's Director of Intellectual Property and Technology Affairs] to [Alparma Ltd's Marketing Manager] in April 2002 stated that:⁵²⁶

'I guess there is little doubt, that GSK will try to nail us. They have many patents and patent applications, of which many are quite strong.

Their strongest weapon will be their Hemihydrate patent. The API in our product is the Anhydrate, and there will initially not be any (significant) Hemihydrate in the product. GSK should therefore not be able to stop us, at launch. The risk comes later, if the moisture content increases. I dont [sic] know which levels of Hemihydrate content a British court [sic] would consider infringing, but I will check it.'

3.327 [Alparma ApS's Director of Intellectual Property and Technology Affairs] anticipation of action from GSK proved to be correct. On 27 May 2002, GSK requested an undertaking from Alparma that it would not market the Alparma Product, and on 30 May 2002 GSK threatened that if Alparma did not provide such an undertaking GSK would ask a High Court judge on 31 May 2002 to order Alparma to refrain from dealing in paroxetine hydrochloride in the UK pending a hearing with both Parties.⁵²⁷ Alparma's solicitors subsequently undertook, on several occasions, that Alparma would not market the Alparma Product before a given date – namely 17 June 2002, 2 July 2002 (or, if earlier, the revocation of the Anhydrate Patent) and 9 July 2002.⁵²⁸

3.328 Notwithstanding that it had given a time-limited interim undertaking, Alparma was '*confident*' about its patent position in June 2002. In an email to various

⁵²⁶ Email chain between [Alparma ApS's Director of Intellectual Property and Technology Affairs], [Alparma Ltd's Marketing Manager], [Alparma's Product Sourcing Manager], [Alparma Ltd's Director of Sales and Marketing], [a Third Party Planner of Alparma], [an Assistant Product Manager of Alparma], [VP New Products – FP at Alparma ApS], [other Alparma employee], [a Demand Planner for Alparma] and [Alparma ApS's Sales and Marketing Director] dated 29 April 2002 (document 1309).

⁵²⁷ Letters from [GSK's external lawyers] to the Directors of Alparma Limited dated 27 May 2002 (documents D185, D186 and D187) and dated 30 May 2002 (document D188).

⁵²⁸ See letter from [Alparma's external lawyers] to [GSK's external lawyers] dated 31 May 2002 (document A0007), letter from [Alparma's external lawyers] to [GSK's external lawyers] dated 11 June 2002 (document A0010) and letter from [Alparma's external lawyers] to [GSK's external lawyers] dated 12 June 2002 (document A0011). In addition, according to a [Alparma's external law firm's] fee note dated 26 June 2002, [Alparma's external lawyer] drafted a letter containing an undertaking not to launch prior to '17 June' and faxed [Alparma Ltd's Director of Sales and Marketing] 're restraining sales team' on 31 May 2002 ([Alparma's external law firm's] fee note dated 26 June 2002 (document 1317)). See also [X]WS, Exhibit [X]2 (document 0276).

Alpharma colleagues, [Alpharma ApS's Director of Intellectual Property and Technology Affairs] reported that:⁵²⁹

'Everybody is still confident that the GSK patent on paroxetine anhydrate will become invalidated, even though GSK is intensifying their daily harassment.

The patent attorney from BASF, [X], has also contributed with some good arguments, as to the content of the other patent in question, the hemihydrate patent.

I still think we are in a good position, but it is no "walk over". GSK is a significant opponent, and we will spend a considerable amount of money on this endeavour.'

3.329 GSK commenced its infringement action against Alpharma on 11 June 2002, before the judgment had been handed down in the BASF Litigation. GSK alleged that Alpharma infringed 'at least' claims 1 and 3 of the Anhydrate Patent (both product claims), and claim 1 of the Hemihydrate Patent (also a product claim), and sought 'an injunction to restrain future infringement'.⁵³⁰

3.330 Alpharma considered that it would be able to enter the UK paroxetine market with a non-infringing product. [Alpharma ApS's Director of Intellectual Property and Technology Affairs] gave the following evidence regarding the Anhydrate Patent position in his witness statement of 21 June 2002 in that litigation:⁵³¹

'BASF have also brought an action in the UK for revocation of GB 297 550 [the Anhydrate Patent] and I understand that judgement in that case is expected very soon ("the BASF action"). Alpharma does not seek disputes with the owners of valid intellectual property rights, but it is my belief that this patent is not valid. On the assumption that validity would have been determined by now, Alpharma made preparations to market its version of the drug.'

⁵²⁹ Email chain between [Alpharma ApS's Director of Intellectual Property and Technology Affairs], [Alpharma Inc's President (Human Generics)], [VP New Products – FP at Alpharma ApS], [Alpharma Ltd's Director of Sales and Marketing], [Alpharma ApS's Sales and Marketing Director], [Alpharma Inc's Vice President of Intellectual Property] and [Alpharma Ltd's Marketing Manager] dated 7 June 2002 (document 1314).

⁵³⁰ Alpharma's Skeleton Argument in the Alpharma Litigation dated 31 July 2002 (document 1328), paragraph 9. See also GSK's Claim Form in the Alpharma Litigation dated 11 June 2002 (document A 0008) and GSK's Particulars of Claim in the Alpharma Litigation dated 11 June 2002 (document A 0009) and GSK's Application Notice and dated 11 June 2002 (document D192) and GSK's Particulars of Infringement dated 11 June 2002 (document D193).

⁵³¹ [X]WS (document 1315), paragraph 8.

3.331 [Alpharma ApS's Director of Intellectual Property and Technology Affairs] witness statement goes on to say in relation to the Hemihydrate Patent (EP 2 233 304) that:⁵³²

'I have not been able to investigate the possible invalidity of this patent in the time available before the hearing of the Claimants' application. I had not investigated the position earlier because I [sic] not believe that the Alpharma product would infringe this patent.'

3.332 On 12 July 2002, Mr Justice Pumfrey in the BASF Litigation found the product claims in the Anhydrate Patent (including claims 1 and 3, the two claims that were the subject of GSK's original infringement claim) to be invalid.⁵³³

3.333 On 15 July 2002, Alpharma observed the positive implication of BASF's partial success in relation to its own position. In an internal email from [Alpharma Ltd's Marketing Manager] to [Alpharma Ltd's Director of Sales and Marketing], she stated that:⁵³⁴

'In light of last weeks [sic] high court ruling in favour of BASF and against GSK covering parts of GSKs patent covering paroxetine hydrochloride it looks as if a big step has been made in the right direction as far as we are concerned regarding any future launch of this product.'

3.334 On 16 July 2002, in an update on the proposed claims for the revised Anhydrate Patent, [Alpharma ApS's patent attorney], continued to consider that all aspects of the Anhydrate Patent were invalid, including claims 10a and 11 (which were process claims), which remained in place after the BASF Litigation.⁵³⁵

3.335 A status summary by [Alpharma ApS's patent attorney] on 17 July 2002 also confirmed that BASF, the supplier of the API based on which the Alpharma Product was manufactured, had told Alpharma that the API did not infringe the remaining claims in the patent, albeit that BASF had not yet produced evidence to that effect.⁵³⁶ [Alpharma ApS's patent attorney] also described as a 'worst case scenario' the possibility that '*the injunction is lifted, we launch*

⁵³² [X]WS (document 1315), paragraph 9.

⁵³³ See *BASF AG v SmithKline Beecham Plc* [2002] EWHC 1373 (Pat), paragraph 88.

⁵³⁴ Email from [Alpharma Ltd's Marketing Manager] to [Alpharma Ltd's Director of Sales and Marketing] and others dated 15 July 2002 (document 1321).

⁵³⁵ Alpharma internal report by [Alpharma ApS's patent attorney] entitled 'Comments for proposed claims on the anhydrate patent (GB 2 297 550)' dated 16 July 2002 (document 1322).

⁵³⁶ Alpharma internal report by [Alpharma ApS's patent attorney] entitled 'Status summary Paroxetine' dated 17 July 2002 (document 1323)

now, but after lapse of some years GSK win an appeal. In this case we might face exceedingly high damages'.

- 3.336 Alparma was therefore aware of the potential for significant damages in the 'worst case scenario', but it continued with the litigation.⁵³⁷ In [Alparma Ltd's Director of Sales and Marketing's] draft witness statement in the Alparma Litigation he relied upon Alparma's turnover, retained profits, and fixed and current assets and shareholder funds to argue that '*Alparma is therefore in a position to meet any claim for monetary damages and costs that may be awarded against it in this action.*'⁵³⁸
- 3.337 Subsequent to the BASF Litigation, GSK amended its infringement claim against Alparma to include claim 11 which relates to displacement. GSK reserved its claim before an interim injunction hearing on 1 August 2002, dropping a separate claim for infringement of the Hemihydrate Patent and significantly changing the nature of its claim against Alparma with respect to the Anhydrate Patent.⁵³⁹ This followed GSK's testing of the Alparma Product which, according to GSK, revealed that the Alparma Product '*contained anhydrate, rather than hemihydrate*'.⁵⁴⁰ The significance of this amendment to GSK's claim is particularly relevant in light of Alparma's view that the Hemihydrate Patent was GSK's '*strongest weapon*', as described at paragraph 3.326.
- 3.338 As mentioned at paragraphs 3.334 to 3.335, Alparma considered that the remaining process claims were not infringed. This is reflected in Alparma's skeleton argument, dated 31 July 2002, for the interim injunction hearing in which Alparma's Counsel stated:⁵⁴¹

'It is submitted that there is no case of infringement [of claim 11] on the evidence as a whole.'

- 3.339 At the hearing of GSK's application for an interim injunction before Mr Justice Jacob on 1 August 2002, Alparma anticipating that GSK's application for an injunction would be granted, gave an undertaking not to launch its product

⁵³⁷ Alparma internal report by [Alparma ApS's patent attorney] entitled 'The cost of infringement', Copenhagen 27 August 2002 (document 1345) set out a brief summary of the relief available for patent infringement in EU countries: '*While damages as well as compensation may be claimed in all these countries for patent infringement, some countries have historically awarded very high damages; the most expensive market being UK [...]*'.

⁵³⁸ [REDACTED]WS1 (draft) (document 1318) paragraph 6.

⁵³⁹ See GSK's Amended Claim Form in the Alparma Litigation dated 1 August 2002 (document 0298) and GSK's Amended Particulars of Claim in the Alparma Litigation dated 1 August 2002 (document 0299). See also Alparma's Skeleton Argument in the Alparma Litigation dated 31 July 2002 (document 1328).

⁵⁴⁰ GSK Second Response, Part Two (document 0734), paragraph 7.3.

⁵⁴¹ See Alparma's Skeleton Argument in the Alparma Litigation dated 31 July 2002 (document 1328), paragraph 19.

(the Alparma Undertaking). At that hearing, Alparma's Counsel Mr D Alexander said:⁵⁴²

'[I]f we can have this matter resolved in October [2002], my clients are prepared to undertake not to put this product on the market in the UK until that early trial date effectively.'

3.340 The Alparma Undertaking was reported by [Alparma Inc's Vice President of Intellectual Property], who sent an email to [Alparma ApS's Sales and Marketing Director], [Alparma Ltd's Director of Sales and Marketing], [Alparma Inc's Chief Legal Officer] and others that said:⁵⁴³

'Unfortunately, I have disappointing news to report on paroxetine. The judge essentially granted the injunction. The good news is that he ordered a prompt full trial on October 23.'

The judge was of the opinion that he did not [have] to reach [a decision on] the evidence presented [to] him on this case because a simple plant inspection would end the matter on whether there was a displacement step in the process. Because he was inclined to grant the injunction, we simply represented that we would not market until the trial. We really had no choice, since he would have granted the injunction. He also suggested that an independent expert simply inspect the plant to see the process and that this would resolve the matter.

[✂ - Recounts Alparma's external patent lawyer's preliminary view on the prospects of success in patent litigation, provides instructions regarding the possible instruction of experts and requests an estimate of legal costs.]

⁵⁴² *Beecham Group Plc, SmithKline Beecham Plc & GlaxoSmithKline UK Ltd v Alparma Ltd*, transcript of hearing before Jacob J, dated 1 August 2002 (document A 0047), page 12, lines 14–17. According to the Draft Order attached to the Alparma-GSK Settlement Agreement, the undertaking set out in the Order of Mr Justice Jacob dated 1 August 2002 given by Alparma was 'not to sell or supply any crystalline paroxetine hydrochloride pharmaceutical preparation in the United Kingdom'. See Alparma-GSK Settlement Agreement (document 1397).

⁵⁴³ Email chain between [Alparma ApS's Sales and Marketing Director], [Patent Specialist and Patent Manager at Alparma ApS], [Alparma ApS's patent attorney], [Alparma Inc's Vice President of Intellectual Property], [Alparma's Head of Purchasing], [Alparma Ltd's Director of Sales and Marketing], [Alparma Inc's President (Human Generics)], [VP New Products – FP at Alparma ApS], [Alparma Inc's Chief Legal Officer], [Alparma's external lawyer] of [external law firm] dated 1 August 2002 (document 1331), entitled 'Disappointing Paroxetine hearing'.

3.341 As a result of providing the Alparma Undertaking, Alparma suspended its customer-facing activities in preparation for launching the Alparma Product, while it continued with the litigation.

3.342 On 19 August 2002, [Alparma ApS's patent attorney] produced an internal report regarding the paroxetine hydrochloride situation around Europe, which included the following extract in relation to the UK, which stated that:⁵⁴⁴

'Alparma was originally accused by SKB of infringing GB 2 297 550 (the "anhydrate patent") and EP 0 223 403 (the "hemihydrate patent").

For EP B 0 223 403 experiments conducted in connection with the present trial showed that no hemihydrate was found in the tablets. Stability studies conducted by Delta indicate the tablets are stable over time, but this may become an issue again. Presently, Alparma is not accused of infringing the hemihydrate patent.

A large part of the anhydrate claims have been declared invalid. The only unamended claim of GB 2 297 550 is (old) claim 11, which claims the use of a displacement agent in order to displace solvated solvent. BASF claims not to use this step, and are willing to allow an inspection, given the right confidentiality assurance. Alparma has given an undertaking not to launch before the present trial in the UK is settled. An inspection is likely to resolve the matter in the beginning of September 2002.

The patent EP B 0 734 260 is currently under opposition in the EPO. The claims on file indicate the anhydrate form will not be covered.'
(emphasis in original)

3.343 In late August 2002, Alparma was still considering that it may be possible to launch in September 2002. Alparma's 'New Product Team Report' dated 30 August 2002, shows that all steps had been completed for the Alparma Product launch (for example, artwork proofs returned, PIP code obtained). This report, dated 30 August 2002, stated that for paroxetine:⁵⁴⁵

[Alparma ApS's Sales and Marketing Director] confirmed we may still launch Sept if the judge removes the injunction. Await further info.

⁵⁴⁴ Alparma internal report by [Alparma ApS's patent attorney] entitled 'Paroxetine hydrochloride anhydride patent situation in Germany, Copenhagen' dated 19 August 2002 (document 1335).

⁵⁴⁵ Document entitled 'New Product Team Report' dated 30 August 2002 (document 1337).

Product packed at Delta ready for release. 20mg – 44.5K packs, 30mg – 10.5K packs.'

- 3.344 The uncertainty regarding the patent had some impact on commercial planning. An email from [Alpharma Ltd's Marketing Manager] to [Alpharma ApS's patent attorney] and others dated 2 September 2002 stated that:⁵⁴⁶

'It is unclear how far SKB will go to defend its market share in terms of pricing. We have been cautious and started with a 45% price erosion growing to 70% over time. If we remain the only true generic distributor for some time I would hope that we would see less erosion than this. Please bear in mind that there needs to be a reasonable price difference between the brand and the generic to encourage large numbers of pharmacists to "double stock" ie keep stock of brand to fill any brand prescriptions and keep stock of the generic for the generic prescriptions [...]

Achieving 22% & 30% market share requires us to get listings with Moss & Lloyds shortly after launch. We are not in a position to negotiate with either of these companies to get listings at launch due to the current uncertainty regarding if and when we will launch.'

- 3.345 [Alpharma Ltd's Marketing Manager] has provided further comments in relation to this email in her witness statement, where she stated as follows:⁵⁴⁷

'As can be seen in the email and in the content of the price erosion estimates I presented, I stated that "if we remain the only true generic distributor for some time", I would hope to see less erosion than this. By the phrase "true generic distributor", I was referring to the situation if Alpharma were the only party distributing paroxetine in the UK that was sourced from someone other than GSK. If other "true" generics entered the market, I expected this to have an impact on price erosion. This is because I would have expected that taking supply from a non-GSK source would enable a generic supplier more flexibility 1) in terms of volume (i.e. the generic would have greater control over volumes it could order) and also in terms of 2) price/cost of goods depending on what we could negotiate with our supplier.'

⁵⁴⁶ Email from [Alpharma Ltd's Marketing Manager] to [Alpharma ApS's patent attorney] and [other Alpharma employee] dated 2 September 2002 (document 1338).

⁵⁴⁷ See [redacted]WS (document 1587), paragraph 3.19.

- 3.346 On 3 September 2002, Alparma prepared internal estimates of Alparma's potential profits, damages, and the effect of a 5% licence fee.⁵⁴⁸ These estimates show that Alparma expected to make a profit of US\$7 million in the UK after launch, but that there was a risk of losing US\$18 million if it had to pay damages to GSK. Alparma stood to make US\$6.4 million if it paid a 5% licence fee to GSK.
- 3.347 As at 4 September 2002, Alparma was still progressing the litigation and preparing to launch, whilst still factoring in the economic and strategic risk associated with the Dry Tableting Patent. An internal Alparma report prepared by [Alparma ApS's patent attorney] on the patent situation dated 4 September 2002 repeated the report for the Hemihydrate Patent and the Anhydrate Patent set out at paragraph 3.342.⁵⁴⁹ This report considered that it was prudent to estimate the economic risk associated with launching in the light of the Dry Tableting Patent:⁵⁵⁰

*'The patent **EP B 0 734 260** (the "dry tablet process patent") has claims directed to a process for formulating tablets containing Paroxetine in the absence of water. Delta has confirmed their process falls within the terms of the issued claims. Therefore, if the patent is upheld in its present form, it may impede the activities of Alparma for the designated states DE, DK, GB, NL, PT, and SE. The patent is currently under opposition in the EPO. [Alparma's external patent attorneys], has prepared advice re infringement and validity of this patent for Alparma. [✂ - Recounts summary of legal advice regarding the claims covering the anhydrate patent and the prospects of success in litigation, including cost estimates and anticipated timing for a decision.]*

[...]

Summary and conclusions

The present summary indicates we may launch by now, as the granted patents and pending applications should not be valid to the extend [sic] they cover Paroxetine hydrochloride anhydrate in Form A and the tablets comprising this API.

⁵⁴⁸ Alparma internal report by [Alparma ApS's patent attorney] and [Alparma employee] entitled 'Cost benefit estimates of damages and license fees' dated 3 September 2002 (document 1343).

⁵⁴⁹ Alparma internal report by [Alparma ApS's patent attorney] entitled 'Paroxetine hydrochloride anhydride patent situation in the European Alparma markets, Copenhagen' dated 4 September 2002 (document 1344). See also Alparma internal document entitled 'Alparma/SKB Tableting Patent' (document 1287) and Alparma internal document entitled 'Alparma Possible action on the SKB tableting patent' (document 1288).

⁵⁵⁰ Alparma internal report by [Alparma ApS's patent attorney] entitled 'Paroxetine hydrochloride anhydride patent situation in the European Alparma markets, Copenhagen' dated 4 September 2002 (document 1344).

While it is unlikely the dry tablet process patent is going to survive the opposition, at least to the extent [sic] it covers the anhydrate form of Paroxetine, it is prudent to estimate any economical risk associated with launch in the face of the presently valid patent.

The annexed estimates, comprising the cost benefit analysis for Alparma of launching and possible [sic] being sentenced to provide relief for patent infringement, indicates our European markets fall into three categories: UK, NL and the rest.

UK is special because in a worst case scenario damages may be exceedingly high.' (emphasis in original)

3.348 In an internal update regarding the BASF case dated 12 September 2002, [Alparma ApS's patent attorney] reported on the Anhydrate Patent proceedings, highlighting some beneficial developments from Alparma's perspective and some negatives:⁵⁵¹

'BASF and Delta has [sic] agreed to give disclosure of their processes, which should work to our benefit [in the anhydrate litigation].

[...]

Lately, the judge seems not to be sympathetic to our [anhydrate] cause; maybe he compares our business to counterfeiting.

[...]

[T]he most recent analysis (IR) shows acetone is present at least immediately before tableting. We will receive updates on the experimental results when they are available.⁵⁵²

[...]

At present our solicitors are struggling to keep our trial date of 22 October 2002. The trial should take 3 to 4 days, and we may expect a

⁵⁵¹ Alparma internal report by [Alparma ApS's patent attorney] entitled 'Paroxetine update' dated 12 September 2002 (document 1346).

⁵⁵² This point is relevant given that a remaining Anhydrate Patent claim related to a process (known as a displacement step), wherein a displacement agent is used to remove acetone (a solvent) from a paroxetine product. Alparma's apparent concern at this point was that prior to tableting, acetone was present in the product, whereas it was negligible following manufacture. It considered that it needed to explain how this occurred to strengthen its position in the Alparma Litigation. Alparma internal report by [Alparma ApS's patent attorney] entitled 'Paroxetine update' dated 12 September 2002 (document 1346) notes that experiments were still being conducted on this issue at this point.

verdict in a few days, extending to possibly as long as a month. This will bring us to November or early December 2002.'

3.349 Various Alparma internal documents produced in September 2002 and October 2002 indicated that Alparma was still considering the possibility of launching paroxetine in the UK in the coming months.

- An internal Alparma presentation entitled 'UK Budget 2003', dated 13 September 2002, shows that Alparma was still considering the possibility of launching paroxetine in October 2002, and was projecting likely forecast sales in the first two quarters of 2003, although in the page of the budget entitled 'Summary of New Product Launches 2002-2007', the page showing that paroxetine will be launched in October 2002 has a question mark against this date for the Alparma Product launch.⁵⁵³
- An internal Alparma email chain dated 12 September 2002 suggests that Alparma was projecting sales for the Alparma Product from November 2002 onwards, but was still considering the possibility that the launch may take place in 2003.⁵⁵⁴
- An internal Alparma email chain dated 4 October 2002 suggests that Alparma was projecting sales for the Alparma Product from 1 April 2003⁵⁵⁵ onwards, albeit in the light of the volumes already ordered from Delta Alparma was proposing to '*cancel all orders we can cancel as of now*'.⁵⁵⁶

3.350 On 15 October 2002 [Alparma ApS's patent attorney] sent an email to [Alparma ApS's Sales and Marketing Director], copied to [Alparma Ltd's Director of Sales and Marketing] and others, regarding the advice he had received about Alparma's ability to bring an invalidation claim regarding the Dry Tableting Patent, and to otherwise argue that the Alparma Product was non-infringing. In this email he stated that:⁵⁵⁷

⁵⁵³ Alparma presentation entitled 'UK Budget 2003' dated 13 September 2002 (document 1349), slide 64.

⁵⁵⁴ See email from [Alparma Ltd's Director of Sales and Marketing] to [Alparma Ltd's Marketing Manager], [Alparma's Distribution Manager] and [Alparma's Quality Operations Manager] dated 12 September 2002 (document A 0049)

⁵⁵⁵ See email from [Alparma Ltd's Director of Sales and Marketing] to [Alparma ApS's Sales and Marketing Director], [Alparma's Quality Operations Manager], [other Alparma employee] and [Alparma Ltd's Marketing Manager] dated 4 October 2002 (document A 0053).

⁵⁵⁶ See email from [Alparma ApS's Sales and Marketing Director] to [Alparma's Quality Operations Manager], [Alparma Ltd's Director of Sales and Marketing], [Alparma's Head of Purchasing] and [other Alparma employee] dated 3 October 2002 (document A 0057).

⁵⁵⁷ Email from [Alparma ApS's patent attorney] to [Alparma ApS's Sales and Marketing Director] and others dated 15 October 2002 (document 1363).

[✂ - Recounts conversation with Alparma's external patent lawyer as to their views on the prospects of success and the anticipated timing for a judgment regarding the Dry Tableting Patent.]

- 3.351 By mid-October, Alparma remained unclear about GSK's case in relation to the Anhydrate Patent. On 16 October 2002, Alparma's solicitors sent a letter to GSK's solicitors, noting that in relation to any infringement of claim 11 of the Anhydrate Patent GSK's case against Alparma was unclear, and requesting from GSK a statement of case.⁵⁵⁸ On 17 October 2002, GSK's solicitors replied that they could not know GSK's case until all relevant experiments had been completed.⁵⁵⁹
- 3.352 As at 22 October 2002, a trial in the Alparma Litigation was due to take place on 9 December 2002.⁵⁶⁰
- 3.353 On the 6 November 2002, shortly before entering into the Alparma-GSK Agreement, [Alparma ApS's patent attorney] reported, in an internal email, that:⁵⁶¹

'While GSK was expected to make a statement of case last monday [sic], 4 November 2002, this statement was very limited. Either [GSK] do not have a very strong case, or they are going to surprise us all just before the trial.

GSK is still claiming infringement of the claim (11) directed to the use of a displacing agent. They have now measured a water content in the formulation after tableting of 2.9% w/w, corresponding to 8 molecules of water for each molecule of paroxetine. They therefore claim the water is a displacement agent, leading to low acetone content in the tablets.

In short, there are [sic] no terribly disturbing news from the trial.'

⁵⁵⁸ Letter from [Alparma's external lawyers] to [GSK's external lawyers] dated 16 October 2002, (document A 0058, page 4), attached to email from [Alparma's external lawyers] to [Alparma Inc's Vice President of Intellectual Property], [Alparma Ltd's Director of Sales and Marketing], [Alparma ApS's patent attorney] and [VP New Products – FP at Alparma ApS] dated 17 October 2002 (document A 0058).

⁵⁵⁹ Letter from [Alparma's external lawyers] to [GSK's external lawyers] dated 17 October 2002 (document A 0058, page 7) attached to email from [Alparma's external lawyers] to [Alparma Inc's Vice President of Intellectual Property], [Alparma Ltd's Director of Sales and Marketing], [Alparma ApS's patent attorney] and [VP New Products – FP at Alparma ApS] dated 17 October 2002 (document A 0058).

⁵⁶⁰ [✂]WS1 (Apotex) (document 0333), paragraph 8.3.

⁵⁶¹ Email from [Alparma ApS's patent attorney] to [Alparma Inc's President (Human Generics)], [Alparma ApS's Sales and Marketing Director], [VP New Products – FP at Alparma ApS], [Alparma Ltd's Director of Sales and Marketing], [Alparma Inc's Vice President of Intellectual Property] dated 6 November 2002 (document 1388).

3.354 That consideration is consistent with later Alparma evidence following the Alparma-GSK Agreement dated 12 November 2002, which demonstrates that Alparma continued to consider that the patent position was such that it could have entered the UK paroxetine market with a non-infringing paroxetine product, including at points when it was considering whether or not to renew that Agreement:

- In an email between [Alparma Inc's Vice President of Intellectual Property] and others on 4 September 2003 considering whether to renew the Alparma-GSK Agreement, [Alparma Inc's Vice President of Intellectual Property] stated that Alparma was '*comfortable*' it would win any patent challenge from GSK if it decided to launch the Alparma Product independently of GSK.⁵⁶²
- In a further document considering the termination or renewal of the Alparma-IVAX Agreement, it is stated that it would be '*tough*' for GSK to prevail in a challenge relating to the Anhydrate Patent:⁵⁶³

'- API supplier does not use this step [a displacement step which could infringe the Anhydrate Patent]

- [...] GSK may argue that displacement step occurs during tablet process at Delta

- Tough argument for GSK to win, likely no infringement.' (emphasis in original)

c) *The negotiation of the Alparma-GSK Agreement*

3.355 On 24 September 2002, an internal Alparma email sent from [Alparma Inc's Chief Legal Officer] to [Alparma ApS's Sales and Marketing Director] and [Alparma Inc's President (Human Generics)], discussed a prospective settlement of the Alparma Litigation:⁵⁶⁴

[✂ - Internal counsel's suggested view as to Alparma's approach to settlement with GSK including proposed terms for settlement.]

⁵⁶² Email from [Alparma Inc's Vice President of Intellectual Property] to [Alparma Inc's CEO] and [Alparma Inc's Chief Financial Officer] dated 4 September 2003 (document 1434).

⁵⁶³ Alparma internal presentation entitled 'Paroxetine UK Patent Situation' (document 1295), slide 1. This document was submitted by Actavis and was described as having been prepared in connection with the decision whether to terminate or extend the supply arrangements with GSK or to launch Alparma's own product.

⁵⁶⁴ Email chain between [Alparma Inc's Chief Legal Officer], [Alparma Inc's President (Human Generics)], [Alparma ApS's Sales and Marketing Director], [Alparma Inc's Vice President of Intellectual Property], [VP New Products – FP at Alparma ApS], [Alparma ApS's patent attorney], [Alparma Ltd's Director of Sales and Marketing] dated 24 September 2002 (document 1350).

- 3.356 As can be seen from this email, Alparma envisaged that a settlement agreement with GSK could include an agreed 'early entry' date of April 2003. Alparma was also aware that GSK would be earning higher profits if generic entry continued to be delayed and considered that any payments received should be based on a share of GSK's profits rather than Alparma's forecast profits.
- 3.357 On 1 October 2002, [Alparma ApS's Sales and Marketing Director] met with [GSK's Finance Director A]. [Alparma ApS's Sales and Marketing Director] reported on this meeting in an internal email to [Alparma Inc's Vice President of Intellectual Property], [Alparma Ltd's Director of Sales and Marketing], [Alparma Inc's Chief Legal Officer] and others on 1 October 2002. The email summarises the key points from that meeting, particularly the benefits which both Parties foresaw in reaching a settlement agreement and their position on the contents of such an agreement:⁵⁶⁵

'I just finished my talks with [GSK's Finance Director A] who is VP Finance for GSK's UK operations and in charge of concluding deals for their tail-end products on a European level. This includes deals for products coming close to patent/exclusivity period expiry.

We started out agreeing that both parties potentially can benefit from an out-of-court settlement of the dispute, and it will be beneficial to conclude talks within the next app. 3 weeks. [GSK's Finance Director A] stated that GSK was very convinced that their intellectual property rights can keep generics out of the UK for the next 12-18 months. I challenged this long period and we agreed that obviously this was uncertain and we also agreed that Alparma was ahead compared to the competitors.

The highlights of the talks are:

GSK prefer a settlement for 12-18 months consisting of a lumpsum [sic] and certain ongoing (monthly) payments. We would refrain from launching in this period and acknowledge the IP of GSK and all legal activities between the two companies would be stopped. I promised to come back with a calculation of what these figures can be.

He understood the value of an early entry by us compared to any other competitor (except IVAX who are on the market with GSK product).

⁵⁶⁵ Email from [Alparma ApS's Sales and Marketing Director] to [Alparma Inc's Vice President of Intellectual Property] and others dated 1 October 2002 (document 1356) entitled 'Today's meeting with [REDACTED], GSK, re settlement possibilities for Paroxetine'.

Consequently this must be factored into a contract. GSK wants to supply product to us if we enter. They want to attack all non-GSK product entering the market, and he stated that he would struggle to get a contract approved by the legal department in which we can launch a Delta product at a later stage. I asked him to think this over again – an issue for further discussion.'

3.358 On 11 October 2002 [Alpharma ApS's Sales and Marketing Director] sent an internal email to [Alpharma Ltd's Director of Sales and Marketing], [Alpharma ApS's patent attorney], [Alpharma Inc's Chief Legal Officer] and others reporting on a further meeting with [GSK's Finance Director A] and [GSK's Associate General Counsel for Europe]. This email sets out Alpharma's view, at that time, on what any settlement with GSK should cover:⁵⁶⁶

'The loss we have suffered since early July. We said the value was £ 2.5 m a month as our gross margin forgone [sic]. That situation was likely to continue well into January if we win in the December trial date.

Inventory we have in Iceland

Attorney fees

Image loss by not launching and relationship loss with Delta

All in all we said this figure was in the region of £ 20 m.'

3.359 That same email, reports GSK's objective of, amongst other things keeping its patent defence intact, and then details the settlement offered by GSK. As can be seen from this email, the central issue in the negotiations became the amount that GSK would transfer to Alpharma in order to reach an agreement. This amount would be made up of product,⁵⁶⁷ and 'a lump sum and/or monthly payment'. Alpharma would, in turn, agree to stop the litigation, and launch the Delta-manufactured Alpharma Product only once all GSK patents had been breached:

'GSK said that figure was much higher than they anticipated. The key issues for them was [sic]:

⁵⁶⁶ Email chain from [Alpharma Ltd's Director of Sales and Marketing] to [Alpharma ApS's Sales and Marketing Director] and others dated 14 October 2002 (document 1361) entitled 'UK settlement negotiations for Paroxetine – meeting October 11, 2002'.

⁵⁶⁷ The CMA notes that in relation to the sales price, the following statement is also consistent with this: 'The Sales price of £13,7 reflects what the negotiation ended up with – a sales price which GSK and [Alpharma Ltd's Director of Sales and Marketing], I believe, agreed on would be the correct one to be able to sell 500' packs. Email chain between [Alpharma Finance Director], and other [Alpharma employees] dated 1 November 2002 (document 1380).

Stay within the law and not making any settlement than can be counter productive for them in other jurisdictions around the globe

Keep patent defence intact

Maintaining stability and predictability (they are also in the middle of budget 2003)

The settlement they will offer has the following elements:

An MA for the "version 2" of the GSK product (ie. a version without GSK imprints on tablet etc.). GSK will supply bulk for IVAX to pack in Alpharma packs. Launch around December 1st, 2002. They will be ready to offer 500,000 packs of the 20 mg 30 tabs pack at a transfer price of £8.45 per pack. They claim generic selling price is around £13.15. [Alpharma Ltd's Director of Sales and Marketing] we have to look into this Monday morning!

All litigation is stopped

We are free to launch the Delta product when we want. Ie. when our competitors at a much later stage have penetrated all GSK defences, most notably the infamous tableting patent which they eluded [sic] to without being explicit.

GSK will offer a lump sum and/or monthly payment which can be turned into either a cross undertaking as part of the settlement or a promotional fee. We clearly have to negotiate this further, and decide the minimum we can accept.

GSK consider us the only serious threat right now, but will be ready to consider similar deals if others make a similar threat.

Next steps:

[Alpharma Ltd's Director of Sales and Marketing], [Alpharma Ltd's Marketing Manager] and [Alpharma ApS's Sales and Marketing Director] to look into market impact of December launch [...]

Decide minimum "lump sum"

[...]

Key issue to evaluate:

The earliest possible time we can have the tableting patent invalidated. As long as that patent is in place we cannot launch any way. If my understanding is correct it will be impossible to launch before well into 2003 due to that patent.

Renegotiations with Delta is an issue we will have to bring forward.'

3.360 [Alpharma Ltd's Director of Sales and Marketing] sent an email in response to this on 14 October 2002 to [Alpharma ApS's Sales and Marketing Director] and others as follows:⁵⁶⁸

'Initial thoughts regarding this proposal from GSK.

- 1) UK price referred by GSK of £13.15 per pack is an accurate reflection of current retail prices.*
- 2) With UK business now 85% wholesale, then on this basis our expected ASP would be circa £10.50.*
- 3) As %GPM now tighter than available via Delta and no longer separate source of product, we would probably not tender for Boots, Lloyds, Moss business. This would clearly limit our market share capabilities but the risk of reneging on supply and penalty claims would be too great.*
- 4) Annual supply quota of 500000 packs of 20mg equated to approx 15%MS, which when considering point 3, would provide us with sufficient stock.*
- 5) Is there any chance we could pack ourselves instead of being packed by Ivax?*
- 6) Is there sufficient time to allow for December 1st, based on no artwork etc?'*

3.361 At a further meeting on 23 October 2002 with [GSK's Finance Director A], [Alpharma ApS's Sales and Marketing Director] and [Alpharma Inc's Vice President of Intellectual Property] agreed in principle with [GSK's Finance Director A] to a settlement with GSK, as set out in the following email from [Alpharma ApS's Sales and Marketing Director] to [Alpharma Ltd's Director of

⁵⁶⁸ Email chain between [Alpharma Ltd's Director of Sales and Marketing], [Alpharma ApS's Sales and Marketing Director], [Alpharma Inc's Vice President of Intellectual Property], [Alpharma Inc's President (Human Generics)], [Alpharma ApS's patent attorney], [VP New Products – FP at Alpharma ApS], [Alpharma Inc's Chief Financial Officer] and [Alpharma Inc's Chief Legal Officer] dated 11–14 October 2002 (document 1361).

Sales and Marketing], [Alpharma ApS's patent attorney] and others. The settlement included the following elements:⁵⁶⁹

- '1. 12 month deal with option to prolong.
2. An MA for the "2nd image" of the GSK product (ie. a version without GSK imprints on tablet etc.). GSK will supply bulk for IVAX to pack in Alpharma packs. Launch around December 1st, 2002. They will be ready to offer 500,000 packs of the 20 mg 30 tabs pack at a transfer price of £8.45. The value of this offer is app. £2.5 m on a 12 month basis. We will receive profit compensation for any delays after December 1st, as time is short for artwork, packing, logistics etc.
3. £0.1 m promotional allowances per month. ie. £1.2 m on a 12 month basis.
4. £3.5 million "other". For this amount we need input from Finance on ideal timing, so we can try to phrase the contract accordingly.
5. Exclusivity period on offer for a range of GSK products with current sales revenue of £11-12 m. Own manufacturing will be an option if we want to. [Alpharma Ltd's Director of Sales and Marketing] and his team will work on the value proposition for this when we receive the details. Linked to this we will get £0.5 m which [Alpharma Inc's Vice President of Intellectual Property] clever suggest [sic] to name "promotional allowance" in the contract to make it hard money.'

3.362 A draft sub-distribution agreement was then emailed from IVAX to Alpharma on 31 October 2002.⁵⁷⁰ This was circulated internally at Alpharma for assessment, including antitrust assessment.⁵⁷¹

d) The Alpharma-GSK Agreement

3.363 The Alpharma-GSK Settlement Agreement was entered into between SmithKline Beecham Plc, GlaxoSmithKline UK Limited (each part of GSK, as noted at paragraph 1.2) and Alpharma Limited, and recorded in a letter dated

⁵⁶⁹ Email from [Alpharma ApS's Sales and Marketing Director] to [Alpharma Ltd's Director of Sales and Marketing] and others dated 24 October 2002 (document 1364) entitled 'Quick note on UK settlement for Paroxetine – meeting October 23 2002'.

⁵⁷⁰ Email from [IVAX Legal Advisor] to [Alpharma ApS's Sales and Marketing Director] dated 31 October 2002 (document 1378).

⁵⁷¹ See email from [Alpharma ApS's Sales and Marketing Director] to [Alpharma Inc's Vice President of Intellectual Property], [Alpharma Inc's Chief Legal Officer], [Alpharma Ltd's Marketing Manager], [Alpharma Ltd's Director of Sales and Marketing], and [Alpharma ApS's patent attorney] dated 31 October 2002 (document 1378).

12 November 2002.⁵⁷² The relevant obligations set out in this letter are set out below.

3.364 In clause 1 of the Alpharma-GSK Settlement Agreement, GSK and Alpharma agreed to:

'consent to an Order in the form of the draft Minute of Order annexed to this Agreement'.

3.365 The relevant parts of this Order reads as follows:⁵⁷³

'each party shall reserve all rights and causes of action they may have [...]'

and that:

'all further proceedings in this claim be dismissed'.

3.366 GSK and Alpharma agreed that the proceedings between them in relation to the Anhydrate Patent be dismissed, with both Parties discharged from their respective undertakings, which for Alpharma was to refrain from selling paroxetine and for GSK a cross undertaking in damages.⁵⁷⁴

3.367 The remaining provisions of the Alpharma-GSK Settlement Agreement were as follows:

- *'Alpharma shall forthwith and during the currency of the Ivax Supply Agreement discontinue all participation in the oppositions to the amendment of UK Patent GB 2,297,550 [...] and GSK and Alpharma agree to instruct their solicitors to consent to whatever Order is necessary to this effect.'*⁵⁷⁵
- *'Alpharma shall as a condition precedent to this agreement becoming legally binding, enter into a sub-distribution agreement with GSK's exclusive sub-distributor Ivax Pharmaceuticals UK [...] ("the Ivax Supply Agreement") for supply to Alpharma of paroxetine with effect from 1 December 2002. GSK shall ensure that it provides Ivax with 500,000 (five*

⁵⁷²Alpharma-GSK Settlement Agreement (document 0356).

⁵⁷³Alpharma-GSK Settlement Agreement (document 0356), see confidential schedule, clause 5 and draft minute of order.

⁵⁷⁴ Alpharma-GSK Settlement Agreement (document 0356), draft minute of order.

⁵⁷⁵ Alpharma-GSK Settlement Agreement (document 0356), clause 1.

hundred thousand) 30x20mg packs of "Product" [...] to allow Ivax to supply Alpharma under that agreement'.⁵⁷⁶

- *'GSK shall pay to Alpharma the sum of £3,000,000 (three million pounds) in respect of the production and preparation costs for launch in the UK market by Alpharma of paroxetine hydrochloride anhydrate.'⁵⁷⁷*
- *'GSK shall contribute £500,000 (five hundred thousand pounds) towards Alpharma's legal costs incurred in the above litigation.'⁵⁷⁸*
- *'GSK shall pay a marketing allowance to Alpharma of £100,000 per month (for a maximum of 12 months) during the term of the Ivax Supply Agreement. In the event of a breach of the terms of this Agreement or in the event of termination of the Ivax Supply Agreement pursuant to Alpharma's breach or insolvency the payment of the marketing allowance shall cease with immediate effect (provided that any partial month shall be paid in a pro rata amount). However, if Alpharma terminates the Agreement due to Ivax's breach or insolvency, the payments shall continue for a maximum of 12 months from commencement of the Ivax Supply Agreement in such circumstances.'⁵⁷⁹*
- *'GSK shall provide immediate access under signature of a confidentiality agreement to Alpharma of information relating to GSK's products in three therapeutic areas (cardiac; antibiotics and neuro-muscular blockers) being candidates for divestment in the UK by GSK. Alpharma shall have an exclusive period of three months from the date of this Agreement to evaluate such products to indicate its interest and sign a Heads of Agreement for the potential purchase of such product(s). Such potential purchase shall ensure the transfer to Alpharma of value in an amount of at least £500,000 (five hundred thousand pounds) failing which an alternative means to achieve such transfer would be agreed.'⁵⁸⁰*
- *'(i) During the currency of the Ivax Supply Agreement Alpharma shall not make, import, supply or offer to supply paroxetine hydrochloride in the United Kingdom save as purchased from Ivax pursuant to the Ivax Supply Agreement or otherwise manufactured or marketed by GSK (or with GSK's consent) in the EU.*

⁵⁷⁶ Alpharma-GSK Settlement Agreement (document 0356), clause 2.

⁵⁷⁷ Alpharma-GSK Settlement Agreement (document 0356), clause 3.

⁵⁷⁸ Alpharma-GSK Settlement Agreement (document 0356), clause 4.

⁵⁷⁹ Alpharma-GSK Settlement Agreement (document 0356), clause 5.

⁵⁸⁰ Alpharma-GSK Settlement Agreement (document 0356), clause 6.

(ii) *Alpharma is authorised to undertake on behalf of each member of the Alpharma group that no such group member shall make, import, supply or offer to supply paroxetine in the United Kingdom during the currency of the Ivax Supply Agreement save in respect of paroxetine hydrochloride manufactured or marketed by GSK (or with GSK's consent) in the EU.*

(iii) *Alpharma shall not assign or transfer its UK marketing authorisation for paroxetine during the currency of the supply period under the Ivax Supply Agreement.*⁵⁸¹

e) The Alpharma-IVAX Agreement

3.368 Following an approval granted on 18 November 2002 by the Executive and Finance Committee of Alpharma Inc's Board of Directors,⁵⁸² the Alpharma-IVAX Agreement was entered into on 20 November 2002.⁵⁸³ Conclusion of the Alpharma-IVAX Agreement was a condition precedent to the Alpharma-GSK Settlement Agreement becoming legally binding.⁵⁸⁴ GSK and IVAX also entered into the Third Addendum, reflecting the amendments necessary for the Alpharma-IVAX Agreement, on 20 November 2002.⁵⁸⁵ The key obligations and definitions included in the Alpharma-IVAX Agreement are set out below:

- Product: the product was defined as paroxetine hydrochloride 20mg tablets. 'Packs' were defined as 30 x 20mg patient packs, with paroxetine hydrochloride as its active substance.⁵⁸⁶
- IVAX appointed Alpharma as a non-exclusive sub-distributor for paroxetine hydrochloride for Great Britain, Northern Ireland, the Channel Islands and the Isle of Man.⁵⁸⁷

⁵⁸¹ Alpharma-GSK Settlement Agreement (document 0356), clause 7.

⁵⁸² See minutes of meeting with the Executive and Finance Committee of the Board of Directors of Alpharma Inc. on 18 November 2002 (documents D 211 and D 212). See also email from [Alpharma Inc's Vice President of Intellectual Property] to [Alpharma ApS's Sales and Marketing Director], [Alpharma Ltd's Director of Sales and Marketing] and [Secretary of Alpharma] dated 18 November 2002 (document A 0055): '[Alpharma Ltd's Director of Sales and Marketing] and [Alpharma ApS's Sales and Marketing Director]: *Please do not sign the Ivax document until I let you know that we have board approval. This contract is greater than US\$5 million so we need board approval. We have an executive committee meeting this afternoon and [Alpharma Inc's Chief Legal Advisor] will be seeking approval, which we expect to be granted.*' See also witness statement of [Alpharma ApS's Sales and Marketing Director] signed on 21 July 2014 ('[redacted]WS') (document 3172, paragraph 3.6): '[T]he direct involvement for the actual settlement agreement with GSK came from senior management – [Alpharma Inc's President (Human Generics)], [Alpharma Inc's Chief Legal Officer] and [Alpharma Inc's Chief Financial Officer]. This contract had to go to the Board of Alpharma Inc. for approval.' See also Alpharma document entitled 'Contract Policy' dated 6 June 2002 (document A 0026, pages 1–3).

⁵⁸³ Alpharma-IVAX Agreement (document 1806).

⁵⁸⁴ Alpharma-GSK Settlement Agreement (document 0356), clause 2.

⁵⁸⁵ Third Addendum (document 0359).

⁵⁸⁶ Alpharma-IVAX Agreement (document 1806), clauses 1.8-1.9 and First Schedule.

⁵⁸⁷ Alpharma-IVAX Agreement (document 1806), clause 1.11.

- Compensation for initial delay in supply: IVAX agreed to compensate Alparma £200,000 per month for up to three months in the event that there was an initial delay in supply after the effective date of the agreement.⁵⁸⁸
- Volume: IVAX committed supply to Alparma during the term of the agreement with five hundred thousand (500,000) packs pursuant to Alparma purchase orders.⁵⁸⁹
- Price: the price for the product per pack was set at £8.45.⁵⁹⁰
- Duration, termination and loss minimisation: the Alparma-IVAX Agreement was specified as being for a term of one year.⁵⁹¹ However, this was subject to the following:⁵⁹²

'Alparma shall be permitted to terminate this Agreement upon one (1) month's written notice to IVAX upon formation of the Generic Market or upon demise (whether by invalidation, surrender, abandonment or otherwise) of current claim 11 of UK Patent GB 2,297,550 or equivalent claim. In the event that ALPHARMA terminates its supply agreement with IVAX due to the Market Price (as defined below) of a pack of paroxetine 20mg thirty (30) tablets falling below £8.45 per pack, IVAX will reimburse Alparma the difference between the Market Price and £8.45 up to a maximum of two hundred thousand pounds sterling (£200,000) per calendar month for a maximum of two (2) calendar months. For the purposes of this clause 11.3 Market Price shall mean the average selling price for the Product in the Territory as determined by calculating the average price for the month following the notice to terminate served by Alparma upon IVAX calculated for all companies offering such products for sale in the Territory but excluding products sold by SB under the trade mark "SEROXAT".'

3.369 In the context of the termination clause, 'Generic Market' was defined as meaning: *'when a monthly average price for the Product (in thirty (30) tablets) sold by any company in the Territory (not including SB and Alparma) falls below nine pounds and fifty pence (£9.50) per Pack or when a paroxetine 20 mg product is sold other than under SB's marketing authorisation'.*⁵⁹³

⁵⁸⁸ Alparma-IVAX Agreement (document 1806), clause 5.1.

⁵⁸⁹ Alparma-IVAX Agreement (document 1806), clause 5.2.

⁵⁹⁰ Alparma-IVAX Agreement (document 1806), clause 6.1.

⁵⁹¹ Alparma-IVAX Agreement (document 1806), clause 11.1.

⁵⁹² Alparma-IVAX Agreement (document 1806), clause 11.3.

⁵⁹³ Alparma-IVAX Agreement (document 1806), clause 1.5.

Subsequent developments regarding Alparma's paroxetine stock

- 3.370 In advance of the Alparma-GSK Agreement, and after discussions with GSK had commenced, Alparma recognised that it needed to consider the possibility for an alternative use for the paroxetine stock which it had intended to supply to the UK market, particularly whether it could be *'repacked to meet demand in other markets'*.⁵⁹⁴
- 3.371 Following the conclusion of the Alparma-GSK Settlement Agreement and Alparma-IVAX Agreement, in February 2003 Alparma entered into an agreement with Medis regarding orders already made by Alparma, which provided amongst other things that Medis would store for a period of time certain stock already ordered by, and prepared for, Alparma. Medis also agreed to retain all other existing stock of Paroxetine tablets 20mg and 30 mg, which had been produced for Alparma to fill the orders made by Alparma, including those produced for the UK market. Pursuant to the agreement with Medis any orders made by Alparma during 2003 would be filled by this stock and *'delivered free of charge'*.⁵⁹⁵
- 3.372 Notwithstanding this stock reportedly having being *'written off'* in 2002, these tablets would ultimately be used by Alparma when it decided to enter the UK market in February 2004.⁵⁹⁶

The extension of the Alparma-GSK Agreement

- 3.373 The Alparma-GSK Settlement Agreement was subsequently renegotiated and extended to be effective until 30 November 2004. The negotiation of the extension to that agreement is reported in an email from [Alparma Inc's Vice President of Intellectual Property] dated 4 September 2003, in which he reports that, notwithstanding Alparma's view that it would prevail in patent litigation with GSK, it had been able to negotiate an extension to the Alparma-GSK Agreement on favourable terms. In particular, Alparma reported that:⁵⁹⁷

'If we do not renew the agreement, we will be faced with launching the paroxetine product in the face of the GSK patent, and while we are

⁵⁹⁴ Email from [Alparma ApS's Sales and Marketing Director] to [Alparma's Quality Operations Manager] dated 4 October 2002 (document A 0053). This consideration had not been concluded by 11 November 2002, the day before the Agreement was entered into. See email from [Alparma's Quality Operations Manager] to [Alparma ApS's Sales and Marketing Director] dated 11 November 2002 (document A 0044).

⁵⁹⁵ Settlement Agreement dated 11 February 2003 between Medis Ltd. and Alparma AS (document A 0045).

⁵⁹⁶ Email from [Alparma's Finance Director] to [Alparma's Financial Controller] and [Alparma's Financial Accountant] dated 5 February 2004 (document A 0054).

⁵⁹⁷ Email from [Alparma Inc's Vice President of Intellectual Property] to [Alparma Inc's CEO] and [Alparma Inc's Chief Financial Officer] dated 4 September 2003 (document 1434) entitled 'Summary of discussions 4th September'.

comfortable we will win, we will incur legal fees, could face an injunction and of course substantial damages if we ultimately lose.

Summary of terms:

- *GSK to supply of 500,000 packs paroxetine 20mg per year*
- *GSK to pay marketing fee of £100,000/month*
- *ALO can terminate contract if generic pricing drops below a certain level (e.g. generic market forms) and will get a price adjustment for any existing stock*

Summary of financials:

Expected profit from sales: £1,000,000

Expected marketing fee: £1,200,000

Total: £2,400,000 = \$4,104,000 (@£1.71=\$1)

If additional settlement of £500,000 outstanding value included:

Total: £2,900,000=\$4,959,000 (@£1.71=\$1)

(emphasis in original)

3.374 The key terms of the amended Alparma-GSK Settlement Agreement are set out below, while the remaining terms of the Alparma-GSK Settlement Agreement were unchanged:⁵⁹⁸

- '(i) The Settlement Agreement shall be amended to expire on 30th November 2004.*
- (ii) The supply shall be for 620,000 packs 30 x 20 mg of Product. The parties acknowledge that in consideration of the supply of this volume of Product the requirement for GSK to transfer to Alparma value in an amount of £500,000 as provided by paragraph 6 of the Settlement Agreement shall be extinguished. In the event of a delay beyond 1 December 2003 of the additional quantity representing an increased volume of 10,000 packs per month, GSK shall pay to Alparma at the end of each calendar*

⁵⁹⁸ Amendment to the Alparma-GSK Settlement Agreement dated 14 November 2003 (document 0441).

month of delay an amount of £48,000 per month of delay (or pro-rata for a partial calendar month) excluding VAT.

- (iii) *GSK shall pay a marketing allowance to Alparma of £100,000 per month (pro-rated for any portion of a month, if the Agreement is terminated) during the term of this variation but should Alparma terminate its supply arrangements with Ivax at any time prior to 30 November 2004 (other than due to Ivax breach or insolvency), the marketing allowance shall cease at the date of termination of such supply and GSK shall have no further obligation to pay the allowance.'*

3.375 The Alparma-IVAX Agreement, and consequently the Alparma-GSK Settlement Agreement, terminated on 13 February 2004, following independent entry by Waymade and Neolab⁵⁹⁹ – and following receipt of approval from Alparma Inc to terminate.⁶⁰⁰ Alparma subsequently entered the UK paroxetine market independently of GSK using the paroxetine stock it had initially intended to use for its proposed entry into the market in 2002 (see paragraphs 3.370 to 3.372).

f) *The Parties' rationale for entering into the Alparma-GSK Agreement*

3.376 GSK's rationale for the settlement (and associated supply) agreements is set out at paragraphs 3.234 to 3.241.

3.377 In the case of GSK's settlement with Alparma, [Alparma ApS's Sales and Marketing Director], in an email of 11 October 2002, reported back to colleagues on a meeting he had with [GSK's Finance Director A] and [GSK's

⁵⁹⁹ Under clause 11.3 of the Alparma-IVAX Agreement dated 20 November 2002, Alparma was entitled to terminate that agreement giving one month's written notice (to be served in accordance with clause 20.1) (Alparma-IVAX Agreement (document 1806), clause 11.3). In accordance with these contractual obligations, Alparma sent a termination letter to IVAX on 13 January 2004 (termination letter from Alparma to IVAX dated 13 January 2004 (document 0455)). The Alparma-GSK Settlement Agreement was effective only 'during the currency of the IVAX Supply Agreement' as set out in Alparma-GSK Settlement Agreement (document 0356), clauses 1 and 7.

⁶⁰⁰ Transcript of Actavis SO Oral Hearing dated 23 October 2013 (document 3088), pages 10 (lines 23–26) and 32 (lines 13–15). See also email from [Alparma Inc's Vice President of Intellectual Property] to [Alparma Ltd's Managing Director] dated 12 January 2004 (document A 0054), at page 2: 'I have spoken to [Alparma Inc's Chief Financial Officer] and explained the GSK contract termination and patent issues surrounding paroxetine UK. I also understand that you have spoken to [Alparma's Vice President Finance, CFO International]. [Alparma Inc's Chief Financial Officer] has indicated that it is OK to terminate the GSK contract and pursue the negotiations w/GSK and also plan for a Delta product launch.'

Associate General Counsel for Europe]and provided a further explanation of GSK's rationale.⁶⁰¹

'The key issues for them [GSK] was [sic]:

Stay within the law and not making any settlement that can be counter productive for them in other jurisdictions around the globe

Keep patent defence intact

Maintaining stability and predictability (they are also in the middle of budget 2003)

[...]

3.378 As is clear from the internal Alparma emails considered above, Alparma's rationale for entering into the Alparma-GSK Agreement was similar to GUK's rationale: a comparison of the risks and rewards of litigation with the certainty and rewards offered by GSK.

3.379 [Alparma ApS's Sales and Marketing Director] in a witness statement to the CMA on 21 July 2014 summarised the position as follows:

'Ultimately, in my view, the reason for entering into the settlement arrangement with GSK was not a commercial one, but more financial. Put simply, it was to remove the uncertainty of potentially winning at a later date with the certainty of getting some money now.'

and

*'Entering the market independently would always entail risk, in particular uncertainty as regards the outcome of the legal action, and the agreement with GSK provided certainty – this was key for Alparma.'*⁶⁰²

⁶⁰¹ Email chain between [Alparma Ltd's Director of Sales and Marketing], [Alparma ApS's Sales and Marketing Director], [Alparma Inc's Vice President of Intellectual Property], [Alparma Inc's President (Human Generics)], [Alparma ApS's patent attorney], [VP New Products – FP at Alparma ApS], [Alparma Inc's Chief Financial Officer], [Alparma Inc's Chief Legal Officer] dated 14 October 2002 (document 1361), entitled 'UK settlement negotiations for Paroxetine – meeting October 11, 2002'.

⁶⁰² [REDACTED]WS (document 3172), paragraphs 8.4 and 8.10.

G. Developments in the UK supply of paroxetine

3.380 This Section provides an overview of trends in the supply of paroxetine between 1998 and 2005,⁶⁰³ that is, the period before, during and immediately after the Agreements were in effect.

3.381 In this Section, the CMA first sets out the main market entry that occurred during the period, then provides a description of price and sales trends for paroxetine 20mg and paroxetine 30mg separately and presents the trends for 20mg and 30mg combined, and then finally sets out market shares by company.

i) Entry in the UK supply of paroxetine

3.382 Between 2001 and 2005, there were a number of changes in the UK supply of paroxetine with a number of companies entering the market as GSK distributors, and others subsequently entering the market independently of GSK.

3.383 Table 3.3 presents the dates and details of each significant paroxetine entry that occurred during the period, with suppliers of paroxetine 20mg and paroxetine 30mg separately identified. Prior to November 2003, the first four generic suppliers to enter the market were distributors of paroxetine that originated from GSK and sold only paroxetine 20mg. Independent generic entry began in December 2003 when Waymade⁶⁰⁴ and Neolab, following the judgment in the Apotex Litigation, began selling generic paroxetine (as distributors for Apotex). Until generic entry occurred in February 2004, GSK was the only supplier of paroxetine 30mg in the UK.⁶⁰⁵

⁶⁰³ Throughout this Section, volume trends are presented between 1998 and 2005, while price and sales value trends are presented between 2001 and 2005, based on accurate GSK price data not being available prior to 2001 (see paragraphs 3.385–3.386).

⁶⁰⁴ Waymade originally supplied third party generic paroxetine sourced from GUK and Alpharma (from May 2002 onwards), so this is not mentioned separately in Table 3.3 (see email from [an employee of Waymade Healthcare Plc] to the OFT dated 25 September 2012 (document 2325)).

⁶⁰⁵ Paroxetine 30mg was not distributed under the Agreements, and nor were there parallel imports of paroxetine 30mg, until after generic entry had occurred.

Table 3.3: Main entry events for paroxetine

Date	Company entering	Product Supplied	20mg	30mg
November 2001	IVAX ⁶⁰⁶	Exclusive distributor of GSK paroxetine, pursuant to the IVAX-GSK Agreement	✓	
December 2001	Tillomed	Sub-distributor (appointed by IVAX) of GSK paroxetine ⁶⁰⁷	✓	
May 2002	GUK	Sub-distributor for IVAX of GSK paroxetine, pursuant to the GUK-GSK Settlement Agreement and GUK-IVAX Agreement	✓	
February 2003	Alpharma	Sub-distributor for IVAX of GSK paroxetine, pursuant to the Alpharma-GSK Settlement Agreement and Alpharma-IVAX Agreement	✓	
December 2003	Neolab and Waymade ⁶⁰⁸	Non-GSK generic paroxetine	✓	
February 2004	Alpharma	Non-GSK generic paroxetine		✓
March 2004	Alpharma	Non-GSK generic paroxetine ⁶⁰⁹	✓	
April 2004	Waymade	Non-GSK generic paroxetine ⁶¹⁰		✓
August 2004	GUK	Non-GSK generic paroxetine		✓
February 2005	GUK	Non-GSK generic paroxetine	✓	
July 2005	Neolab	Non-GSK generic paroxetine		✓

Source: based on data submitted by relevant parties.

ii) Price trends in the UK supply of paroxetine

3.384 This sub-section describes the main price⁶¹¹ trends that characterised the UK supply of paroxetine between 2001 and 2005. It focuses first on the price

⁶⁰⁶ Although the IVAX-GSK Agreement took effect from 1 December 2001 (see IVAX-GSK Agreement (document 0168)), IVAX's sales records show that it made its first sale of GSK-distributed paroxetine in November 2001 (Teva spreadsheet entitled 'Annex 1: Monthly sales values paroxetine 2000 to 2005, Annex 2: Monthly sales volumes paroxetine 2000 to 2005, Annex 3: Monthly COGs paroxetine 2000 to 2005' dated 4 May 2012 (document 2050)).

⁶⁰⁷ Tillomed was a distributor for IVAX, pursuant to the IVAX-Tillomed Supply Agreement (document 1751).

⁶⁰⁸ The CMA notes that Neolab's and Waymade's entry was followed by other generic companies supplying paroxetine sourced independently of GSK. For example, according to IMS diagnostics data dated 6 December 2011, supplied by GSK in response to the Section 27 Notice dated 2 December 2011 sent to GSK ('GSK Section 27 Notice') (document 0680), other paroxetine being marketed at the time was 'paroxetine Sandoz', 'paroxetine S+V' and 'paroxetine W8P'.

⁶⁰⁹ Note that Alpharma began supplying its own paroxetine, and at the same time ceased supplying paroxetine under the Alpharma-GSK Agreement (March 2004 was the last month that Alpharma supplied GSK sourced paroxetine (see Alpharma spreadsheet entitled 'Annex 4.1 Alpharma's UK sales of paroxetine between January 2000 and December 2005' (document 1293)).

⁶¹⁰ Note that Waymade supplied generic paroxetine 30mg sourced from third parties until October 2005, and it entered supplying its own generic paroxetine from July 2005, see spreadsheet entitled 'Waymade paroxetine sales data for parallel imports, 3rd party generics 2000-2005' dated 22 August 2012 (document 2316).

⁶¹¹ The word 'price' will be used in this sub-section to mean 'price per Defined Daily Dose ('DDD')'. Prices have been computed by dividing sales values by the corresponding sales volumes expressed in DDDs. Prices have been computed on the basis of the data supplied by relevant parties, and are the prices charged to pharmacies, net of rebates and discounts where available, and where a wholesale price was supplied, the CMA has applied a mark-up to adjust for the mark-up a wholesaler would have applied in selling to pharmacies. Specifically, the CMA has applied a mark-up of 11.25% to IVAX's prices, 20% to GUK's and Alpharma's prices, and 3–5% to parallel import prices. The mark-ups for IVAX and parallel importers are based on estimates provided by those companies (Teva suggested a range of 5–17.5% and the CMA has used the mid-point of this range: response dated 17 October 2012 to the Section 26 Notice dated 1 October 2012 sent to Teva (document 2160), Waymade suggested a mark-up of 5%: see response dated 19 November 2012 to Section 26 Notice dated 30 October 2012 sent to Waymade (document 2493), and a trade association for parallel importers suggested a range of 3–5%, see email chain between the OFT and [the Secretary General of the British Association of European Pharmaceutical Distributors] dated 29 October–29 November 2012 (document 2300)). The CMA notes that had it applied any higher mark-up for the parallel importers this would have resulted in parallel import prices exceeding GSK's Seroxat prices which would not have made sense (see footnote 616). The mark-up of 20% for GUK and Alpharma is based on a confirmation by [Alpharma Ltd's Director of Sales and Marketing] [Alpharma Ltd's Director of Sales and Marketing] of Alpharma that 20% would have been the industry norm at the time (Witness statement of [Alpharma Ltd's Director of Sales and Marketing], signed on 27 August 2014 (document 3232), paragraph 7.9): this recollection is based on a contemporaneous email in which [Alpharma Ltd's Director of Sales and Marketing] stated that a retail price of £13.15 would imply an average selling price of £10.50 for Alpharma (of which 85% of sales would be made to wholesalers), suggesting that the wholesale mark-up was expected to be in the region of 25–30% (email chain between [Alpharma Ltd's Director of Sales and Marketing], [Alpharma ApS's Sales and Marketing Director], [Alpharma Inc's Vice President of Intellectual Property], [Alpharma Inc's President (Human Generics)], [Alpharma ApS's patent attorney], [Alpharma employee], [Alpharma Inc's Chief Financial Officer], [Alpharma Inc's Chief Legal Officer], dated 11–14 October 2002 (document 1361)). The CMA notes that a mark-up of 20% based on this document is itself cautious since a mark-up of 25% can be computed based on the expected average selling price of £10.50 mentioned in document 1361 being the selling price to wholesalers, rather than a weighted average selling price to all customers. The CMA notes that a mark-up of 20% is within the range provided by Actavis (Actavis suggested a range of 5–100% for short-line wholesalers and 15–20% for full-line wholesalers, see the response dated 18 October 2012 to the Section 26 Notice dated 1 October 2012 sent to Actavis (document 1510)), while GUK did not provide an estimate, see response dated 17 October 2012 to the Section 26 Notice dated 1 October 2012 sent to GUK (document 1273). The CMA notes that, as set out at paragraphs 3.385–3.386, GSK identified two different sources for its 2001 paroxetine pricing data as a result of having concluded there was a high likelihood that the data previously used by the CMA for its analysis was not net of rebates. For 2001 the CMA has adjusted the price data as described at footnote 615 and used CIMS data from 2002 onwards as there are no known issues with the accuracy of that data.

trends for paroxetine 20mg and paroxetine 30mg separately and then presents the trends for 20mg and 30mg combined.

3.385 Following the merger between SB and Glaxo Wellcome in 2000, GSK was, during 2001, in the process of consolidating its financial data systems. GSK has identified two databases containing sales data on paroxetine relating to the relevant period:

- 'Unison' was GSK's global financial reporting system. GSK has stated that during the relevant period the Unison system contained the most accurate data recorded by GSK, as the relevant data was audited and used for the production of annual accounts and financial reporting. GSK has stated that all rebate adjustments would have been recorded in Unison.⁶¹² Unison reported only annual sales totals, but did not, for example, provide break-downs of data into pack sizes or customer level data.
- The Customer Information Management System (the 'CIMS') also contains data for the period pre-2002, but the figures are unaudited. This data is however of a greater granularity than the Unison data, and includes monthly data for different pack sizes and customer level data.

3.386 For 2001, Unison reported paroxetine sales of £60.8 million whereas CIMS reported paroxetine sales of £67.9 million, a difference of £7.089 million or approximately 10%.⁶¹³ There was no material discrepancy between Unison and CIMS data from 2002 onwards, and the discrepancy only affected paroxetine 20mg.⁶¹⁴ Given its stated accuracy and that it was audited, the CMA has used the 2001 Unison data for reporting paroxetine 20mg sales values and prices⁶¹⁵ throughout this Section.

⁶¹² Part one of the response dated 17 April 2015 to the Section 26 Notice dated 30 March 2015 sent to GSK by the CMA (document 3930).

⁶¹³ Response dated 19 February 2015 to the Section 26 Notice dated 4 February 2015 sent to GSK (document 3872), pages 2–3 and Annex 1 (document 3873).

⁶¹⁴ The CMA considers that the discrepancy applies only to Seroxat 20mg and not to Seroxat 30mg because GSK did not face competition from parallel importers in relation to Seroxat 30mg and therefore, GSK was not offering discounts to its list price through brand equalisation deals to meet such competition. GSK's information responses indicate that the source of the discrepancy was that certain customer rebates across a range of medicines were not netted off, and in particular GSK stated that: '*GSK Finance now believes it is unlikely that the explanation [for the differences between the CIMS and Unison data of £7.089m in 2001] has to do with provisions taken in 2001 that were reversed in 2002. It seems more likely that the Unison figure for 2001 is net of rebates that were not recorded in CIMS, although sufficiently granular data no longer exists to prove the position either way*' (part three of the response dated 1 May 2015 to the Section 26 Notice dated 30 March 2015 sent to GSK (document 3941), paragraph 2.8). Given that rebates appear to be the source of the discrepancy, the absence of rebates or discounts for Seroxat 30mg should ensure that the two data sources are consistent with each other for this tablet strength.

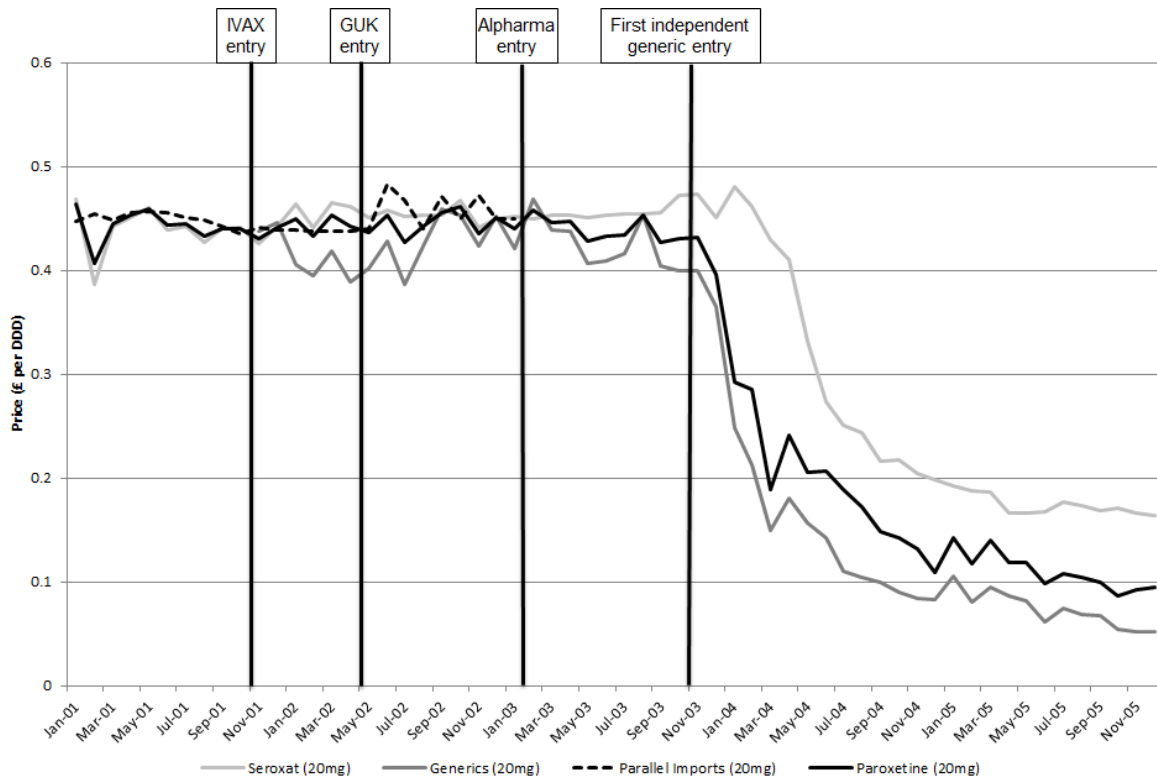
⁶¹⁵ Specifically, the CMA has adjusted down the monthly sales values for paroxetine 20mg taken from the CIMS dataset by 14%, which is the difference between the total sales values from Unison and CIMS databases. The CMA has used the reduced monthly sales value to calculate prices accordingly.

3.387 Figure 3.1 illustrates the main price trends for paroxetine 20mg, which are as follows:

- Generic paroxetine was being sold at around the same price as parallel imported paroxetine, during the period that both were available.⁶¹⁶
- During the period the Agreements were in effect and prior to independent generic entry, the price of both Seroxat and generic paroxetine remained fairly constant and there was no apparent price change following the entry of any of the Generic Companies pursuant to their respective Agreements with GSK.⁶¹⁷
- The most significant variation in price occurred following independent generic entry in December 2003. Prices fell by 34% in the first three months, 52% in the first six months and 69% by one year later. This represented a fall from £0.43 to £0.13 per Defined Daily Dose ('DDD') after one year and from £12.95 to £3.97 per pack.

⁶¹⁶ The CMA notes that after January 2003, as set out in Figure 3.4, volumes of parallel imported paroxetine 20mg fell to virtually nothing. Therefore, prices for parallel imports after this date may not be representative of actual prices as, in the absence of other information, the CMA has calculated estimated prices by applying an appropriate discount to the Seroxat list price. For this reason, parallel import prices of paroxetine 20mg have not been presented beyond January 2003 in Figures 3.1 and 3.3. Even for the period in which the CMA has actual price data for parallel importers from Waymade and Sandoz, the CMA notes that these companies made up less than 20% of parallel import volumes overall (based on IMS data) and therefore those prices may not have been representative of parallel import prices more generally. Further, the price comparison between parallel import prices and generic paroxetine prices is further complicated by the fact that whereas prices for GSK and the Generic Companies were adjusted for sales rebates (albeit that those rebates were not product specific for the Generic Companies and therefore may have been too high), it appears unlikely that the price data supplied by parallel importers was adjusted for rebates. In this regard, the CMA considers that parallel import prices recorded in this section appear to be higher than they would have been in practice, because it is unrealistic for parallel import prices to exceed GSK's Seroxat prices given that GSK would have been selling UK packaged product (for which pharmacies had an apparent preference), and that GSK was matching parallel import prices through deals similar to brand equalisation deals (see paragraph 3.115).

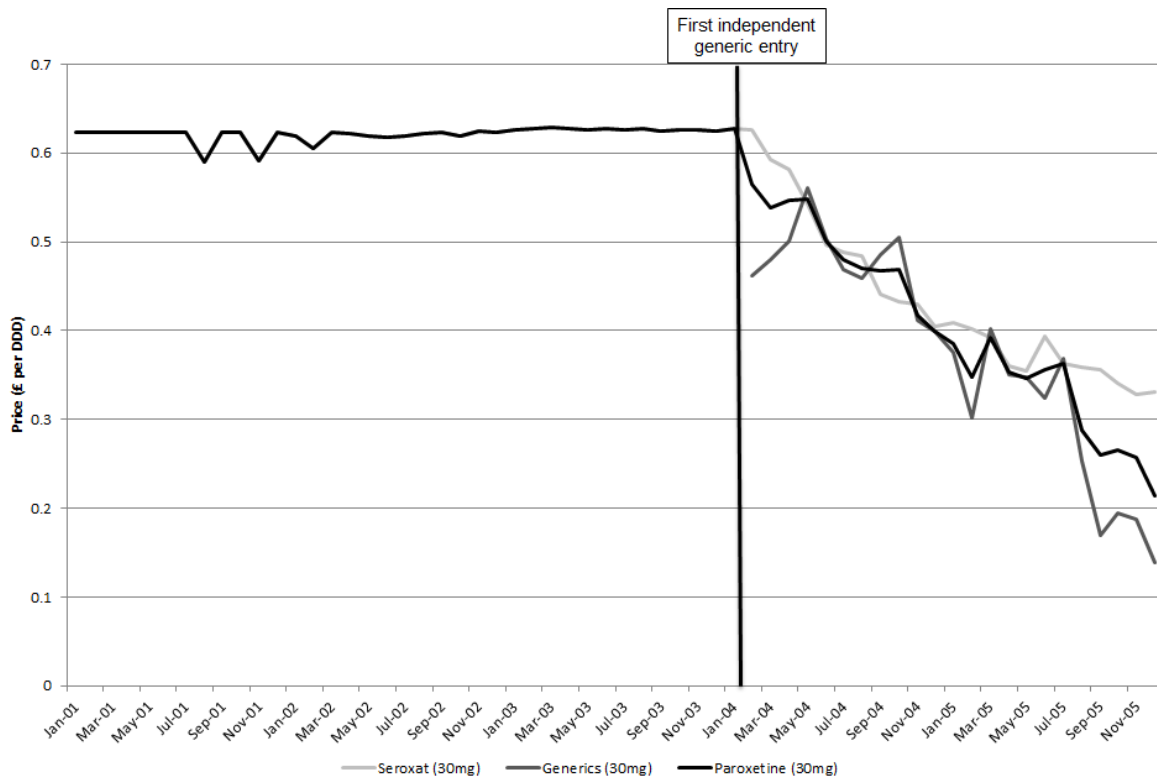
⁶¹⁷ Had Seroxat 20mg prices been presented based on CIMS data for 2001 instead, there would have been a price fall in the region of 9% between December 2001 and January 2002. For the reasons set out at paragraphs B.164–B.165, the CMA considers the Unison data to be robust for the purposes of this analysis.

Figure 3.1: UK prices of paroxetine 20mg, 2001-2005

Source: CMA calculations based on data submitted by relevant parties.

3.388 Figure 3.2 illustrates the main price trends for paroxetine 30mg, which are as follows:

- The price of paroxetine (or Seroxat) 30mg was broadly constant until February 2004.
- Following independent generic entry, the price of paroxetine 30mg declined dramatically, falling by around 66% by December 2005.
- By the end of the period for which the CMA has data, generic paroxetine 30mg was considerably cheaper than Seroxat 30mg. For example, in December 2005 generic paroxetine was 55% cheaper than Seroxat, a price of £0.21 per DDD compared to £0.33 respectively.

Figure 3.2: UK prices of paroxetine 30mg, 2001-2005

Source: CMA calculations based on data submitted by relevant parties

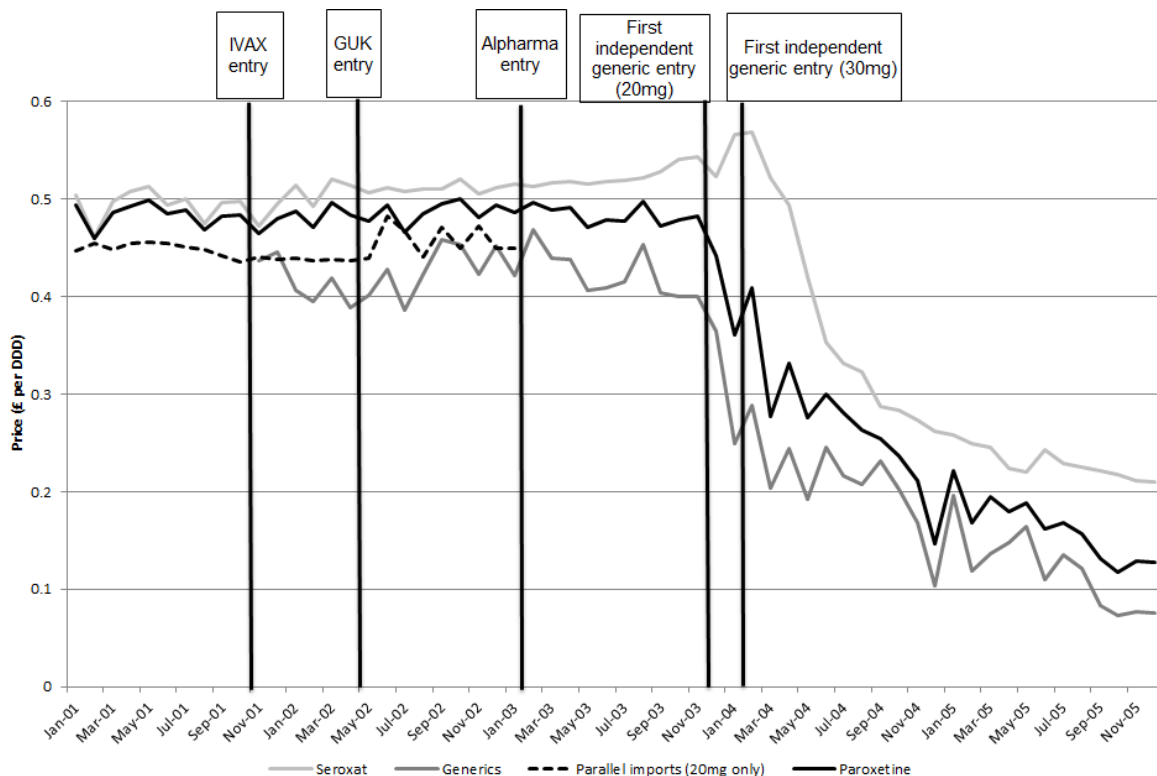
3.389 Average paroxetine prices (including both the 20mg and 30mg tablet strengths), are shown in Figure 3.3. In interpreting the trends it is relevant to note that, as described in paragraph 3.395, paroxetine 20mg accounted for the majority of sales by volume. Paroxetine 30mg was relatively more expensive than paroxetine 20mg on a per DDD basis throughout the period between 2001 and 2005.

3.390 As paroxetine 20mg accounted for the majority of total sales, the key trends in average paroxetine prices are broadly similar to those of the 20mg strength alone, as set out in paragraph 3.387. However, noteworthy differences are as follows:

- Whereas Seroxat 20mg prices were broadly flat during the Agreements and prior to independent generic entry, Seroxat prices on average for the 20mg and 30mg tablet strengths increased until February 2004, such that the average Seroxat price had reached a higher level by late 2003 than it had in early 2001.
- The price fall following independent generic entry was more gradual for paroxetine on average (that is, 20mg and 30mg tablet strengths) than the decrease observed for paroxetine 20mg alone. This is because the sales

of generic paroxetine 30mg were made at a higher price, and paroxetine 30mg prices fell more gradually following independent generic entry than paroxetine 20mg prices did. In this regard, the CMA notes that fewer companies supplied generic paroxetine 30mg than generic paroxetine 20mg, and often began supplying generic paroxetine 30mg later than paroxetine 20mg.⁶¹⁸ Nevertheless, average paroxetine prices (including both the 20mg and 30mg tablet strengths) had fallen by around 74% by December 2005.

Figure 3.3: UK prices of paroxetine, 2001-2005



Source: CMA calculations based on data submitted by relevant parties.

iii) Sales trends in the UK supply of paroxetine

3.391 This sub-section describes the main sales trends that characterised the UK supply of paroxetine between 1998 and 2005 for sales volumes, and between 2001 and 2005 for sales values. The analysis focuses first on the sales trends for paroxetine 20mg and paroxetine 30mg separately, and then presents the trends for paroxetine in aggregate (including 20mg and 30mg tablet strengths).

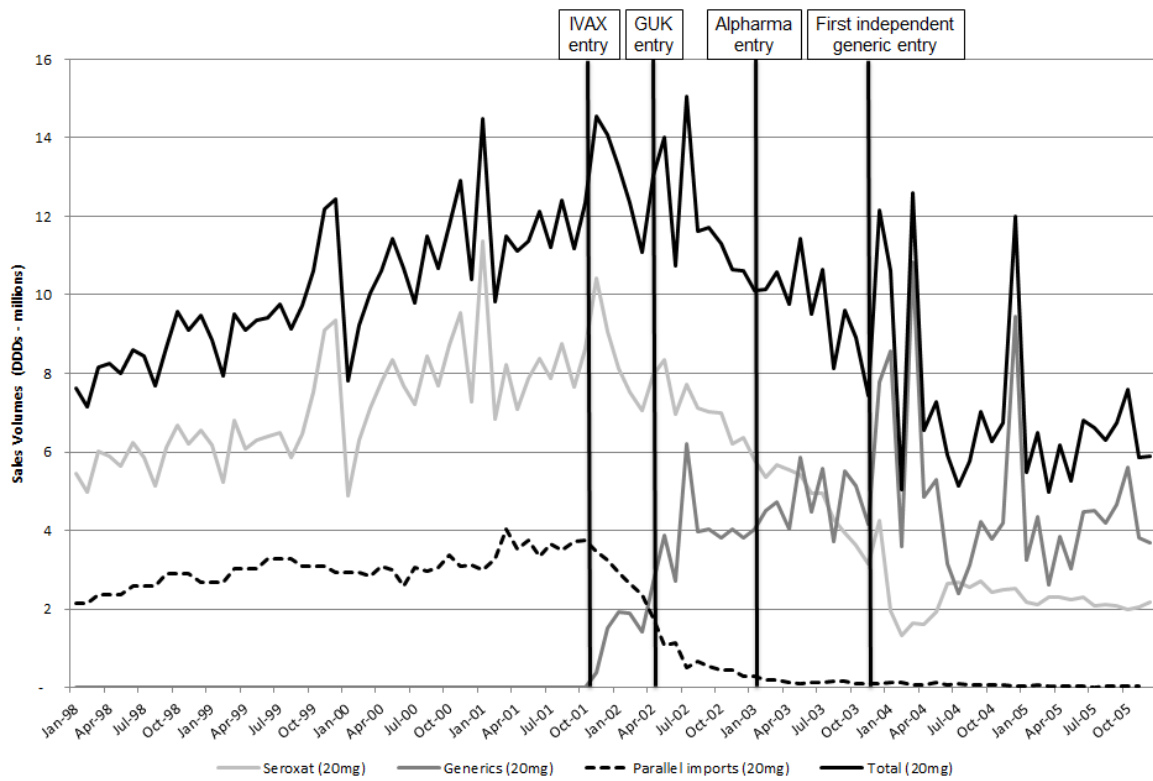
⁶¹⁸ See Table 3.3 for entry dates, and see also IMS diagnostics data dated 6 December 2011, supplied by GSK in response to the GSK Section 27 Notice (document 0680).

3.392 Figures 3.4 and 3.5 illustrate sales volumes and values for 20mg tablets of Seroxat, generic paroxetine (either supplied under the Agreements or independently sourced) and parallel imports. The key trends, apparent from both sales volumes and values, were as follows:

- After entry by the Generic Companies selling GSK paroxetine, sales of parallel imported paroxetine fell to virtually nothing. It is evident from the graphs that sales of generic paroxetine substituted for sales of parallel imports between November 2001 and January 2003.
- After November 2001, GSK's sales of Seroxat started falling, while the Generic Companies' sales of GSK paroxetine pursuant to the Agreements increased until early 2003 and then remained broadly constant until independent generic entry occurred in December 2003. There was a decrease in the total sales of paroxetine overall.
- Following independent generic entry, there was a sharp drop in Seroxat 20mg sales volumes, which fell by almost 70% between December 2003 and February 2004. Following a spike in generic sales at this time,⁶¹⁹ the decline in overall sales continued, though GSK's relative share compared to before independent generic entry declined such that generic suppliers between them accounted for approximately two thirds of all sales volumes by 2005.

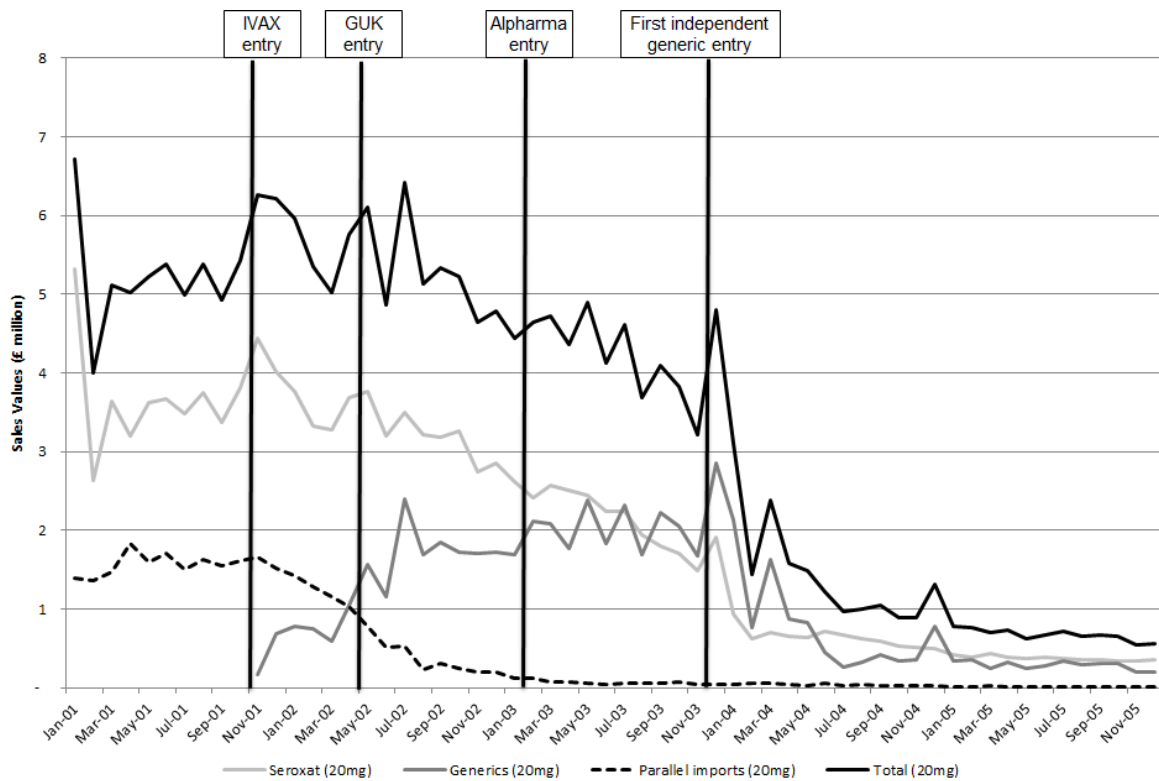
⁶¹⁹ The CMA notes that a spike in sales upon generic entry is consistent with [GSK's Finance Director A's] expectations (see footnote 84).

Figure 3.4: UK sales volumes of paroxetine 20mg, 1998-2005



Source: CMA calculations based on data submitted by relevant parties.

Figure 3.5: UK sales values of paroxetine 20mg, 2001-2005

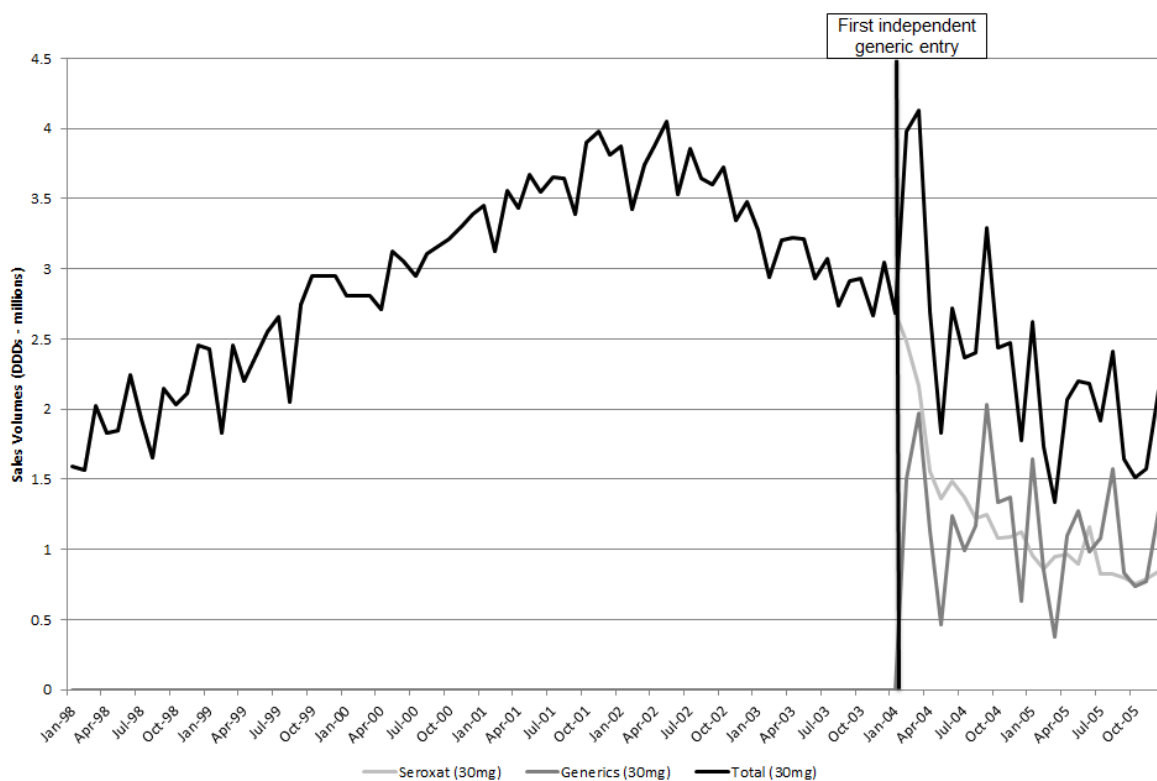


Source: CMA calculations based on data submitted by relevant parties.

3.393 Figures 3.6 and 3.7 illustrate sales trends by both volumes and values for paroxetine 30mg, with Seroxat and generic paroxetine shown separately.⁶²⁰ It is notable that:

- Total paroxetine 30mg sales were increasing until May 2002 and then began to decline significantly, before levelling out by Q4 2004.
- Following independent generic entry in February 2004, Seroxat sales volumes decreased sharply (falling by 45% between February 2004 and May 2004). This decline was not fully offset by generic paroxetine 30mg, such that sales of paroxetine 30mg continued to decline overall.

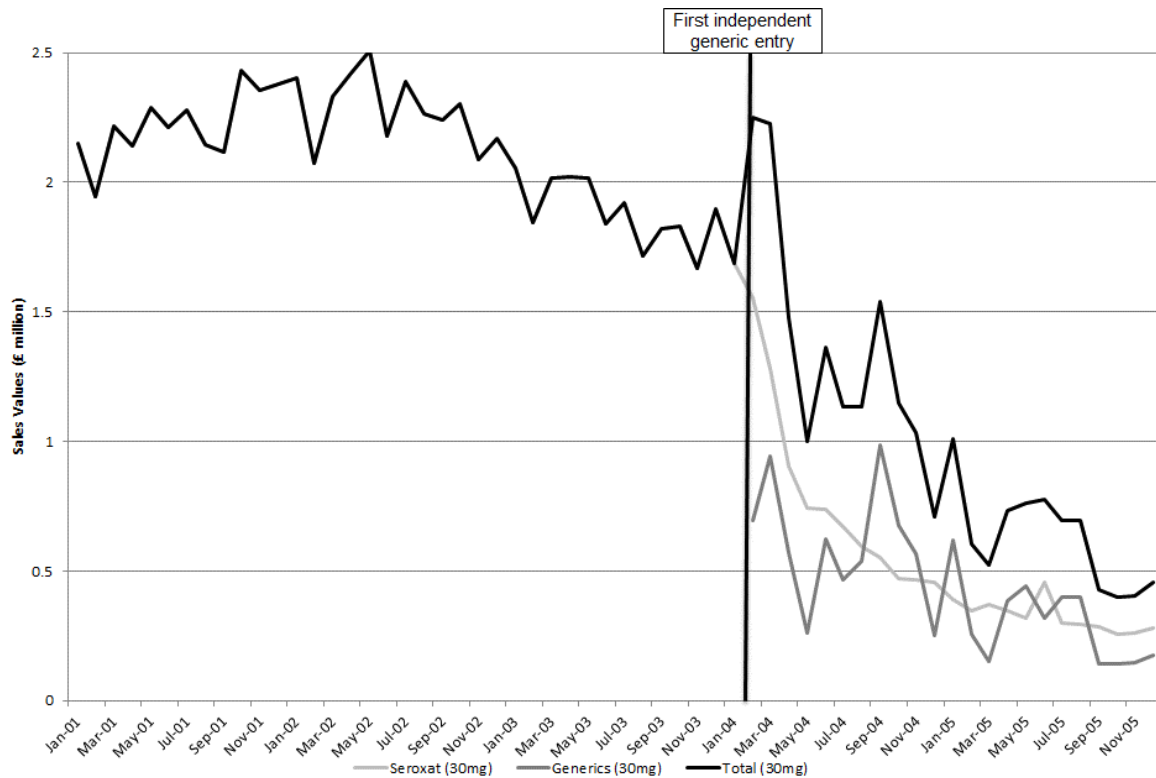
Figure 3.6: UK sales volumes of paroxetine 30mg, 1998-2005⁶²¹



Source: CMA calculations based on data submitted by relevant parties.

⁶²⁰ Parallel imports of Seroxat 30mg are not included since their proportion of total sales of paroxetine 30mg was very low.

⁶²¹ The CMA used IMS data for Seroxat 30mg sales volumes between October 1999 and February 2003 since the data provided by GSK appeared to be missing some sales.

Figure 3.7: UK sales values of paroxetine 30mg, 2001-2005⁶²²

Source: CMA calculations based on data submitted by relevant parties.

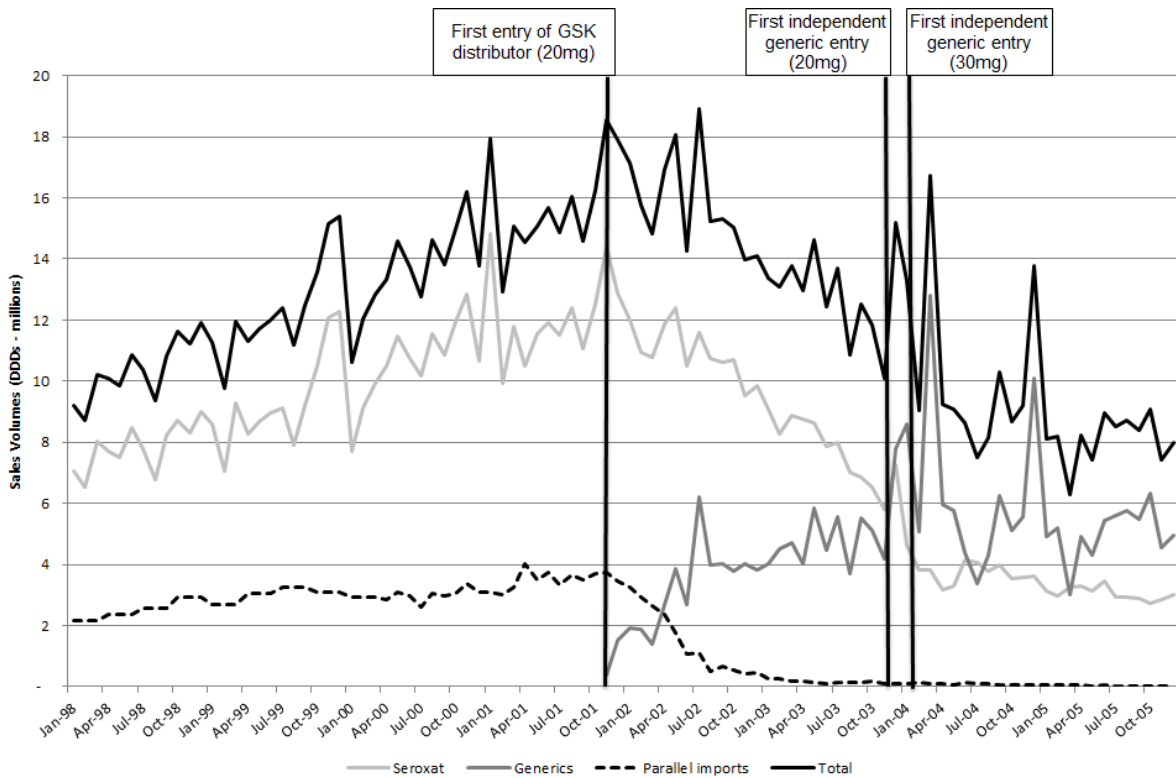
3.394 In Figures 3.8 and 3.9, the trends for the aggregate sales of paroxetine (including both 20mg and 30mg tablet strengths), are shown.

3.395 In interpreting these trends, it is worth noting that paroxetine 20mg was more significant than paroxetine 30mg in terms of volume of sales (for example, in 2001, over 75% of paroxetine volumes (measured in DDDs) were sales of paroxetine 20mg).

3.396 As paroxetine 20mg accounted for a large proportion of total sales, the trends of aggregate sales of paroxetine are similar to those of paroxetine 20mg. However, one noteworthy difference is that the decline in total sales, in terms of volumes and values, of paroxetine overall began later when looking at paroxetine in aggregate, than when considering just paroxetine 20mg (sales began to decline in November 2001 for paroxetine 20mg compared to May 2002 for aggregate paroxetine).

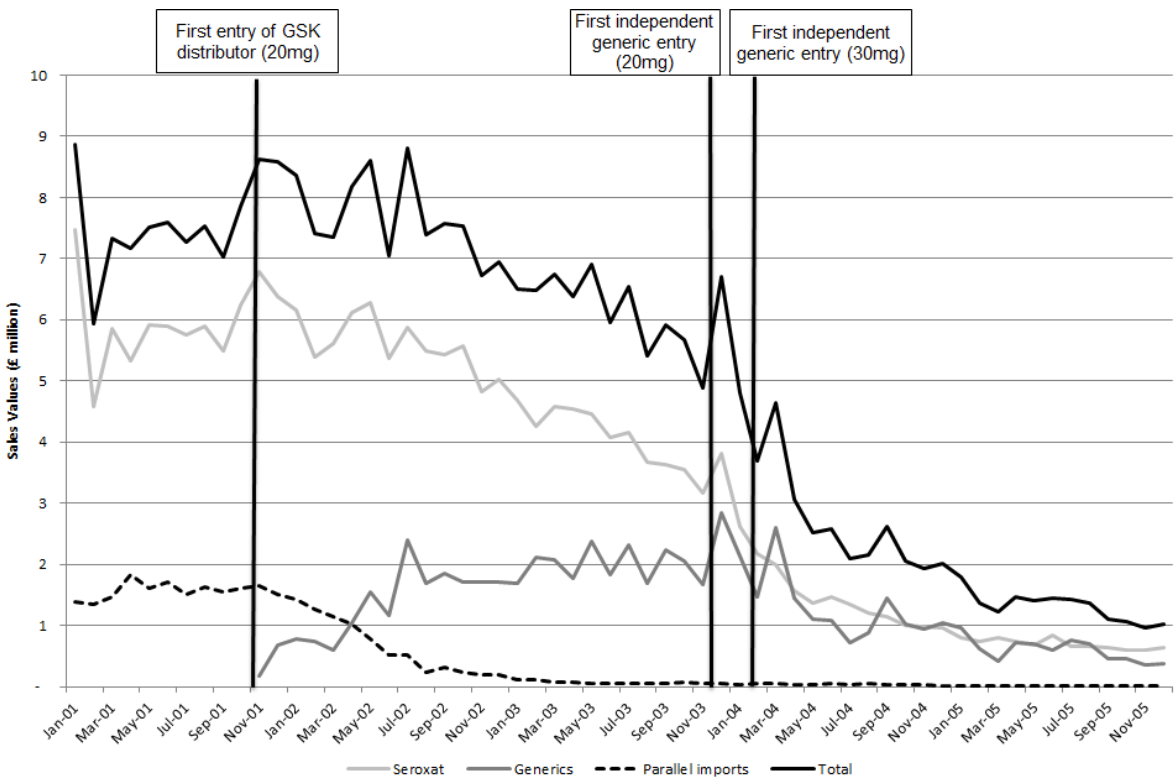
⁶²² Seroxat 30mg sales values have been computed by multiplying volume data described in footnote 621 with the relevant price, calculated as sales values divided by sales volumes, as submitted by GSK.

Figure 3.8: UK sales volumes of paroxetine, 1998-2005



Source: CMA calculations based on data submitted by relevant parties.

Figure 3.9: UK sales values of paroxetine, 2001-2005



Source: CMA calculations based on data submitted by relevant parties.

iv) Market shares by company

3.397 Tables 3.4 and 3.5 illustrate the market shares of the companies which produced and/or distributed paroxetine in the UK during the relevant period. Market shares by value are presented between 2001 and 2005 and market shares by volume are presented between 1998 and 2005. The CMA notes that GSK retained market share at the production level for any paroxetine supplied pursuant to the Agreements. Therefore, Tables 3.4 and 3.5 identify separately paroxetine sourced from GSK and paroxetine sourced from elsewhere.

Table 3.4: Market shares by value of paroxetine suppliers, 2001-05

<i>a) Sales value - £millions</i>		2001	2002	2003	2004	2005
GSK (Seroxat)		71.6	67.1	48.5	17.8	8.4
Parallel importers		18.4	7.7	0.9	0.5	0.1
IVAX – GSK product		0.8	9.7	8.4	0.3	0.1
GUK	GSK product	-	5.9	8.5	1.9	0.0
	Non-GSK product	-	-	-	1.6	2.0
Alpharma	GSK product	-	-	5.0	0.7	-
	Non-GSK product	-	-	-	5.8	1.9
Other Generic Suppliers	GSK product	0.0	0.9	1.2	0.1	0.0
	Non-GSK product	-	-	0.7	5.0	2.9
<i>Total</i>	<i>GSK product</i>	<i>91</i>	<i>91</i>	<i>72.5</i>	<i>21.3</i>	<i>8.6</i>
	<i>Non-GSK product</i>	<i>-</i>	<i>-</i>	<i>0.7</i>	<i>12.3</i>	<i>6.8</i>
TOTAL		91	91	73	34	15

<i>b) Sales value - %</i>		2001	2002	2003	2004	2005
GSK (Seroxat)		78.8	73.5	66.4	53.0	54.6
Parallel importers		20.3	8.5	1.2	1.4	0.8
IVAX – GSK product		0.9	10.7	11.5	0.8	0.4
GUK	GSK product	-	6.4	11.6	5.8	-0.1
	Non-GSK product	-	-	-	4.7	12.8
Alpharma	GSK product	-	-	6.8	2.1	-
	Non-GSK product	-	-	-	17.1	12.2
Other generic suppliers	GSK product	0.0	0.9	1.6	0.2	0.1
	Non-GSK product	-	-	0.9	14.9	19.1
<i>Total</i>	<i>GSK product</i>	<i>100</i>	<i>100</i>	<i>99.1</i>	<i>63.3</i>	<i>55.8</i>
	<i>Non-GSK product</i>	<i>-</i>	<i>-</i>	<i>0.9</i>	<i>36.7</i>	<i>44.2</i>
TOTAL		100	100	100	100	100

Source: CMA calculations based on data submitted by relevant parties.

Table 3.5: Market shares by volume paroxetine suppliers, 1998-05

<i>a) Volumes (in DDDs) - millions</i>		1998	1999	2000	2001	2002	2003	2004	2005
GSK (Seroxat)		94.2	111.9	127.5	145.3	131.5	93.1	45.4	36.5
Parallel importers		30.0	36.2	35.8	42.1	17.7	1.9	1.0	0.4
IVAX - GSK product		-	-	-	1.9	23.3	20.2	0.1	0.5
GUK	GSK product	-	-	-	-	14.9	22.1	11.7	-

	Non-GSK product	-	-	-	-	-	-	3.8	18.6
Alpharma	GSK product	-	-	-	-	-	12.5	2.9	-
	Non-GSK product	-	-	-	-	-	-	16.5	6.1
Other generic suppliers	GSK product	-	-	-	0.0	2.0	2.8	0.3	0.1
	Non-GSK product	-	-	-	-	-	1.9	41.9	35.2
Total	GSK product	124.2	148.2	163.3	189.3	189.5	152.6	61.5	37.7
	Non-GSK product	-	-	-	-	-	1.9	62.2	59.9
TOTAL		124.2	148.2	163.3	189.3	189.5	154.5	123.7	97.4

<i>b) Volumes (in DDDs) - % of total</i>									
	1998	1999	2000	2001	2002	2003	2004	2005	
GSK (Seroxat)	75.8	75.5	78.1	76.8	69.4	60.2	36.7	37.5	
Parallel importers	24.2	24.5	21.9	22.2	9.4	1.3	0.8	0.4	
IVAX - GSK product	-	-	-	1.0	12.3	13.1	0.1	0.5	
GUK									
	GSK product	-	-	-	-	7.9	14.3	9.5	-

	Non-GSK product	-	-	-	-	-	-	3.1	19.0
Alpharma	GSK product	-	-	-	-	-	8.1	2.3	-
	Non-GSK product	-	-	-	-	-	-	13.4	6.3
Other generic suppliers	GSK product	-	-	-	0.0	1.1	1.8	0.2	0.1
	Non-GSK product	-	-	-	-	-	1.3	33.9	36.0
Total	GSK product	100	100	100	100	100	98.7	49.7	38.6
	Non-GSK product	-	-	-	-	-	1.3	50.3	61.5
TOTAL		100	100	100	100	100	100	100	100

Source: CMA calculations based on data submitted by relevant parties.

3.398 The following trends in market shares are significant:

- GSK's market share at the production level by value remained at 100% throughout the period from 2001 to 2002 and remained at 100% by volume throughout the period from 1998 to 2002.
- There was a progressive substitution from sales of Seroxat and parallel imports to sales by Generic Companies during the Relevant Period.⁶²³

⁶²³ The CMA notes that during the GUK Litigation, [GSK's Finance Director A] stated that 'a substantial proportion (about 40%) of SEROXAT (paroxetine) dispensed in the UK is in the form of parallel imports' ([redacted]WS1 (GUK) (document 0885), paragraph 3.3). This implies that GSK's market share (for the supply of finished product to pharmacies/wholesalers) was 60% during 2001. However, as set out in Tables 3.4 and 3.5, GSK's market share, based on data submitted by GSK, was actually higher than this, 79% by value and 77% by volume in 2001.

- The switch from parallel imports to the Generic Companies occurred following the commencement of the Agreements between GSK and the Generic Companies. The result was that parallel importers' proportion of total sales decreased noticeably after 2001, at the time during which IVAX and later GUK entered the market as distributors of GSK's paroxetine, and had declined to less than 2% by either value or volume from 2003 onwards.⁶²⁴
- There was some erosion of GSK's market share for the supply of finished product to pharmacies/wholesalers following the entry of the Generic Companies under the Agreements. However, the most substantial decrease in GSK's market share for the supply of finished product to pharmacies/wholesalers only took place after independent generic suppliers entered the market at the end of 2003.
- Following independent generic entry and the end of the Agreements, GSK's market share at the production level (by volume) fell from 98.7% in 2003⁶²⁵ to 49.7% in 2004. GSK's market share for the supply of finished product to pharmacies/wholesalers (by volume) fell from 60.2% in 2003 to 36.7% in 2004, having fallen by less than 20 percentage points (from 76.8% to 60.2%) during the two years that the Agreements were in place prior to independent generic entry in December 2003.

⁶²⁴ The displacement of parallel imports is consistent with a statement by [GSK's Finance Director A]: 'Before the coming into effect of the Ivax Agreement, about 40% of paroxetine dispensed against prescriptions in the UK was parallel imported. I believe that Distributed Paroxetine sold by Ivax and its sub-distributors has now largely displaced that parallel imported product' [§]WS1 (Apotex) (document 0333), paragraph 6.8. A consistent observation is made at second witness statement of [GSK's Finance Director A] in the litigation between GSK and the Apotex Parties, dated 11 November 2002 ('[§]WS2 (Alpharma)') (document 0289), paragraph 3.1, and [§]WS2 (document 1325), paragraph 29.

⁶²⁵ The CMA notes that of the 98.7%, only 1.3% was parallel imports, so the remaining 97.4% was sales by GSK in the UK.

4. MARKET DEFINITION AND DOMINANCE

A. Introduction

- 4.1 This Part considers whether GSK held a dominant position in the relevant market for the UK supply of paroxetine at the time at which the Agreements were entered into.
- 4.2 The CMA considers that there is strong and compelling evidence that GSK had substantial market power prior to entering into the Agreements. The evidence shows that following the eventual emergence of true generic competition in December 2003, GSK experienced a significant decline in its paroxetine prices, profits and market share, demonstrating that the constraints exerted by other medicines in the period prior to December 2003 were insufficient to prevent GSK, as the sole supplier of paroxetine⁶²⁶ in that period, from sustaining prices and profits that were significantly higher than those observed following independent generic entry. The CMA considers that the only plausible explanation for these trends is that (i) the relevant market is no wider than the supply of paroxetine in the UK, as the competitive constraint of other medicines in the treatment area was insufficient to prevent GSK (as the monopolist supplier of paroxetine) from sustaining significantly higher prices and profits prior to true generic competition; and (ii) GSK held a dominant position between at least January 1998 and November 2003, and as such was able to profitably sustain significantly higher prices and profits prior to independent generic entry than afterwards.
- 4.3 This Part is structured as follows:
- Section B sets out the relevant legal framework to market definition and dominance.
 - Section C provides an overview of the CMA's approach and findings in relation to the relevant market and whether GSK held a dominant position in that market.
 - Section D sets out the CMA's assessment of the relevant product market. The CMA's assessment draws upon qualitative evidence such as the ATC and BNF classification systems, the modes of action of the different medicines in the treatment area, the therapeutic uses of the different

⁶²⁶ The CMA notes that although during the period prior to independent generic entry, the Generic Companies were supplying paroxetine pursuant to the Agreements with GSK, such generic entry did not lead to falls in paroxetine prices (as set out at paragraphs 7.44, 7.97 and B.166) and GSK was the sole manufacturer of paroxetine at that time.

medicines as described by prescribing literature, and evidence from GSK in which it considers the competitive constraints relevant to Seroxat sales in the prescription channel. The CMA then assesses quantitative evidence including sales and pricing trends and how certain developments in the treatment area, including the entry of generic paroxetine, have affected the sales and pricing of paroxetine. Section D also sets out the CMA's assessment of the relevant geographic market.

- Section E considers whether GSK held a dominant position in the relevant market. The assessment considers GSK's share of the relevant market, its ability to sustain profits that were above the competitive level, the barriers to expansion faced by existing competitors, the barriers to entry faced by potential competitors, and the extent of countervailing buyer power.

B. Legal framework

i) *Market definition*

- 4.4 For the purposes of applying the Chapter I prohibition and Article 101(1) TFEU, the determination of the relevant market is not intrinsic to, nor normally necessary for, a finding of infringement.⁶²⁷ However, the CMA will define the relevant market, or at least a range of candidate markets, in an assessment of the Chapter I prohibition or Article 101 TFEU where it considers it appropriate to do so, for example, where this is necessary to determine whether the agreement has as its object or effect the prevention, restriction or distortion of competition.⁶²⁸
- 4.5 For the purposes of applying the Chapter II prohibition, when assessing dominance, it is necessary to define the relevant market in which the undertaking operates.⁶²⁹
- 4.6 In assessing the relevant market for the purpose of applying the Chapter I prohibition, Article 101 TFEU and/or the Chapter II prohibition, the CMA

⁶²⁷ *Argos Ltd and Littlewoods Ltd v Office of Fair Trading* [2005] CAT 13, at [176]–[178]. Judgment of 6 July 2000, *Volkswagen v Commission*, T-62/98, ECR, EU:T:2000:180, paragraph 230.

⁶²⁸ Judgment of 16 June 2011, *Ziegler v Commission*, T-199/08, ECR, EU:T:2011:285, paragraph 45, upheld in the Judgment in *Ziegler SA v Commission*, C-439/11 P, EU:C:2013:513, paragraphs 63 and 71. Furthermore, the CMA will determine the 'relevant turnover' for the purposes of assessing the appropriate penalties: see *Guidance as to the appropriate amount of a penalty*, (OFT423 adopted by the CMA, September 2012), paragraph 2.7.

References to CMA guidance in this Decision include OFT guidance that has been adopted by the CMA.

⁶²⁹ *Abuse of a dominant position* (OFT402, December 2004), adopted by the CMA, paragraph 4.4.

follows the approach set out in the relevant market definition guidance of the Commission and the CMA.⁶³⁰

- 4.7 OFT403 and the Market Definition Notice state that, in order to define the relevant market, one must consider the competitive pressures faced by companies active in that market. A market definition is established by analysing the closest substitutes to the product that is the focus of the investigation. These products are usually the most immediate competitive constraints on the behaviour of the undertaking controlling the product in question.⁶³¹
- 4.8 The Commission has repeatedly rejected the proposition that products that are used to treat the same medical condition are necessarily regarded as substitutes. For example, in *AstraZeneca* the Commission noted that:⁶³²
- 'In determining the functional substitutability of medicines it is not enough, for the purposes of product market definition, to state that different medicines are prescribed for the same general illness or disease.'*
- 4.9 What primarily matters for the definition of the relevant product market is the extent to which different product types can be expected materially to constrain the conduct of a given undertaking.⁶³³
- 4.10 The CMA's assessment of the relevant market is set out below.

ii) Dominance

- 4.11 The CJ has defined a dominant position in *United Brands* as:⁶³⁴

'a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers'.

⁶³⁰ The Commission's approach is set out in Commission Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372/5, 9.12.1997 ('Market Definition Notice'). The CMA's approach to market definition is set out in Market definition (OFT403, December 2004), adopted by the CMA ('OFT403'), which follows a similar approach to that of the Market Definition Notice.

⁶³¹ OFT403, paragraph 2.5.

⁶³² Commission Decision of 15 June 2005, *AstraZeneca*, Case COMP/A. 37.507/F3, paragraph 381.

⁶³³ Commission Decision of 15 June 2005, *AstraZeneca*, Case COMP/A. 37.507/F3, paragraph 370.

⁶³⁴ Judgment in *United Brands v Commission*, C-27/76, EU:C:1978:22, paragraph 65.

- 4.12 When assessing whether an undertaking holds a dominant position, the CMA will consider whether that undertaking has substantial market power.⁶³⁵ Market power is not an absolute term, but a matter of degree, and the degree of market power will depend on the circumstances of each case.⁶³⁶ The existence of a dominant position does not require the undertaking enjoying it to have eliminated all possibility of competition.⁶³⁷
- 4.13 When assessing dominance it is necessary to define the relevant market. The CMA's approach to the relevant market is set out at paragraph 4.4 above. Market definition provides a frame of reference for a competition analysis. The relevant market typically has two dimensions: the relevant goods or services (the relevant product market) and the geographic extent of the market (the relevant geographic market).
- 4.14 In assessing whether an undertaking has a dominant position within the relevant market, the CMA will first consider market shares. The European Courts have held that very large market shares are, save in exceptional circumstances, evidence of the existence of a dominant position. In *Akzo Chemie*, the CJ stated that a market share of 50% is sufficient to establish the existence of a dominant position.⁶³⁸
- 4.15 In addition to the market share of the undertaking suspected of holding a dominant position, the CMA will consider the position of other undertakings operating in the same market and how market shares have changed over time.⁶³⁹
- 4.16 The CMA will also consider the extent to which an undertaking faces competitive constraints. Important constraints include the presence of actual or potential competitors, including the relative strength of those competitors, and barriers to entry. Other factors such as strong buyer power from the undertaking's customers can also be relevant.⁶⁴⁰

⁶³⁵ *Abuse of a dominant position* (OFT402, December 2004), adopted by the CMA, paragraph 4.11.

⁶³⁶ *Assessment of market power* (OFT415, December 2004), adopted by the CMA, paragraph 2.10.

⁶³⁷ Judgment in *United Brands v Commission*, C-27/76, EU:C:1978:22, paragraph 113.

⁶³⁸ Judgment in *AKZO Chemie v Commission*, C-62/86, EU:C:1991:286, paragraph 60.

⁶³⁹ *Assessment of market power* (OFT415, December 2004), adopted by the CMA, paragraph 3.3.

⁶⁴⁰ The CMA's approach to assessing dominance is set out in more detail in *Abuse of a dominant position* (OFT402, December 2004), adopted by the CMA.

C. Overview, approach and key findings

i) *Market definition*

- 4.17 This Section provides an overview of the approach that the CMA has taken to analysing the relevant market in this case, and of its key findings.
- 4.18 The 'hypothetical monopolist test' is the conceptual framework that competition authorities normally use to define the relevant product and geographic markets. The test asks whether it would be profitable for a hypothetical monopolist of the 'focal product' (the product under investigation, in this case paroxetine) which operates in a 'focal area' (the geographic area under investigation where the focal product is sold) to increase the price of the focal product by a small but significant amount (for example, 5 to 10%) above competitive levels for a sustained period of time.⁶⁴¹ If such an increase in the price of the focal product would be profitable, the test is complete and the focal product sold by the hypothetical monopolist is (usually) the relevant market.⁶⁴²
- 4.19 The application of the hypothetical monopolist test in dominance cases is complicated by the fact that the current profits⁶⁴³ of the focal product may be substantially higher than competitive levels, for example because the undertaking has already raised the price or reduced marketing to its profit-maximising level. Given this, a further increase in price might induce consumers to purchase other products. In these circumstances, however, it would be wrong to conclude that the undertaking under investigation lacks market power and to include these other products in the same relevant market as the focal product.⁶⁴⁴ Caution must therefore be exercised in the assessment of the evidence on demand-side substitution when market conditions are distorted by the presence of market power and prices and

⁶⁴¹ This increase is usually referred to as SSNIP, a small but significant non-transitory increase in price.

⁶⁴² If the price increase would not be profitable (for example, because a sufficiently large number of customers would switch some of their purchases to other substitute products), the test continues by assuming that the hypothetical monopolist controls both the focal product and its closest substitute. If necessary the process is repeated, including other substitute products until the smallest collection of products for which the hypothetical monopolist can profitably impose a price increase is found. This collection of the focal product and its closest substitutes is then the relevant product market. See OFT403, paragraphs 2.5–2.13 and Market Definition Notice, paragraphs 15–19.

⁶⁴³ See paragraphs 4.74–4.75 for a description of the role of profits and marketing in the way the CMA has applied the hypothetical monopolist test.

⁶⁴⁴ This problem is usually referred to as the 'cellophane fallacy' after a US case involving cellophane products, see *US v E.I. du Pont de Nemours & Co*, 351 US 377 (1956).

profits are likely to differ substantially from their competitive levels.⁶⁴⁵ This can be a particular problem in markets where products are protected by patents.

4.20 The likely outcome of the hypothetical monopolist test is a matter of judgement using both the qualitative and quantitative information available.⁶⁴⁶

4.21 The CMA has adopted the SSNIP framework in this case and, consistent with the approach taken in the *AstraZeneca*⁶⁴⁷ and *Reckitt Benckiser*⁶⁴⁸ cases, the CMA has considered a wide and diverse range of evidence in relation to Seroxat and potential competitor medicines in order to define the relevant product market.⁶⁴⁹ The evidence considered by the CMA includes:

- product characteristics and intended use, in particular the EPhMRA, WHO and BNF classification systems
- therapeutic uses and modes of action of the various medicines, as set out in the guidelines and literature used by prescribers, for instance the BNF guidelines
- evidence from GSK setting out its commercial strategy in relation to other medicines, and
- prices, sales and prescription trends, and the impact of specific events on them.

⁶⁴⁵ See OFT403, paragraphs 5.4–5.6. See also Market Definition Notice, paragraph 19: *'In particular, for the investigation of abuses of dominant positions, the fact that the prevailing price might already have been substantially increased will be taken into account.'* Similarly, the Competition Appeal Tribunal ('CAT') noted in *Aberdeen Journals* that *'the fact that market conditions were already distorted, means that extreme caution must be exercised when dealing with the presence or absence of switching patterns. Such evidence is not a reliable guide to what would occur in normal competitive conditions.'* (*Aberdeen Journals v Director General of Fair Trading* [2003] CAT 11, at [262]; see also at [274]–[276]).

⁶⁴⁶ In *Aberdeen Journals Limited v Office of Fair Trading* [2003] CAT 11, at [258], the CAT said that *'there is no hierarchy of evidence under the 1998 Act on such issues as market definition. It is for the Director to decide what evidence he considers is sufficient for his decision, and for the Tribunal to decide whether that evidence is sufficient or not.'*

⁶⁴⁷ Commission Decision of 15 June 2005, *AstraZeneca*, Case COMP/A. 37.507/F3.

⁶⁴⁸ Decision No. CA98/02/2011, *Reckitt Benckiser*, 12 April 2011.

⁶⁴⁹ See also *Aberdeen Journals Limited v Director General of Fair Trading* [2002] CAT 4, at [96]–[97]: *'96. ...the relevant product market is to be defined by reference to the facts in any given case, taking into account the whole economic context, which may include notably (i) the objective characteristics of the products; (ii) the degree of substitutability or interchangeability between the products, having regard to their relative prices and intended use; (iii) the competitive conditions; (iv) the structure of the supply and demand; and (v) the attitudes of consumers and users. 97. However, this checklist is neither fixed, nor exhaustive, nor is every element mentioned in the case law necessarily mandatory in every case. Each case will depend on its own facts, and it is necessary to examine the particular circumstances in order to answer what, at the end of the day, are relatively straightforward questions: do the products concerned sufficiently compete with each other to be sensibly regarded as being in the same market? The key idea is that of a competitive constraint: do the other products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm?'* The CAT followed the same approach in *Aberdeen Journals Limited v Office of Fair Trading* [2003] CAT 11 and in *Genzyme v Office of Fair Trading* [2004] CAT 4.

4.22 As set out in more detail below, the CMA has found that the qualitative evidence demonstrates that paroxetine is one of a range of medicines that can be used to treat conditions including depression. Although a number of these medicines work in a similar way and are referred to by the prescribing literature as possible treatments for depression, these medicines were differentiated, for example as evidenced through GSK's marketing efforts. In summary:

- Paroxetine and other SSRIs such as citalopram or fluoxetine, as well as other molecules such as venlafaxine, were generally considered in the prescribing guidance to each be suitable treatments for depression.
- While a number of different medicines were present in the treatment area, prescribing guidance emphasised that medicines should be prescribed on an individual basis.
- Evidence from GSK indicates that while GSK considered a number of medicines competed with Seroxat to some extent, GSK appears to have considered that the constraint from such medicines was relatively limited in comparison to the expected constraint from generic paroxetine.

4.23 While the above factors indicate that a number of antidepressant medicines may in principle be therapeutically substitutable with paroxetine to some degree, it is necessary to consider actual consumption patterns to determine whether the prescribing decisions of GPs was such that other antidepressants were capable of exerting a significant competitive constraint on paroxetine.

4.24 The Market Definition Notice states that *'functional interchangeability or similarity of characteristics may not, in themselves, provide sufficient criteria [to determine whether two products are demand substitutes], because the responsiveness of customers to relative price changes may be determined by other considerations as well.'*⁶⁵⁰ Moreover, the guidance states that the relevant evidence to assess whether two products are demand-side substitutes⁶⁵¹ includes *'evidence of substitution in the recent past,'* and that where such information is available *'it will normally be fundamental for market definition.'*⁶⁵² Consistent with this guidance, and with the approach taken in

⁶⁵⁰ Market Definition Notice, paragraph 36, which also states that: *'Conversely, differences in product characteristics are not in themselves sufficient to exclude demand substitutability, since this will depend to a large extent on how customers value different characteristics.'*

⁶⁵¹ Medicines that are 'demand-side substitutes' are those which are substitutable or interchangeable for the focal product, paroxetine, from a consumer's viewpoint.

⁶⁵² Market Definition Notice, paragraph 38.

the *AstraZeneca*,⁶⁵³ *Reckitt Benckiser*⁶⁵⁴ and *Servier*⁶⁵⁵ cases, the CMA considers that what primarily matters for the definition of the relevant product market is the extent to which different product types can be expected to materially constrain the conduct of a given undertaking:

*'When products such as pharmaceutical products can be broadly used for the same purpose but differ in terms of price, quality, consumer preferences or other significant attributes, the products are considered to be differentiated. Although differentiated products may 'compete' in some dimensions, a relevant market in competition cases should only include those products that are capable of significantly constraining an undertaking's behaviour and of preventing it from behaving independently of an effective competitive pressure.'*⁶⁵⁶

4.25 In this case, while the qualitative evidence demonstrated a number of other SSRIs were therapeutically similar to paroxetine, such evidence was inconclusive as to the extent of competitive constraint exerted by other medicines in the treatment area because such evidence only provided information on how the medicines in the treatment area might interact *in theory*. It is however necessary to analyse actual consumption patterns to determine the extent of the competitive constraints from other medicines on paroxetine *in practice*, in particular because prescribing literature does not provide evidence of how GPs prescribed different medicines in practice, and how GPs with a lack of price awareness of different medicines responded to the prices charged for the formulations within the treatment area. In fact, a quantitative analysis of the actual consumption patterns demonstrates that the relevant market in this case should be no wider than the supply of paroxetine in the UK. In particular, during the relevant period, other treatments for depression (including other SSRIs) did not prevent a monopolist supplier of paroxetine (GSK) from sustaining prices and profits that were significantly higher prior to true generic competition than could be sustained thereafter. In summary:

- The CMA finds that prior to independent generic paroxetine entry, competition from all other medicines in the treatment area had been insufficient to prevent GSK, as the only supplier of paroxetine, from sustaining prices and profits that were significantly higher than it could

⁶⁵³ Commission Decision of 15 June 2005, *AstraZeneca*, Case COMP/A. 37.507/F3.

⁶⁵⁴ Decision No. CA98/02/2011, *Reckitt Benckiser*, 12 April 2011.

⁶⁵⁵ Commission Decision of 9 July 2014, *Perindopril (Servier)*, Case AT.39612.

⁶⁵⁶ Commission Decision of 15 June 2005, *AstraZeneca*, Case COMP/A. 37.507/F3, paragraph 370.

sustain following independent generic entry. Prices were some 90%⁶⁵⁷ higher and profits were around 8.5 times higher⁶⁵⁸ than those observed following independent generic entry.

- This analysis is consistent with evidence from GSK, which indicates that while GSK considered a number of medicines competed with Seroxat to some extent, GSK appears to have considered that the constraint from such medicines was limited when compared to the threat of generic paroxetine entry.
- The CMA considers that the only plausible explanation for these trends is that other antidepressant medicines were not sufficiently close competitors to paroxetine to be regarded as belonging to the same relevant market as paroxetine.⁶⁵⁹

4.26 The CMA therefore concludes that the relevant market is no wider than the supply of paroxetine in the UK.

ii) Dominance

4.27 The CMA finds that GSK held a dominant position within the UK paroxetine market at least between January 1998 and November 2003. In particular:

- GSK's market share for the supply of finished product to pharmacies/wholesalers (by volume) was in excess of 60% and it remained the sole manufacturer of paroxetine sold in the UK between January 1998 and November 2003 (with a market share by value or volume of 100% at the production level).
- Prior to independent generic entry, GSK was able to sustain prices and profits that were significantly higher than those observed following generic

⁶⁵⁷ Calculated by comparing the average paroxetine price for September–November 2003 of £0.54 per DDD with the average paroxetine price for September–November 2004 of £0.28 per DDD.

⁶⁵⁸ Calculated by comparing average annual profits between 2001 and 2002 of £48.7 million with profits of £5.8 million in 2005. These are profits on GSK's sales of Seroxat 20mg and Seroxat 30mg in the UK, and as such, do not include profits from parallel imports credited to GSK's UK business or from sales to the Generic Companies pursuant to the Agreements.

⁶⁵⁹ Consistent with the CAT's position that issues of market definition overlap with the closely related question of whether an undertaking is dominant in a particular market (*Aberdeen Journals Limited v Director General of Fair Trading* [2002] CAT 4, at [101]), the CMA considers that GSK's ability to sustain prices and profits that were so far in excess of those which it was able to sustain following generic entry is indicative of both a narrow market definition of the supply of paroxetine only, and of GSK's market power. In particular, GSK's ability to sustain higher prices and profits prior to generic entry than subsequently demonstrates both the lack of competitive constraints from other medicines in the treatment area leading to a narrow market definition, and GSK's ability to behave independently of its competitors which is indicative of its market power.

entry. Prices were some 90% higher and profits were around 8.5 times higher than those observed following independent generic entry.

- Barriers to expansion were significant in this market. Parallel importers were limited in their ability to expand and exercise a greater competitive constraint on GSK. The volume restrictions imposed by GSK limited the competitive constraint from the Generic Companies that supplied its product.
- GSK's patents in relation to paroxetine represented a barrier to entry and, for as long as they remained unchallenged, enabled GSK to litigate, and seek injunctions, in response to the proposed market entry of potential competitors.
- Over the relevant period, the NHS did not exert countervailing buyer power vis-à-vis GSK for the supply of Seroxat.

4.28 The CMA's dominance assessment is at Section E.

D. Market Definition

i) The relevant product market

a) Introduction

4.29 The focal product in this case is paroxetine (brand name Seroxat). As outlined in more detail at paragraphs 3.22 to 3.46, paroxetine is an SSRI antidepressant primarily used to treat the symptoms of depression, social anxiety disorders (for example, panic disorder or generalized anxiety disorder), obsessive compulsive disorder and post-traumatic stress disorder.

4.30 As set out at paragraphs 3.96 to 3.99, GPs make a decision over which medicine to prescribe based on a range of factors including therapeutic substitutability. GPs may take into account the price of different medicines to some extent although the evidence demonstrates that GPs are relatively insensitive to price (see paragraph 3.95). On receipt of a prescription pharmacies are unable to substitute between molecules, however pharmacies can supply either a branded or generic product (if available) when faced with an open prescription for a particular molecule.

4.31 Prior to generic entry (as set out at paragraphs 3.53 to 3.57), branded manufacturers primarily compete by investing in marketing to influence GPs' prescribing behaviour. After generic entry has taken place, investment in marketing by branded manufacturers is likely to decrease significantly as price

competition between branded manufacturers and generic suppliers becomes the primary form of competition. This is because pharmacies are incentivised to substitute the cheapest product available when faced with an open prescription.

- 4.32 Given this context, the CMA has considered both marketing and prices in its analysis set out below to capture the change in focus from marketing-led competition as manufacturers compete for molecules to be prescribed by GPs prior to generic entry to price-led competition at the pharmacy level after generic entry has taken place. In particular, the CMA has considered whether the high prices observed prior to generic entry were simply a reflection of marketing focussed competition between branded manufacturers by taking account of profitability (see paragraph 4.75).

b) Qualitative analysis

The WHO, EPhMRA and the BNF classification systems

- 4.33 The Commission,⁶⁶⁰ the General Court (the 'GC')⁶⁶¹ and the CMA⁶⁶² have noted in previous decisions that a starting point for defining the relevant product market in the case of pharmaceutical products is the ATC classification system, which is recognised and used by EPhMRA, and the corresponding system maintained by the WHO. The relevant paragraphs of the BNF provide a useful indication of which products may belong to the same market.⁶⁶³ As a first step in identifying the products that may belong to the relevant market in this case, this sub-section therefore considers the position of paroxetine in relation to other medicines within the WHO and EPhMRA

⁶⁶⁰ Commission Decision of 28 February 1995, *Glaxo/Wellcome*, Case IV/M.555; Commission Decision of 10 March 1995, *Behringwerke AG/Armour Pharmaceutical Co*, Case IV/M.495 ; Commission Decision of 10 January 1996, *Adalat*, Case IV/34.279/F3 ; Commission Decision of 29 July 1997, *Ciba-Geigy/Sandoz*, Case IV/M.737; Commission Decision of 4 February 1998, *Hoffmann-La Roche/Boehringer Mannheim*, Case IV/M.950; Commission Decision of 26 February 1999, *Astra/Zeneca*, Case IV/M.1403; Commission Decision of 22 May 2000, Case IV/M.1878 *Pfizer/Warner-Lambert*; Commission Decision of 28 February 2001, *Abbott/Basf*, Case IV/M2312.

⁶⁶¹ Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraphs 154–156, upheld by the CJ in Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770.

⁶⁶² Decision No. CA98/02/2011, *Reckitt Benckiser*, 12 April 2011; Decision No. CA98/2/2001, *Napp Pharmaceutical Holdings Limited*, 30 March 2001; and Decision No. CA98/3/2003, *Genzyme Limited*, 27 March 2003.

⁶⁶³ For example, in its PPRS Market Study, the OFT noted that '*to treat a given condition, GPs choose between groups of medicines that are therapeutically substitutable... Often, but by no means always, the list of products appearing in a relevant 'Paragraph' of the British National Formulary (BNF) represents the available scope for choice.*' See *The Pharmaceutical Price Regulation Scheme, an OFT market study* (OFT885, February 2007), paragraph 2.31.

ATC classification systems, as well as their positions in the BNF, to identify similarities based on product characteristics and intended use.⁶⁶⁴

- 4.34 The classification systems indicate that paroxetine belongs to the ‘Antidepressants’ class (WHO ATC N06A, EPhMRA ATC N6A, BNF section 4.3), along with other SSRIs, tricyclic medicines, MAOIs and SNRIs.⁶⁶⁵ However, while in all three classification systems SSRIs constitute one sub-class, at the next level SSRIs do not belong to the same category as other antidepressants (see paragraph 3.37).

Prescribing considerations

- 4.35 This sub-section considers information that was relevant to GPs’ decisions as to which medicine to prescribe during the relevant period.⁶⁶⁶ The following factors are considered:

- modes of action;
- indications applicable to each medicine;
- therapeutic uses; and
- side effects.

Modes of action

- 4.36 Examining modes of action can provide important insights for the purposes of market definition in the pharmaceutical sector. To the extent to which they determine functional properties of the medicine, differences in modes of action set exogenous limits to the ability of various medicines to exercise material constraints on each other.
- 4.37 As set out at paragraphs 3.29 to 3.34, the mode of action of SSRIs is comparable to tricyclic antidepressants, MAOIs and most ‘Other Antidepressants’ (for example, the SNRI venlafaxine) because they all act to

⁶⁶⁴ For more information on the various classification systems, see Decision No. CA98/02/2011, *Reckitt Benckiser*, 12 April 2011, paragraphs 4.39–4.42.

⁶⁶⁵ See also tables at Annex N.

⁶⁶⁶ As set out at paragraph 3.23, paroxetine was primarily prescribed by GPs and was consequently sold through pharmacies rather than through hospitals. For example, sales to hospitals accounted for approximately 2.9% of GSK’s sales by value in 2002 (calculated based on the response dated 31 August 2012 to the Section 26 Notice dated 3 August 2012 sent to GSK (document 0772)). As such, the CMA does not consider that the limited sales being made in the hospital channel could have affected in any appreciable way the overall prices and volumes obtained through the pharmacy channel, such that any competitive constraints in relation to GSK’s behaviour regarding Seroxat could not have originated from the hospital distribution channel. Therefore, this analysis focuses on sales through the pharmacy channel.

prevent the re-uptake of neurotransmitters. SSRIs have a different mode of action from mood stabilisers and some 'Other Antidepressants'.

Indications

- 4.38 Despite the similarities in the modes of action of various antidepressants, there were material differences in the indications that the relevant medicines were licensed to treat during the relevant period.
- 4.39 For example, a Seroxat marketing brochure emphasised that Seroxat was licensed to treat a greater range of indications than other antidepressants,⁶⁶⁷ and included the table, reproduced below as Table 4.1, comparing different antidepressants and indications they were licensed to treat.⁶⁶⁸ GSK's [Finance Director A] highlighted the importance of specific indications by saying: *'it is naive to suggest that general practitioners do not prescribe specific types of SSRIs according to specific indications'*.⁶⁶⁹

⁶⁶⁷ GSK submitted that PTSD and social phobia (the indications for which Seroxat was the only licensed antidepressant) were minor indications accounting for less than 1% of prescriptions written during the relevant period. On this basis, GSK submitted, these smaller indications are immaterial for market definition purposes (see GSK SO Written Response (document 2755), paragraphs 3.75–3.78). However, given their relevance to prescriber behaviour, the CMA is satisfied that the smaller indications for which a given medicine is approved are relevant to an assessment of market definition. In this regard, the CMA notes that GSK sought to differentiate and competed on smaller indications (see GSK SO Written Response (document 2755), paragraph 3.84), and indeed described continued differentiation as *'crucial in light of new competitors entering the antidepressant market with increasing levels of marketing spend'* (see GSK SO Written Response (document 2755), paragraph 3.119), and that GSK must therefore have been of the view that such differentiation was worthwhile and material to a significant proportion of prescribers.

⁶⁶⁸ [REDACTED]WS, Exhibit [REDACTED]3 (document 0866), page 28.

⁶⁶⁹ [REDACTED]WS2 (GUK), Exhibit [REDACTED]6 (document 0887), paragraph 49.

Table 4.1: Seroxat licensed indications compared to other antidepressants

	Seroxat	Branded fluoxetine	Sertraline	Citalopram	Venlafaxine
Depression	✓	✓	✓	✓	✓
Depression accompanied by anxiety	✓	✓	✓		✓
Panic disorder	✓			✓	
OCD	✓	✓	✓		
Social phobia	✓				
Pre-Menstrual Dysphoric Disorder		✓			
PTSD	✓				

Source: Exhibit [X]3 to the [GSK's Marketing Manager A for Seroxat's] witness statement in the GUK Litigation dated September 2001 (document 0866), page 28.

Therapeutic uses

4.40 Medical guidelines provide advice on the prescription of paroxetine and antidepressants more generally in the treatment of depression.⁶⁷⁰ Medical guidelines therefore provide useful information on the therapeutic uses for paroxetine and other potential competitor medicines which can inform product market definition. The information presented below demonstrates that while the therapeutic uses of medicines in the treatment area were largely similar, GPs were advised to tailor their selection of a medicine to each patient's

⁶⁷⁰ The focus of this sub-section is on depression, as the other conditions which Seroxat was licensed to treat (anxiety disorders (generalized anxiety disorders and panic disorder) and obsessive-compulsive disorder) did not have separate guidelines until the publication of the National Institute for Health and Clinical Excellence ('NICE') guidelines from late 2004 onwards.

individual circumstances given the risk of intolerance to a particular first-line treatment.

4.41 The primary guideline available at the time providing information on therapeutic indications was the BNF guideline on antidepressants.⁶⁷¹ In addition to the BNF guidelines, the CMA has also consulted other guidelines and articles that were available at the time and which provided advice on prescribing antidepressants.⁶⁷² Key points highlighted by these guidelines are as follows (see paragraphs 3.36 to 3.46):

- Both the BNF and WFSBP guidelines advised that a range of antidepressants could be used to treat many patients.
- In terms of specific recommendations, both publications did however note that specific medicines may be more appropriate in certain circumstances, and that consideration should be given to the potential side effects of the available medicines.
- Although the guidelines did not recommend particular medicines for the treatment of particular conditions,⁶⁷³ they did recommend that when deciding which medicine to prescribe, physicians should take a wide range of factors into account.

4.42 The WFSBP guidelines reported that establishing the right treatment for any given patient could often require a process of trial and error. For example, it stated that *'regardless of the initial choice of antidepressant, about 30% to 50% of depressions will not respond sufficiently to adequately performed first-line treatment.'*⁶⁷⁴ In such a situation, if a patient failed to respond to the initial treatment, the recommendation in the BNF guidelines was to either increase the dosage or switch to a different class of antidepressant.

⁶⁷¹ BNF Guidelines (document 2505), Antidepressant drugs, section 4.3. Although more recent BNF Guidelines exist which may provide different advice, the CMA has referred to the March 2001 guidelines because they fall within the Relevant Period (2001-2004) and therefore represent the information available to prescribers during the relevant period for this market definition.

⁶⁷² GSK stated in its response to the SO that, based on the responses from primary care trusts to a freedom of information request, the most frequently cited guidelines during the relevant period were the BNF Guidelines, the Maudsley Guidelines and the NICE Guidelines (GSK SO Written Response (document 2755), paragraphs 3.74(b), 3.136–3.138 and Annex 6).

⁶⁷³ For example, the WFSBP Guidelines for Biological Treatment of Unipolar Depressive Disorders, Part 1: Acute and Continuation Treatment of Major Depressive Disorder 2002 (document 2507), paragraph 2.12 state that *'although robust differences in tolerability, side effects and theoretical risk of drug-drug interactions are lacking, subtle differences exist and may be important in selecting the appropriate SSRI compound for the individual patient'*.

⁶⁷⁴ WFSBP Guidelines for Biological Treatment of Unipolar Depressive Disorders, Part 1: Acute and Continuation Treatment of Major Depressive Disorder 2002 (document 2507), page 7.

4.43 In relation to other indications, the BNF guidelines cited antidepressants in the treatment of panic disorders and social phobia, but they did not specify which type of antidepressant could be used.⁶⁷⁵ The BNF guidelines did not cite antidepressants for the treatment of anxiety.

4.44 These recommendations are consistent with those in the NICE guidelines. Although not published until later, the NICE guidelines⁶⁷⁶ were in development during the period of the Agreements,⁶⁷⁷ and as such, offer a balanced summary of the medical knowledge that was available at the time. The key difference between the NICE guidelines and those presented above is that the NICE guidelines made recommendations on the other conditions, in addition to depression, that Seroxat was licensed to treat as follows:

- Anxiety disorder: the NICE guidelines advised prescribing an SSRI or venlafaxine to treat an anxiety disorder because of their effectiveness.⁶⁷⁸ However, the guidelines warned that before prescribing venlafaxine practitioners should take into account the increased likelihood of patients stopping treatment because of side effects, and its higher cost compared with equally effective SSRIs.⁶⁷⁹
- Panic disorder and obsessive-compulsive disorder: the NICE guidelines considered that the initial pharmacological treatment should be an SSRI.⁶⁸⁰ Tricyclic antidepressants were advised as potential second-line treatments.

4.45 The CMA has also consulted the Maudsley Guidelines,⁶⁸¹ which are prescribing guidelines produced by the Maudsley hospital specifically in relation to psychiatric conditions, and although primarily intended for use by

⁶⁷⁵ BNF Guidelines (document 2505), Antidepressant drugs, section 4.3.

⁶⁷⁶ Specifically, NICE guidelines for Depression: Management of depression in primary and secondary care, December 2004 (document 2575), NICE guidelines for Anxiety: Management of anxiety (panic disorder with or without agoraphobia, and generalised anxiety disorder) in adults in primary, secondary and community care, December 2004 (document 2574) and NICE guidelines for Obsessive-compulsive disorder: core interventions in the treatment of obsessive-compulsive disorder and body dysmorphic disorder, November 2005 (document 2573).

⁶⁷⁷ In particular, the draft guideline on depression was released for consultation in September 2003, and had been in development since 2001. A Datamonitor In-Depth Analysis, Commercial Insight: Antidepressants, February 2004, Product Code: DMHC1942, page 7.

⁶⁷⁸ NICE guidelines for Anxiety: Management of anxiety (panic disorder with or without agoraphobia, and generalised anxiety disorder) in adults in primary, secondary and community care, December 2004 (document 2574), page 26.

⁶⁷⁹ NICE guidelines for Anxiety: Management of anxiety (panic disorder with or without agoraphobia, and generalised anxiety disorder) in adults in primary, secondary and community care, December 2004 (document 2574), page 28.

⁶⁸⁰ NICE guidelines for Obsessive-compulsive disorder: core interventions in the treatment of obsessive-compulsive disorder and body dysmorphic disorder, November 2005 (document 2573), pages 24 and 27.

⁶⁸¹ GSK stated in its representations that the Maudsley Guidelines were frequently consulted by those prescribing antidepressants during the relevant period (GSK SO Written Response (document 2755), paragraph 3.74).

prescribers and pharmacists working in secondary care, were also intended to be of benefit to general practitioners and community pharmacists. The recommendations in the Maudsley Guidelines are broadly in line with the other prescribing guidelines cited above, and in particular the advice that doctors should prescribe on an individual basis using a trial and error approach to choose the appropriate medicine for each patient.⁶⁸²

Side effects

- 4.46 Despite the similarities in the modes of action of several different classes of antidepressants, these medicines differed in their side effects, both between and within classes. For example, the WFSBP guidelines noted that *'Antidepressants differ in their side effect profile, potential to interact with other drugs and safety in overdose.'*
- 4.47 It is noteworthy that for any given medicine, the different guidelines did not present a consistent view of the side effects identified, which provides further support for the view in paragraph 4.41 that choice of medicine is heavily dependent on an individual's response and tolerance of side effects. For further information on specific differences in side effects for selected antidepressants, see the tables presented in Annex O.

Conclusion on prescribing considerations

- 4.48 When prescribing a medicine for one of the conditions for which paroxetine was licensed to treat, there were no clear-cut recommendations in the guidelines on which specific medicine should be preferred for a given condition and GPs would have faced a choice between a range of different antidepressant classes, and molecules within those classes, in particular, SSRIs, SNRIs and tricyclics. Given this, the prescribing guidelines recommended that GPs take a wide range of factors into account when prescribing and prescribe on an individual basis as patients often did not respond to the first medicine prescribed.

GSK witness evidence, internal documents and marketing literature

- 4.49 GSK provided evidence, including witness statements and contemporaneous documents, containing information on its perception of the main competitors to Seroxat. GSK's assessment provides a useful insight into the extent to which it considered SSRIs and other antidepressants constrained prices or

⁶⁸² Maudsley Guidelines (document 3255), page 59.

sales of Seroxat, and helps to provide context for its assessment of how competitor activity relating to antidepressants would impact upon Seroxat. In assessing these documents, the CMA observes that the evidence of most significance to an analysis of market definition is objective evidence that relates to the parameters of competition such as considerations of a pricing response to the entry of a new competitor product, commentary around how a new product launch is affecting sales and assessments of how changes to GSK's own product portfolio may have an impact upon the sales and pricing strategies of its competitors.

- 4.50 As set out below, in witness statements provided in the period prior to the onset of independent generic entry, GSK officials described the competitive constraints faced by GSK in general terms. GSK officials stated that Seroxat competed with various formulations, and identified Cipramil and Cipralex as its closest or key competitors. However, GSK officials also explained that independent generic entry would lead to significant price, profit and market share erosion, which suggests that competition from other formulations did not prevent GSK from sustaining significantly higher profits than it could sustain thereafter.
- 4.51 The extent of competition faced by Seroxat was discussed by the relevant marketing manager, [REDACTED], in a witness statement relevant to the GUK Litigation. It was stated that competition had been intense among antidepressants, which had led to high marketing expenditures and competitive pricing.⁶⁸³ In the same document, [GSK's Marketing Manager A for Seroxat] identified the '*major antidepressants on the United Kingdom market with which SEROXAT competes*' to be other SSRIs (citalopram, fluoxetine, fluvoxamine, nefazodone, paroxetine and sertraline), SNRIs (reboxetine and venlafaxine), tricyclics (amitriptylene and dothiepin) and mirtazapine.⁶⁸⁴
- 4.52 More specifically, [GSK's Marketing Manager A for Seroxat] stated that '[Seroxat's] *closest branded competitor is CIPRAMIL (citalopram)*'.⁶⁸⁵ Indeed, he said that responding to competitive pressures, especially from Lundbeck (the supplier of Cipramil), was a major reason for the list price reduction⁶⁸⁶ of Seroxat 20mg from £33.90 when it was launched to £17.76 in October

⁶⁸³ [REDACTED]WS (document 0150), paragraph 2.1.

⁶⁸⁴ [REDACTED]WS (document 0150), paragraph 2.3.

⁶⁸⁵ [REDACTED]WS (document 0150), paragraph 2.4.

⁶⁸⁶ See footnote 1896 which explains that at least some of this price decrease was required as part of the PPRS required price falls.

1999.⁶⁸⁷ A quantitative analysis of the extent of competition between paroxetine and citalopram is considered at paragraphs 4.91 to 4.93.

- 4.53 In the view of the then Seroxat Marketing Manager, [REDACTED] (who succeeded [GSK's Marketing Manager A for Seroxat] in that role), Cipralex (escitalopram, also marketed by Lundbeck) became Seroxat's key competitor following Cipramil's patent expiration at the beginning of 2002. In a witness statement, [GSK's Marketing Manager B for Seroxat] stated that *'The key competitor to SEROXAT is now CIPRALEX as Lundbeck have switched their resources from CIPRAMIL to CIPRALEX.'*⁶⁸⁸
- 4.54 However, a contemporaneous witness statement indicates that even the competitive constraint from the medicine identified as paroxetine's closest competitor, citalopram (brand name Cipramil), may have been limited. In reference to the impending genericisation of Cipramil (and the expected decline in citalopram prices), [REDACTED] (Finance Director [A] of GSK) stated that *'the extent of switching from paroxetine to citalopram in the next six months is likely to be very small.'*⁶⁸⁹ Among the reasons that [GSK's Finance Director A] highlighted for this are:
- the differences between the indications for which citalopram and paroxetine were approved, stating that *'Citalopram is only approved for two of the seven indications for which paroxetine is approved and it is naïve to suggest that general practitioners do not prescribe specific types of SSRI according to specific indications';* and
 - lack of product awareness and price sensitivity on the part of doctors: *'since generic companies spend so little in marketing and hardly ever promote to doctors, it can take a surprisingly long time for doctors to appreciate that a product which competes with the product which they*

⁶⁸⁷ [REDACTED]WS (document 0150), paragraph 2.2.

⁶⁸⁸ Witness statement of [GSK's Marketing Manager B for Seroxat] in the Apotex Litigation, dated 22 October 2002 (document 0328), paragraph 4.6. GSK submitted that the section of [GSK's Seroxat Marketing Manager B's] witness statement the CMA has quoted does not support the CMA's case, and instead indicates the importance of non-price competition as Lundbeck switched its focus from Cipramil to promotion of Cipralex in response to GSK's own promotion of Seroxat. (GSK SO Written Response (document 2755), paragraph 3.110). The CMA recognises that [GSK's Seroxat Marketing Manager B's] witness statement refers to non-price competition between Seroxat and Cipralex. However, given that GSK was able to sustain profits that were far higher prior to true generic competition than subsequently (see paragraphs 4.78–4.84), it is evident that [GSK's Seroxat Marketing Manager B's] statement does not imply that the extent of competition was such that paroxetine and escitalopram belong to the same relevant market. GSK's representations on Lundbeck's change in focus on its marketing are considered further at paragraphs C.27–C.28.

⁶⁸⁹ [REDACTED]WS2 (GUK), Exhibit [REDACTED]6 (document 0887), paragraph 49. This comment was made to directly refute [GUK's General Manager's] suggestion that [GSK] *must be extremely concerned about the impending genericisation of Cipramil* [and the consequent decline in citalopram prices] [REDACTED]WS (document 0901), paragraph 67.

usually prescribe is available generically. Also, doctors in the UK do not tend to be particularly sensitive to the cost of competing products.'

- 4.55 In the context of assessing damages, GSK considered that independent generic entry by GUK would *'inevitably have a long-term effect on the drug's pricing structure.'*⁶⁹⁰ In particular, [GSK's Finance Director A] stated that *'If [GUK] is not injuncted until the trial of this action the entire pricing structure of paroxetine will have changed. As I have said above the launch of [GUK's] product will result in commercial pressure for other generic companies to enter also. I believe it will therefore precipitate a premature decline in the price paid by pharmacists for paroxetine.'*⁶⁹¹ That GSK was making comparatively large profits that could be protected by delaying the threat of independent generic entry must mean that the extent of competition that paroxetine faced from other medicines was limited, such that profits had not been eroded to competitive levels prior to generic entry.
- 4.56 Similarly, as set out at paragraphs 3.161 to 3.164, GSK was aware that independent generic entry would lead to significant price, profit and market share erosion and was developing strategies, such as supply agreements with generic companies, to prevent this. These assessments demonstrate that GSK considered that competition from generic paroxetine would be more effective than competition from other antidepressants had been in constraining Seroxat prices and profits:
- A presentation entitled *'Overview of Generic Defences and Impact on Price Strategy'* considered possible defence strategies for Seroxat, including strategies to *'Maintain monopolistic position [...] Third party supply agreement'*.⁶⁹²
 - As part of GSK's strategy of concluding supply agreements, GSK had identified that it was important to select a *'big generic company'* to partner

⁶⁹⁰ [X]WS1 (GUK) (document 0885), paragraph 6.1.

⁶⁹¹ [X]WS1 (GUK) (document 0885), paragraph 9.1.

⁶⁹² GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100). Given that this statement was made in the context of a presentation within a project tasked with defending Seroxat from generic competition, the CMA considers that [GSK's Pricing Manager for Europe] intended to refer to its 'monopoly' position rather than 'monopolistic' position. The CMA notes that GSK submitted that in this context [GSK's Pricing Manager for Europe] was using the word 'monopolistic' to refer colloquially to maintaining the integrity of the patent in terms of the ability it confers to oppose patent infringement, rather than to define a market in the competition law sense (GSK SO Written Response (document 2755), paragraph 3.117). The CMA considers that its interpretation of this document is consistent with an understanding that [GSK's Pricing Manager for Europe's] comment was made in the context of protecting Seroxat from generic competition.

with so that it would be able to '*control the market*'⁶⁹³ in the relevant country in question.⁶⁹⁴

- By entering into supply agreements with large generic suppliers GSK found that it could '*Maintain peace and quiet, both in GSK and in the market.*'⁶⁹⁵
- One of GSK's (draft) stated strategies for its lifecycle management of paroxetine was to '*[d]evelop line extensions and indications in order to protect the brand from generic and competitor erosion*'.⁶⁹⁶

4.57 There are a limited number of documents in which GSK makes reference to its strategy relative to its competitors. For example:

- An internal memorandum considering the strategic rationale for changes in GSK's pricing in the 1999 PPRS noted as one factor that '*All of Seroxat's competitors are competing on a price platform*'. However, although this reference to price competition suggests GSK perceived there were some constraints from other antidepressants, the proposed PPRS price decrease was, of itself, expected to be unprofitable for GSK.⁶⁹⁷ This demonstrates that absent the 1999 PPRS, GSK expected that it would not have been profitable to respond to those constraints by lowering its price. From this the CMA infers that competition from other antidepressants was not sufficient to prevent GSK from sustaining the higher price.

⁶⁹³ GSK presentation entitled 'Generic offence strategy in Germany' by [GSK's Head of Marketing (CNS Gastro & Urology)](document 0094).

⁶⁹⁴ The CMA notes that GSK submitted that as this document refers to the position in Germany it is not relevant to the UK position (GSK SO Written Response (document 2755), paragraph 3.117). However, given that this document is referring to the rationale for entering into supply agreements, the CMA considers it reasonable to infer this rationale was also applicable to the UK.

⁶⁹⁵ GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100).

⁶⁹⁶ GSK internal paroxetine report entitled 'Integrated Project Plan, Paroxetine/Paxil/Seroxat' dated 2 August 2002 (document 0301). GSK submitted that in quoting this document the CMA has misunderstood that the line extensions to which the document refers are not relevant in the EU, or, therefore, to the CMA's case (GSK SO Written Response (document 2755), paragraph 3.119). However, the CMA does not consider that this undermines the CMA's use of this document to illustrate the range of steps GSK was taking in preparing for independent generic entry.

⁶⁹⁷ SmithKline Beecham document entitled 'PPRS pricing strategy' (document D155). GSK submitted that GSK's PPRS pricing team had confirmed that the price impact of a list price change was calculated based on actual volumes, and therefore this document does not show that the price decrease was expected to be unprofitable for GSK (GSK response dated 25 September 2015 to the Second Letter of Facts, document 4159). The relevant document refers to modulation being used to deliver greater savings to DH than the impact on SB profits and notes that '*By using modulation to SB's competitive advantage, the benefits of the price cut will deliver to DoH £15.0M while impacting SB profits by an estimated £6.9M in 2000. This upside of £8.1 M is generated by market share gains through competitive pricing of Seroxat, and maximising the cushioning effect of equalisation deals and rebates through effective targeting of the price decrease using Amoxil, Floxapen and Fluarix.*' From this, the CMA considers it is clear that the forecast of the impact of PPRS took into account volume gains as a result of the proposed price change and was not based, as GSK submitted, on actual volumes.

- One document contains a SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis which refers to fluoxetine generic entry specifically by noting the opportunity that *'Fluoxetine patent expiry will lower promotional spend from Lilly'* and the threat that *'[I]aunch of generic fluoxetine impacts market share and/or price.'*⁶⁹⁸

- 4.58 Although a number of internal documents do monitor all antidepressants within category N6A of the ATC classification, and present market shares within this context,⁶⁹⁹ the CMA considers that such documents are of limited value as they do not provide objective evidence as to the competitive responses that GSK considered appropriate in response to changes within the treatment area (see paragraph 4.49). For example, these presentations do no more than refer to key competitors or present market shares for a selection of medicines.⁷⁰⁰ The CMA notes that although the specific medicines mentioned varied, citalopram and fluoxetine were virtually always amongst those cited, and escitalopram, venlafaxine, sertraline and mirtazapine were sometimes cited.⁷⁰¹
- 4.59 There are a number of qualitative features of Seroxat which GSK relied upon in its marketing materials in an attempt to differentiate its product from other

⁶⁹⁸ 'Seroxat/Paxil Global 3/1 Product Plan (2001/2003)' dated April 2000 (document 0118), page 18.

⁶⁹⁹ See for example, GSK presentation entitled 'Seroxat Salts Update' dated 14 December 2001 (document 0192), slide 15, GSK presentation entitled 'Generic offence strategy in Germany' by [GSK's Head of Marketing (CNS Gastro & Urology)] undated (document 0094), slide 8, GSK presentation entitled 'Seroxat – Sales 2002 and future budget' dated 2002 (document 0194), page 3 and GSK internal document entitled 'European Commercial Development June Monthly Report' undated (document 0089), page 4.

⁷⁰⁰ Teva submitted that this statement is not correct as the available evidence shows the extent to which paroxetine competes with other antidepressants or SSRIs (see Teva Response dated 3 July 2013 to the SO ('Teva SO Written Response') (document 2750), paragraph 246). Having reviewed the documents cited by Teva, the CMA continues to be satisfied that these documents merely observe the strategy of other SSRI suppliers, rather than detailing GSK's proposed approach in response.

⁷⁰¹ See, for example:

- GSK presentation entitled 'Seroxat Salts Update' dated 14 December 2001 (document 0192), slide 15 contains a graph of market shares for citalopram, fluoxetine, sertraline and paroxetine.
- GSK presentation entitled 'Generic offence strategy in Germany' by [GSK's Head of Marketing (CNS Gastro & Urology)] undated (document 0094), slide 6 and 12 contain graphs comparing market shares and sales values for Seroxat, fluoxetine, citalopram (Cipramil), sertraline (Zoloft), mirtazapine (Remergil) and venlafaxine (Trevilor).
- Extract from CNS Psychiatry- Depression and Anxiety document (document 0105), pages 8 and 9. The main competitors in an anxiety context and a depression context are listed as being *'Ciprallex (escitalopram), Effexor (Venlafaxine), Alternative salt forms of paroxetine'*. Additionally on page 3 a chart of prescriptions numbers for use treating anxiety presents data for paroxetine, fluoxetine, citalopram, sertraline, and venlafaxine.
- GSK internal document entitled 'European Commercial Development June Monthly Report' undated (document 0089) contains a table on page 4 comparing Seroxat to citalopram (Cipramil), venlafaxine (Effexor), sertraline (Zoloft), mirtazapine (Remeron) and fluoxetine (Prozac).
- GSK internal paroxetine report entitled 'Integrated Project Plan, Paroxetine/Paxil/Seroxat' dated 2 August 2002 (document 0301), page 10 states that *'Primary competitors pose the greatest threat and include fluoxetine, sertraline, venlafaxine, citalopram, escitalopram and duloxetine.'*

antidepressants. GSK's marketing materials sought to differentiate Seroxat in the following ways:⁷⁰²

- on the basis of its anxiolytic profile⁷⁰³ in order to demonstrate superior efficacy, *'60-90% of depressed patients will also suffer anxiety symptoms'*,⁷⁰⁴
- on the basis that no other antidepressant molecule was indicated for the full range of depression and anxiety disorder indications, for example *'Seroxat treats a wider range of anxiety symptoms than any other antidepressant'*,⁷⁰⁵
- by making direct comparisons with other SSRIs to demonstrate Seroxat's superiority on a range of features such as indications, side effects and cost, for example:⁷⁰⁶
 - *'Citalopram and Escitalopram do not have a licence for depression accompanied by anxiety'*.
 - *'Citalopram and Escitalopram are only licensed for the treatment of depression and panic disorder'*.
 - *'Seroxat has more licensed indications than fluoxetine'*.
 - *'Anxiety and agitation are more common with fluoxetine (15%) than other SSRI's (1-8%)'*.
 - *'A once daily dose of [venlafaxine] 75mg costs 85p compared to Seroxat 20mg once daily dose, which costs 59p'*.
- Emphasising Seroxat's safety profiles and its comparatively fast onset within the first week of treatment.⁷⁰⁷

4.60 Internal strategy documents demonstrate that GSK perceived product differentiation to be important for maintaining its competitive advantage, and that it was effective:

⁷⁰² GSK stated that manufacturers spent significant sums seeking to differentiate their very similar SSRI products in order to win sales, and that such activity would only be rational when manufacturers were competing strongly with each other (GSK SO Written Response (document 2755), paragraphs 3.84–3.85, 3.122 and 3.140–3.142).

⁷⁰³ This relates to inhibiting anxiety.

⁷⁰⁴ GSK document entitled 'Seroxat Promotional Campaign Brief August 2003' (document D 091), page 4.

⁷⁰⁵ GSK document entitled 'Seroxat Promotional Campaign Brief August 2003' (document D 091), page 4.

⁷⁰⁶ GSK document entitled 'Seroxat Promotional Campaign Brief August 2003' (document D 091), page 6.

⁷⁰⁷ [REDACTED]WS, Exhibit [REDACTED]3 (document 0866), pages 10, 23 and 27.

- the 2002-2004 Seroxat Strategic Marketing Plan stated that *'[s]trong anxiety profile and range of indications gives established differentiation'* and noted as a driver of growth that the market is *'responsive to promotion'*⁷⁰⁸
- GSK's pricing strategy was to maintain prices at current levels with the focus instead on driving brand differentiation and maintaining profitability.⁷⁰⁹
- GSK's pre-clinical strategy sought to support the message that *'all SSRI's are not the same'* and to exploit pharmacological and metabolic differences in the profiles of different SSRIs, which can be linked to clinical differences.⁷¹⁰
- GSK's 2003-2005 Strategic Marketing Plan⁷¹¹ noted that one of the strengths of Seroxat was that it *'has a wide usage across GP's, is well known and has strong familiarity'*, and in a chart ranking different medicines based on whether each had a *'clear and compelling proposition'*, GSK placed Seroxat second to citalopram but ahead of escitalopram, sertraline, venlafaxine and fluoxetine.
- The importance of developing new indications to increase Seroxat's differentiation was highlighted by [GSK's Finance Director A] who attributed a 12% increase in prescriptions for paroxetine (in 2000) to GSK's *'continuing investment in marketing and in developing and approving new indications.'*⁷¹²

4.61 Overall, the CMA considers that GSK's documents demonstrate that GSK perceived there to be a number of competing products in the relevant treatment area, with citalopram, fluoxetine and escitalopram being most frequently cited. GSK's marketing materials also indicate a degree of competition between Seroxat and these products, as GSK sought to use its marketing to differentiate Seroxat versus those products. However, a number of documents demonstrate that GSK considered those medicines to constrain paroxetine only to a limited extent when contrasted to the anticipated impact of generic entry. In particular, its documents refer to an expectation that (i) generic entry in relation to citalopram would result in only limited switching from paroxetine to citalopram, and (ii) generic entry in relation to paroxetine

⁷⁰⁸ GSK document entitled 'Strategic Marketing Plan 2002-2004, Seroxat' (document A0078), pages 21 and 22.

⁷⁰⁹ GSK document entitled 'Strategic Marketing Plan 2002-2004, Seroxat' (document A0078) and GSK document entitled 'Strategic Marketing Plan 2003 -2005, Seroxat' (document A0079), page 26.

⁷¹⁰ 'Seroxat/Paxil Global 3/1 Product Plan (2001/2003)' dated April 2000 (document 0118), page 24.

⁷¹¹ GSK document entitled 'Strategic Marketing Plan 2003-2005, Seroxat' (document A0079), pages 16 and 22.

⁷¹² [REDACTED]WS1 (GUK) (document 0885), paragraph 3.2.

would result in price and profit decreases, with the implication that prior to that time competition from competing medicines had not prevented GSK from sustaining prices and profits that were significantly higher than could be expected following independent generic entry.

Conclusion on qualitative evidence

4.62 The key aspects of the evidence outlined above can be summarised as follows:

- Paroxetine and other SSRIs such as citalopram or fluoxetine, as well as other molecules such as venlafaxine, were generally considered to each be suitable treatments for depression. In particular, escitalopram, citalopram and fluoxetine were identified by GSK as being the closest competitors to paroxetine.
- While a number of different medicines were present in the treatment area, prescribing guidance emphasised that medicines should be prescribed on an individual basis given that often a first-line treatment may not be well tolerated.
- Evidence from GSK demonstrates that while GSK considered a number of medicines competed with Seroxat to some extent, GSK considered that the constraint from such medicines was relatively limited in comparison to that of true generic competition.

4.63 The CMA considers that because GPs may value different characteristics differently and may therefore differentiate between products that appear to have similar characteristics, considering functional substitutability is insufficient to determine which products are capable of exerting a significant competitive constraint on paroxetine as this only provides information on how medicines may interact *in theory*, and is by itself inconclusive. Given this, and GPs' apparent lack of price awareness, it is necessary to consider actual consumption patterns as a means of determining whether, in practice, the degree of product differentiation was such that GPs would substitute between products to an extent that would prevent a monopolist supplier of paroxetine from sustaining a SSNIP. The CMA notes that such an approach is consistent with the Market Definition Notice (see paragraph 4.24).

4.64 The next sub-section considers the quantitative evidence relevant to paroxetine and the products considered by GSK to be its closest competitors,

and the extent to which such products were demand-side substitutes that were significantly constraining GSK's behaviour.⁷¹³

c) Quantitative analysis

Introduction

- 4.65 This sub-section considers whether, in the context of the differentiation that existed between medicines in the relevant treatment area, such medicines were in practice regarded as demand-side substitutes to such a degree that they formed part of the same market.
- 4.66 The qualitative evidence detailed above allowed the CMA to identify a category of potential substitutes. For the purposes of the analysis in this sub-section, the CMA has focussed on those products identified in GSK's documents as being the closest potential substitutes to paroxetine, that is, citalopram, escitalopram and fluoxetine (see paragraph 4.61). Further, by considering the impact of true generic competition on paroxetine, an assessment can be made of the extent to which competition from all medicines in the treatment area was, until that time, capable of constraining paroxetine. If the products regarded as being the closest alternatives to paroxetine are found not to have exercised a competitive constraint on paroxetine that is as significant as that from generic paroxetine itself, then it can be presumed that alternatives that are perceived to be less close substitutes would have exercised even less of a competitive constraint. In the absence of a constraint that prevented GSK from sustaining significantly higher prices and profits prior to the emergence of generic paroxetine, it can be concluded that the relevant market should be limited to paroxetine only.

Prescribing data

- 4.67 The sub-section above on prescribing considerations (see paragraphs 4.35 to 4.48) indicated that although there were no clear-cut recommendations in the guidelines on which specific medicine would be preferred for a given condition, there were differences between the medicines in terms of individual

⁷¹³ This is consistent with the Commission's approach in *AstraZeneca*, where it noted that '*although differentiated products may 'compete' in some dimensions, a relevant market in competition cases should only include those products that are capable of significantly constraining an undertaking's behaviour and of preventing it from behaving independently of an effective competitive pressure.*' See Commission Decision of 15 June 2005, *AstraZeneca*, Case COMP/A. 37.507/F3, paragraph 370.

tolerability such that GPs would need to take a wide range of factors into account when prescribing.

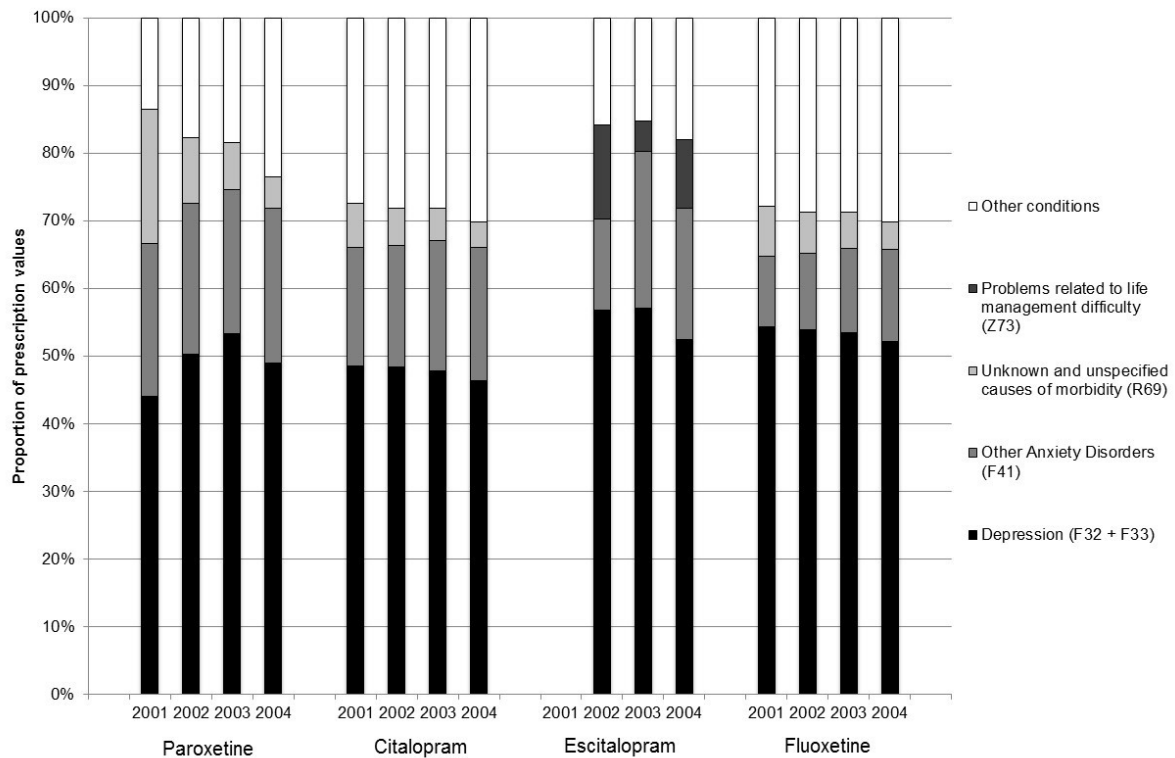
- 4.68 To assess whether there were significant differences between the conditions that antidepressants were used to treat, the CMA has analysed prescribing data⁷¹⁴ for the conditions⁷¹⁵ for which Seroxat and several other antidepressants were prescribed.
- 4.69 As illustrated in Figure 4.1, the analysis for paroxetine and the three largest SSRIs in prescription value terms (citalopram, escitalopram and fluoxetine) for the period 2001 to 2004 shows that there are similarities between the conditions they were being prescribed to treat:
- Depression was the main condition for which these medicines were prescribed, and accounted for a proportion varying between 40 and 60% of total prescriptions value for each medicine in each year.⁷¹⁶
 - The second largest condition in prescriptions shares for all four SSRIs was 'Anxiety Disorder', accounting for between 11 and 24% of total prescriptions' value.

⁷¹⁴ IMS diagnostics data dated 6 December 2011, supplied by GSK in response to the GSK Section 27 Notice (document 0680).

⁷¹⁵ Conditions are categorised according to the International Classification of Diseases Revision 10. The CMA has separately identified conditions which accounted for more than 5% of prescription values in any given year. All other conditions are captured within the category 'Other'. The CMA has combined categories 'F32 – depressive disorder' and 'F33 – recurring depressive disorder', into a category called 'depression'. It was not always possible to separately identify prescriptions for certain conditions. For example, generalised anxiety disorder and panic disorder both fall within the category of 'F41 other anxiety disorders', PTSD comes under the category of 'reaction to severe stress and adjustment disorders' and Social phobia falls within the category of 'phobic anxiety disorders'. Neither of the latter categories are separately identified as prescription values amounted to less than 5% in any given year.

⁷¹⁶ Source: IMS diagnostics data dated 6 December 2011, supplied by GSK in response to the GSK Section 27 Notice (document 0680).

Figure 4.1: Prescription values for paroxetine, citalopram, escitalopram and fluoxetine, 2001-04⁷¹⁷



Source: IMS diagnostics data dated 6 December 2011, supplied by GSK in response to the GSK Section 27 Notice (document 0680).

4.70 The CMA has also reviewed the number of times that each of paroxetine, citalopram, escitalopram and fluoxetine were prescribed to treat depression or anxiety conditions.⁷¹⁸ As illustrated in Figures 4.2 and 4.3:⁷¹⁹

- Between 2001 and mid-2002 citalopram, fluoxetine and paroxetine were all popular treatments for depression. However, from early 2002 onwards the use of paroxetine to treat depression declined (see paragraph 4.88).
- Until mid-2002 paroxetine was prescribed more often than either citalopram or fluoxetine to treat anxiety conditions. However, after this date, and following the launch of escitalopram, its use declined while that

⁷¹⁷ Escitalopram was not available until May 2002.

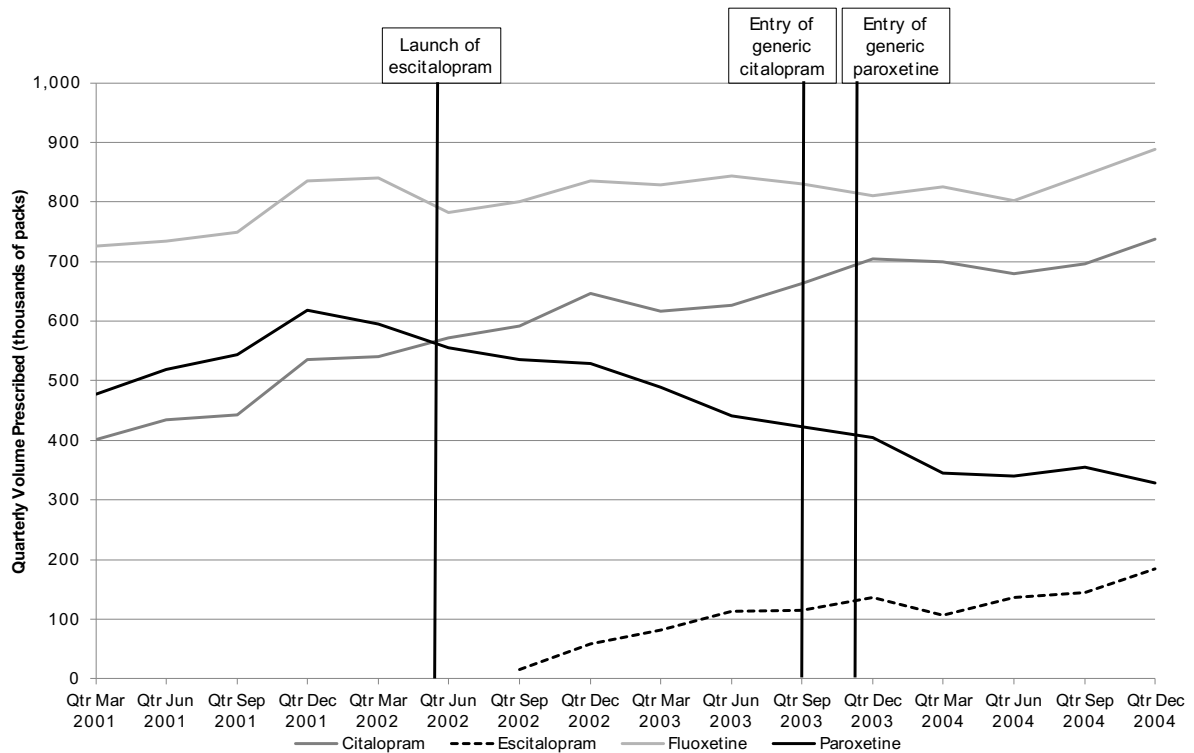
⁷¹⁸ In its representations, GSK cited this paragraph as evidence that the CMA had not paid due attention to the existence of co-morbidity (GSK SO Written Response (document 2755), paragraph 3.83). The CMA notes in this regard that the reason it has presented the data separately for depression or anxiety conditions is that it was not possible to separately identify a 'both' category within the data.

⁷¹⁹ The CMA has chosen to use volume data rather than value data in order to identify changes in overall prescribing numbers, without trends being driven by changes in relative medicine prices. The CMA notes that as this data has been derived from prescription values and average price per pack, it does not take account of different pack sizes or strengths, and as such, volumes are average volumes.

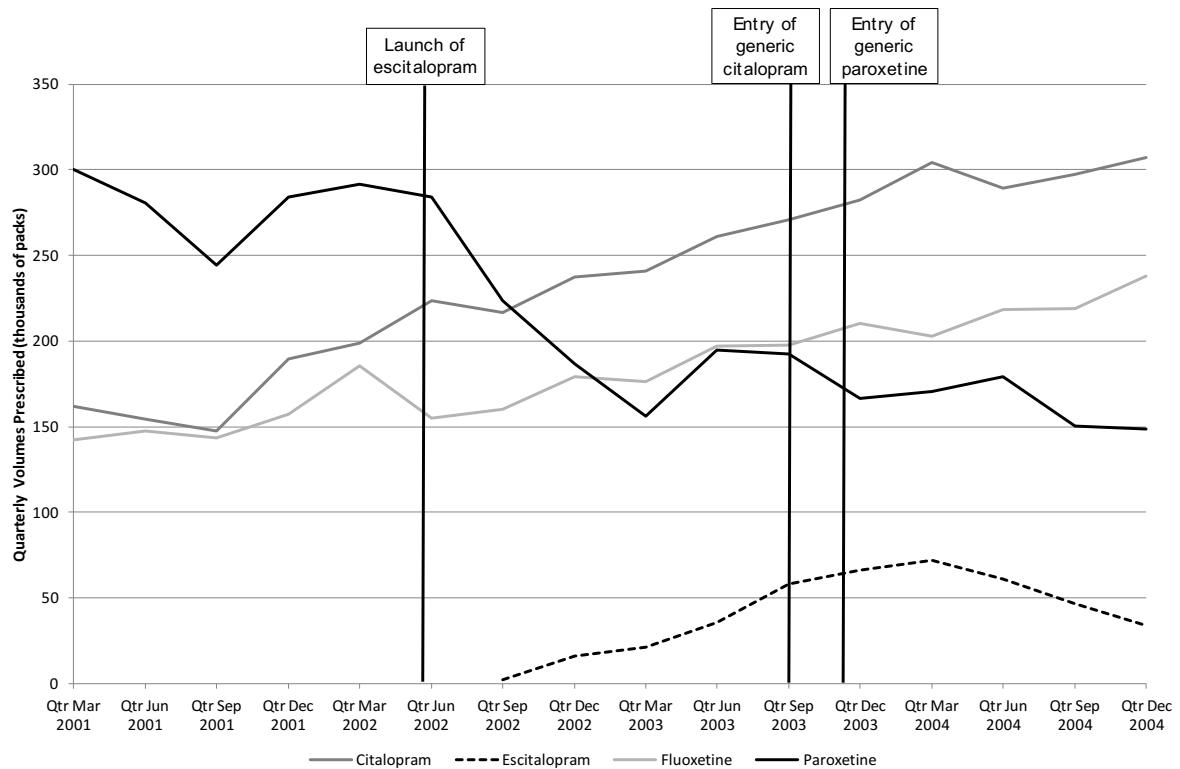
of citalopram and fluoxetine increased, such that citalopram and fluoxetine were preferred treatments by the end of the period.

- Overall diagnosis volumes for escitalopram remained relatively low for both depression and anxiety during the period.

Figure 4.2: Prescription volumes (000s) for Depression



Source: IMS diagnostics data dated 6 December 2011, supplied by GSK in response to the GSK Section 27 Notice (document 0680).

Figure 4.3: Prescription volumes (000s) for Anxiety

Source: IMS diagnostics data dated 6 December 2011, supplied by GSK in response to the GSK Section 27 Notice (document 0680).

Sales and prices analysis

4.71 This sub-section presents a quantitative analysis of the extent of the competitive constraint imposed on paroxetine by the medicines identified in GSK's documents as paroxetine's closest competitors: citalopram, escitalopram and fluoxetine. This is examined using a natural events analysis and by reviewing relevant price and sales trends.⁷²⁰

4.72 The CMA has identified the natural events related to those medicines identified by GSK's documents to be paroxetine's closest competitors,

⁷²⁰ In *AstraZeneca*, the GC found that the specific circumstances of the pharmaceutical sector (for example, the extent of price regulation) did not undermine the use of pricing data in market definition analysis, but noted that the specific features of the sector must be recognised when determining the significance of such data: *'the specific features which characterize competitive mechanisms in the pharmaceutical sector do not negate the relevance of price-related factors in the assessment of competitive constraints, although those factors must be assessed in their specific context.'* Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 183. The CJ subsequently upheld the GC's findings on appeal (Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraphs 170–182).

citalopram, escitalopram, and fluoxetine, and considered these in detail. The following natural events are considered as part of the analysis:

- the entry of generic fluoxetine in Q4 1999;
- the launch of CipraleX (escitalopram) in Q2 2002;
- the entry of generic citalopram in Q4 2003;⁷²¹ and
- the entry of independently sourced generic paroxetine in Q4 2003.

4.73 A natural events analysis can be informative about the nature of competition encountered by the medicine in question, in this case paroxetine. If two products are close substitutes, then it is generally expected that a shock affecting the price or sales volumes of one product will be reflected by sales and/or price variation in the other. For example, it might be expected that if two medicines are close competitors then a substantial price decrease, such as after generic entry, in one medicine would be expected to result in a significant price and/or sales decrease on the part of competing medicines.

4.74 In analysing the impact of the natural events in the present case, the CMA notes that the events identified above all relate to entry, either of a generic version of a medicine (in the case of fluoxetine, citalopram and paroxetine) or a launch of a new product (in the case of escitalopram). To put these events in the context of the hypothetical monopolist test, the CMA observes that each entry is equivalent in analytical terms to a fall in prices of a potential competing product,⁷²² or, viewed another way, an increase in paroxetine prices relative to another product. Moreover, the observed relative increase in paroxetine prices is in general bigger than a SSNIP (which is the magnitude of price increase relevant for market definition, often 5 to 10%). Therefore, if no or limited switching was observed in response to such a price shock then it can be confidently concluded that there would be insufficient switching in

⁷²¹ It should be noted that although there was entry of generic citalopram suppliers in Q1 2002, generic entry to supply citalopram did not result in downwards pressure on average prices until Q4 2003. Therefore, it would not be informative for the purpose of defining the relevant market to include the earlier generic entry in the analysis. Indeed, in an internal document Lundbeck attributed the sharp drop in citalopram prices to intense price competition from new entrants supplying a generic version of citalopram. (Extract of Lundbeck Board of Management Report of November 2003 provided in response to the Section 26 Notice sent on 2 October 2012 (document 2346), page 2). The CMA observes that agreements concluded in 2002–2003 by Lundbeck with four generic competitors concerning citalopram were found by the Commission to have infringed Article 101 of the TFEU, and that decision is now subject to appeal (Commission Decision of 19 June 2013, *Lundbeck*, Case AT.39226). See http://europa.eu/rapid/press-release_IP-13-563_en.htm

⁷²² That is, entry is equivalent to a very large drop in the price of the product entering, essentially from an infinitely high price (such that none is sold) to a finite one.

response to a SSNIP to make a price increase unprofitable, and the focal product comprises the relevant product market.⁷²³

- 4.75 In analysing the impact of the natural events in the present case, it is relevant to note that competition between originators may be focussed to some extent on marketing and seeking to promote the advantages of their medicines to prescribers (see paragraphs 3.53 to 3.57). Therefore it will be necessary to take account of this when analysing sales and price trends. For example, in the context of the hypothetical monopolist test, the test would then ask whether a hypothetical monopolist was able to sustain pricing and marketing expenditure that enabled it to persistently earn profits that were above the competitive level.
- 4.76 Figures 4.4, 4.5 and 4.6 show how the events listed above (in paragraph 4.72) affected actual transaction prices (as opposed to list prices),⁷²⁴ sales values and sales volumes⁷²⁵ of the relevant medicines.⁷²⁶ The vertical lines denote the dates of the natural events, although our results are robust to treating the date of entry more flexibly, for example, should there be a lag between the natural event and any effect on paroxetine sales or prices (see also paragraphs C.29 to C.31 as regards the entry of generic citalopram).

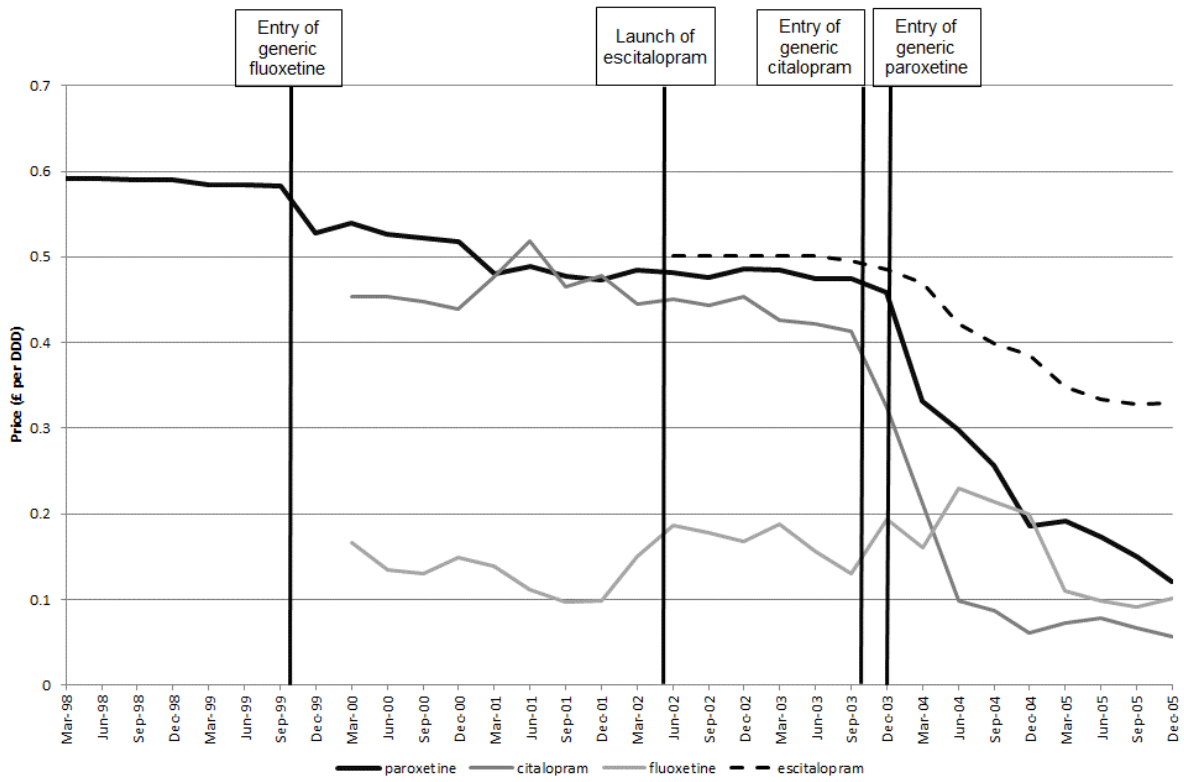
⁷²³ The CMA also notes that the SSNIP test posits a non-transitory price increase (where transitory is measured relative to the frequency of purchase/consumption of the product). Given that the events identified, and corresponding price shocks, all resulted in permanent market entry, the CMA is satisfied that the price shocks observed are of a sufficient duration that switching would be observed were the products of interest substitutes.

⁷²⁴ Prices refer in this Section to weighted average prices per DDD. They are computed by dividing sales values by the corresponding sales volumes expressed in DDDs. The CMA notes that, as set out at paragraphs 3.385–3.386, GSK identified two different sources for its 2001 paroxetine pricing data as a result of having concluded there was a high likelihood that the data previously used by the CMA for its analysis was not net of rebates. Although the CMA considers that the data from Unison provides the most accurate data to use (for the reasons set out at paragraphs B.164–B.165), for the purposes of this Section the CMA has continued to use the unadjusted CIMS data for the years 1998–2000 because it considers that the trends in prices continue to be reliable even though the price level may not be. For 2001 the CMA has adjusted the price data as described at footnote 615 and from 2002 onwards there are no known issues with the accuracy of the CIMS data used throughout this Section.

⁷²⁵ Volume figures are reported in terms of DDDs as defined by the WHO. A DDD is the assumed average maintenance dose per day for a medicine used for its main indication in adult patients. DDDs for all medicines that are part of the ATC classification are available on the WHO website. See www.whooc.no/atc_ddd_index/. One of the benefits of using DDD as a volume measure compared to, for instance, number of packs is that it allows for the aggregation of medicines with different dosages without facing the risk of misinterpreting sales trends influenced by substitution patterns between medicines of different strengths. The DDD is 20mg for citalopram, fluoxetine and paroxetine, and 10mg for escitalopram. In this context the CMA notes that GSK used DDDs as a measure of volume internally. See for example GSK presentation entitled 'Serostat Salts Update' dated 14 December 2001 (document 0192), slide 16.

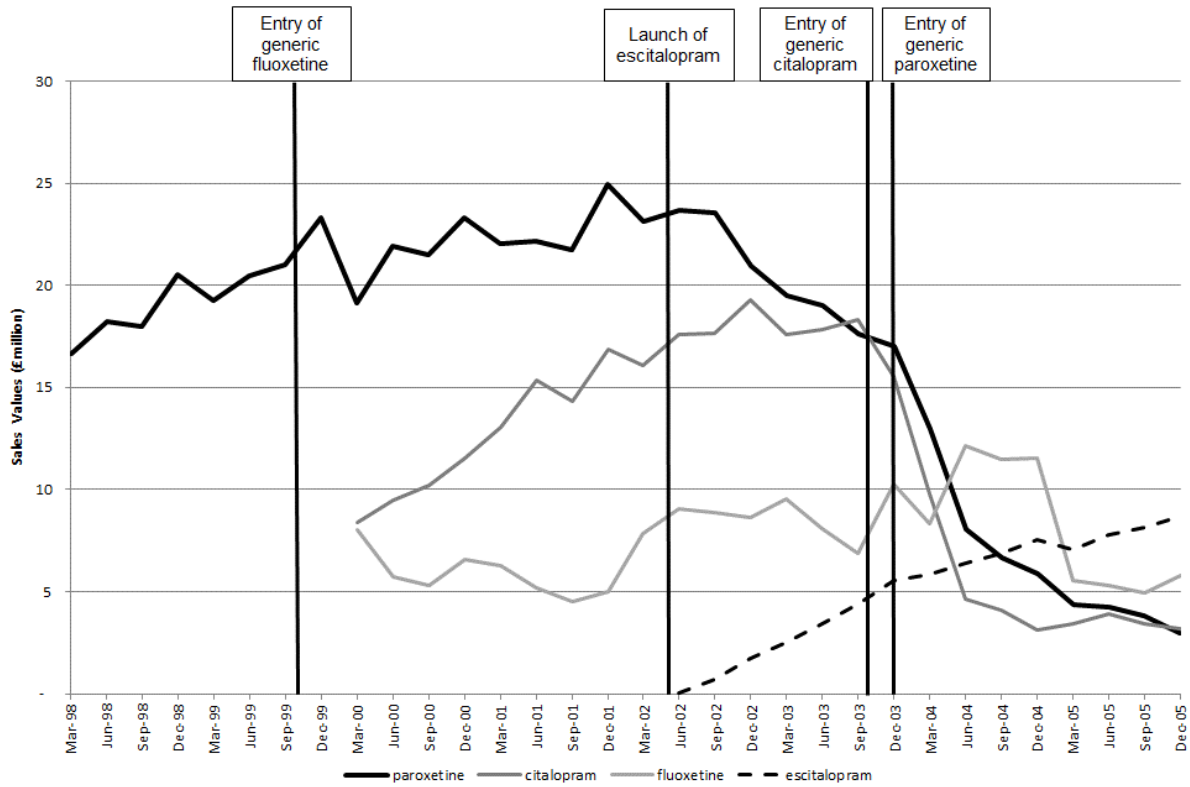
⁷²⁶ Most of the data used in this Section is actual sales and prices data submitted by relevant parties. The CMA has chosen to use data provided by relevant parties rather than IMS data because it believes that internal sales data provides more accurate information on actual prices, including the discounts that were applied. For example, in GSK Second Response, Part Two (document 0734), paragraph 12.4, GSK explained that prices in IMS data are 'ex-manufacturer' prices, which are defined as list prices for the branded medicine discounted by 12.5%. IMS prices therefore do not account for the further discounts that may be added by suppliers according to the degree of competition in the market.

Figure 4.4: Prices of paroxetine, citalopram, escitalopram and fluoxetine



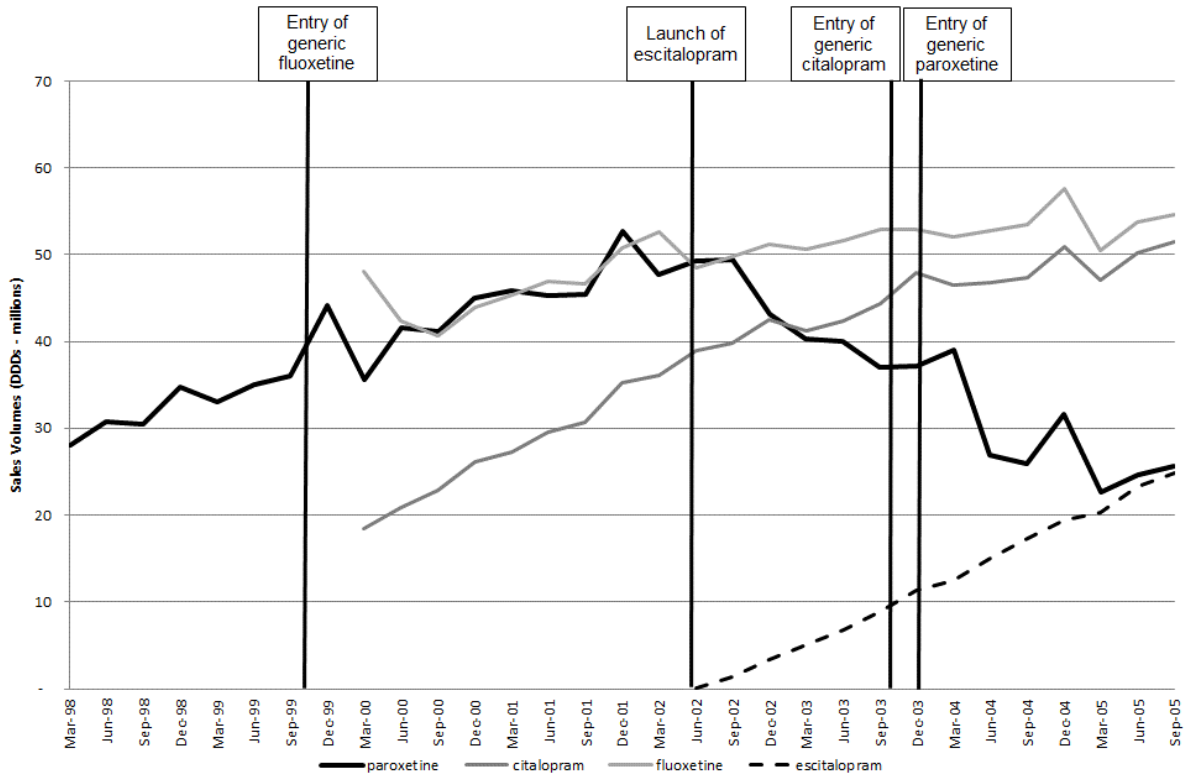
Source: CMA calculations based on data submitted by relevant parties.

Figure 4.5: Sales values of paroxetine, citalopram, escitalopram and fluoxetine



Source: CMA calculations based on data submitted by relevant parties.

Figure 4.6: Sales volumes of paroxetine, citalopram, escitalopram and fluoxetine

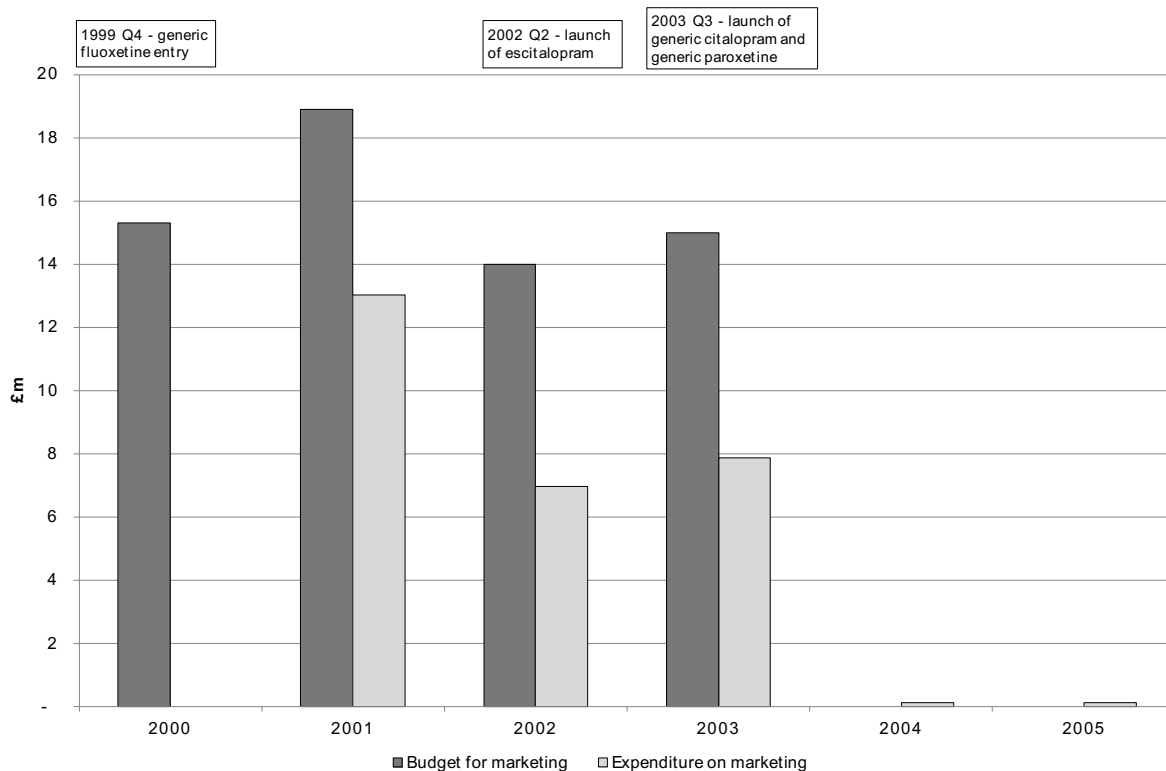


Source: CMA calculations based on data submitted by relevant parties.⁷²⁷

4.77 Figure 4.7 shows GSK's budgets and expenditure on marketing and promotion of Seroxat between 2000 and 2005. By either measure, GSK's marketing of Seroxat fell between 2001 and 2002, before subsequently increasing in 2003.

⁷²⁷ For paroxetine, the data includes the following products: Seroxat 20mg and 30mg, as well as paroxetine 20mg and 30mg. For citalopram, the data includes the following products: Cipramil 10mg, 20mg, 40mg and citalopram 10mg, 20mg and 40mg. For fluoxetine, the data includes the following products: Prozac 20mg and 60mg, and fluoxetine 20mg and 60mg.

Figure 4.7: GSK's budgets and expenditure on Seroxat promotion, 2000-05



Sources: [X]WS (document 0150), paragraph 3.6; witness statement of [GSK's Marketing Manager B for Seroxat] in the Apotex Litigation, dated 22 October 2002 (document 0328), paragraph 1.2 (referring to [X]WS (document 0150), paragraph 3.6); witness statement of [GSK's Finance Director B] in the Apotex Litigation, dated 5 December 2003 (document 0446), paragraph 14; GSK Second Response, Part Two (document 0734).

Entry of generic paroxetine

4.78 Figure 4.4 demonstrates that the most significant change in paroxetine prices during the period occurred following the entry of generic paroxetine sourced independently of GSK in Q4 2003. Following independent generic entry:

- There was a substantial decrease in average paroxetine prices: prices fell by 15% in the three months from November 2003 to February 2004, 43% in the six months to May 2004 and had fallen by 56% by November 2004.⁷²⁸

⁷²⁸ Prior to independent generic entry, GSK's prices were some 90% higher than following generic entry - calculated by comparing the average paroxetine price for September–November 2003 of £0.54 per DDD with the average paroxetine price for September–November 2004 of £0.28 per DDD.

- GSK's unit profit margins also fell significantly: for 20mg tablets, per unit margins were 66% lower in 2005 than in 2003.
- GSK's sales volumes declined significantly, such that its market share for the supply of finished product to pharmacies/wholesalers by volume was 37.5% in 2005 compared to 60.2% in 2003 prior to independent generic entry.

Table 4.2: Seroxat 20mg profits, 2000-05

£m	GSK sales net of rebates & discounts	Volumes (DDDs millions)	Total GSK costs	GSK profits	Profit margin per DDD (pence)
2001	44.9	102.1	17.8	27.2	27
2002	39.8	87.4	10.5	29.2	33
2003	25.9	56.9	8.6	17.3	30
2004	7.7	26.5	1.9	5.8	22
2005	4.5	25.9	1.8	2.7	10
Total				110.2	

Source: CMA calculations based on Annex 4 of GSK Second Response, Part Two (document 0738).

Table 4.3: Seroxat 30mg profits, 2000-05

£m	GSK sales net of rebates & discounts	Volumes (DDDs millions)	Total GSK costs	GSK profits	Profit margin per DDD (pence)
2001	26.7	21.6	7.6	19.1	44
2002	27.4	38.1	5.4	22.0	50
2003	22.6	36.0	5.5	17.1	47
2004	10.1	18.9	1.4	8.7	46
2005	3.9	10.6	0.8	3.1	29
Total				85.2	

Source: CMA calculations based on Annex 4 of GSK Second Response, Part Two (document 0738).

4.79 Tables 4.2 and 4.3 illustrate that GSK's unit profit margin for Seroxat 20mg fell sooner and to a lower level than GSK's unit profit margin for Seroxat 30mg. This is because, as set out at paragraphs 3.380 to 3.398, independent generic entry occurred earlier in relation to paroxetine 20mg than paroxetine 30mg, and there were also more entrants supplying paroxetine 20mg than paroxetine 30mg.⁷²⁹

4.80 The significant declines in pricing coincided with declines in marketing expenditure (as set out in Figure 4.7, marketing expenditure fell by 98.5% between 2003 and 2004). However, the impact of the per unit marketing cost decreases were modest in comparison to the price declines,⁷³⁰ such that independent generic entry nevertheless resulted in significant decreases in GSK's unit profit margins. This outcome was envisaged by [GSK's independent expert] in a witness statement:⁷³¹

⁷²⁹ See for example, GSK Third Response, Annex A (document 0730).

⁷³⁰ The following costs have been included: cost of goods sold and direct costs including marketing and distribution costs. For a description of cost information supplied, see GSK Second Response, Part Two (document 0734), section 12D.

⁷³¹ This outcome was also envisaged by GSK in the context of damages. For example, in a witness statement during the GUK Litigation, [GSK's Finance Director A] stated that: *'The potential damage therefore extends not only to a loss of sales to the Defendant [GSK] and a premature reduction in the price of SEROXAT but to a premature slide or downward spiral in the price of generic paroxetine.'* ([REDACTED]WS1 (GUK) (document 0885), paragraph 9.4).

*'it is clear that the launch of several generic versions of paroxetine in the UK will have a serious, detrimental effect on the sales volume, market share and actual income attributable to GlaxoSmithKline's Seroxat. Such loss of income can be cushioned only to a very limited extent by cutting promotional expenditure.'*⁷³²

- 4.81 The difference in price levels cannot therefore be explained by a change in focus from marketing-led competition between originators, to price-led competition with generic suppliers. While GSK did make significant investments in Seroxat marketing prior to independent generic entry as illustrated above, it was nevertheless able to sustain far higher profit margins prior to independent generic entry than was the case following independent generic entry.
- 4.82 As a consequence, it is evident that the competitive constraint from other medicines in the treatment area was not strong enough to prevent GSK from sustaining profits that were significantly higher prior to independent generic entry than afterwards.
- 4.83 The entry of generic paroxetine sourced independently of GSK is therefore of particular significance to market definition analysis, as it demonstrates that prior to independent generic entry, GSK was able to sustain prices and marketing expenditure that enabled it to earn profits that were substantially higher than those observed following independent generic entry. In particular, as the resulting price decrease in the twelve months following independent generic entry was about six times greater than a SSNIP of 10%, this indicates that a SSNIP from a more competitive price, by a hypothetical monopolist of paroxetine, would be profitable. This implies that it would be possible for a hypothetical monopolist of paroxetine (that is Seroxat and generic paroxetine) to earn profits above the competitive level, such that the relevant market would be no wider than paroxetine.
- 4.84 This analysis therefore demonstrates that, prior to the entry of generic paroxetine, the constraints exerted by other medicines were insufficient to prevent GSK, as the sole supplier of paroxetine in that period, from sustaining prices and profits that were significantly higher than those observed following independent generic entry. This analysis in turn demonstrates that were all suppliers of paroxetine to merge following generic entry and the associated price drop, such that a hypothetical monopolist supplied both generic and branded paroxetine, the constraint of other SSRIs would be insufficient to

⁷³² [X]WS (document 0143), paragraph 21.

prevent that supplier from sustaining a significant increase to its prices and profits.

- 4.85 It is in this context that the events observed prior to independent generic entry are assessed below.

Entry of generic fluoxetine

- 4.86 As explained by [GSK's independent expert], the launch of generic fluoxetine was associated with price decreases of some 57% in the nine months following generic entry,⁷³³ and this resulted in a significant increase in the price differential between fluoxetine and paroxetine. As can be seen from Figure 4.4, the launch of generic fluoxetine in Q4 1999 resulted in fluoxetine price levels that, in the period January 2000 to September 2003 were, on average, 70% lower than paroxetine prices over the same period (or, paroxetine prices were around 3.5 times higher than fluoxetine prices). To the extent that fluoxetine and paroxetine competed in the same market, the emergence of such a significant price differential would be expected to result in a significant impact on sales of paroxetine. As set out below, the CMA considers that the entry of generic fluoxetine had only a limited impact in this regard:

- Paroxetine prices fell only modestly, and this fall can in large part be explained by the renegotiation of the PPRS agreement. It was this renegotiation that led to the decrease in price of around 9% between September and October 1999.⁷³⁴ The subsequent gradual price decrease amounted to a fall of only 2.2% on average by August 2000, by which time paroxetine prices remained some four times higher than fluoxetine prices.
- The launch of generic fluoxetine in Q4 1999 occurred during a period in which the sales of paroxetine followed an upward trend. The launch of generic fluoxetine had no discernible impact on this trend, despite the fact that the fluoxetine price of £0.17 per DDD was less than a third that of paroxetine, at £0.54.⁷³⁵
- Moreover, as paroxetine profits were already at supra-competitive levels (see paragraph 4.84) a limited amount of switching to generic fluoxetine may be expected, simply because fluoxetine becomes a substitute to a

⁷³³ [X]WS, Confidential exhibit [X]2 (document 0874), paragraph 2.4.

⁷³⁴ See SmithKline Beecham document entitled 'PPRS pricing strategy' (document D155) in which GSK sets out its rationale for modulating a proportion of the required price decrease onto Seroxat.

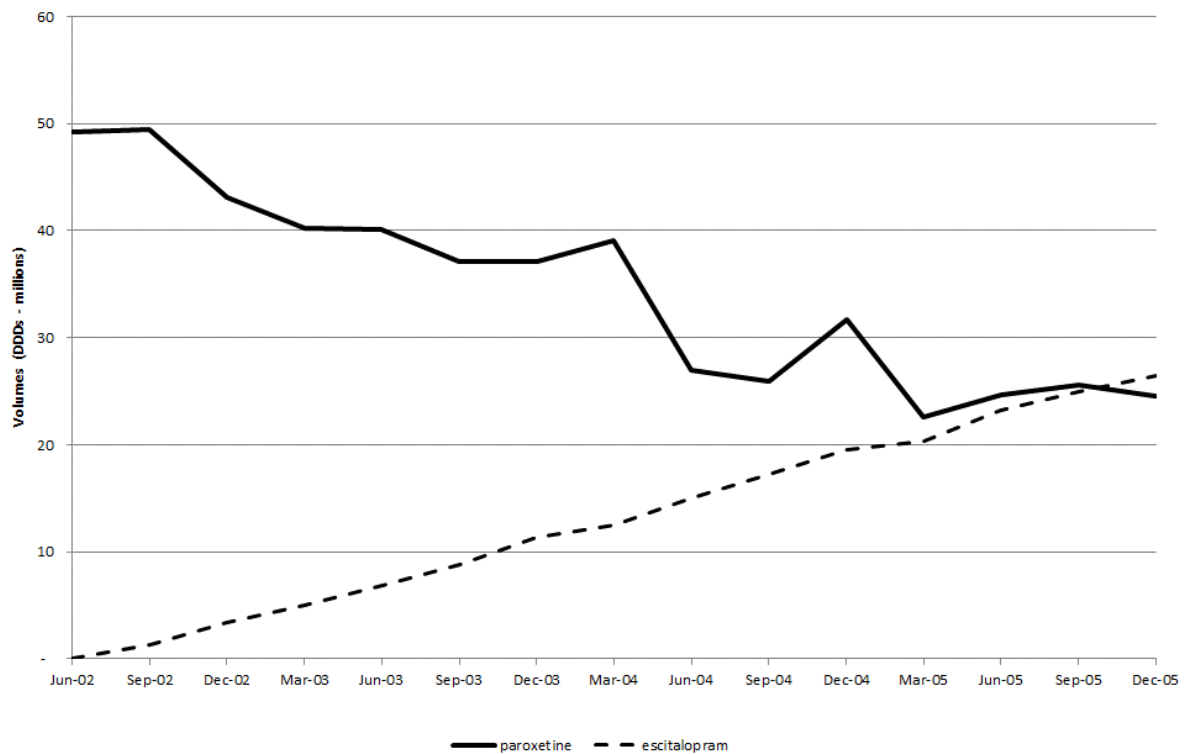
⁷³⁵ Prices for Q1 2000.

greater degree than it would have had the prices and/or marketing levels of paroxetine been closer to competitive levels.⁷³⁶

Launch of Cipralex

4.87 Cipralex (escitalopram) was launched in Q2 (May)⁷³⁷ 2002, and this subsection considers its impact on sales of paroxetine.

Figure 4.8: Quarterly paroxetine and escitalopram sales volumes, Jun '02 – Dec '05



Source: CMA calculations based on data submitted by relevant parties.

4.88 As can be seen from Figure 4.8, there was a downwards trend in paroxetine sales volumes between June 2002 and March 2005. This trend began at around the same time as the launch of Cipralex. It was also around the same time as paroxetine became the subject of significant negative publicity. For example, in January 2002, the US Food and Drug Administration warned of

⁷³⁶ A phenomenon known as the 'cellophane fallacy' – see paragraph 4.19.

⁷³⁷ Lundbeck response to Section 26 Notice dated 9 July 2012 (document 2243) and spreadsheet entitled 'Cipralex 10mg 20mg 2002 to 2005' dated 9 July 2012 (document 2244).

severe withdrawal symptoms associated with paroxetine,⁷³⁸ and this was reported in the UK British Medical Journal in February 2002.⁷³⁹ Further, between 2002 and 2004 there were several television programmes, including the BBC Panorama programme, which highlighted the severe withdrawal symptoms associated with paroxetine. In 2003, the MHRA instructed doctors not to prescribe paroxetine to under-18s.⁷⁴⁰ A study examining paroxetine prescribing noted that the adverse publicity itself '*did not appear to increase the rate of reduction in paroxetine prescribing but such exposure may have maintained the decline*'.⁷⁴¹

4.89 When considered in detail, the evidence indicates that the decline in paroxetine volumes was largely the result of the negative publicity surrounding Seroxat, and that the impact of the launch of CipraleX was more limited:

- As shown in Figure 4.8, the erratic quarter to quarter sales losses of paroxetine did not correspond to the steady growth in sales of CipraleX. Although sales of escitalopram grew gradually at a fairly constant rate in the first two and a half years following its launch, about 50% of the decline in paroxetine sales over that period occurred during the three months between March 2004 and June 2004. In those three months, quarterly paroxetine sales fell by 12.1 million DDDs, whereas quarterly escitalopram sales only increased by 2.6 million DDDs. During that time, Seroxat/paroxetine was the subject of significant adverse publicity in the UK (as explained in paragraph 4.88). Given this, and the very different trends relevant to paroxetine and escitalopram, the majority of the paroxetine sales decline appears attributable to negative publicity rather than the launch of escitalopram.
- The quarter to quarter losses in anxiety and depression prescriptions for paroxetine did not correspond to gains for which CipraleX was prescribed for these two conditions: for example, there is no correlation between the quarterly increases in prescriptions for depression and anxiety for CipraleX and the quarterly decreases in the same prescriptions for paroxetine,

⁷³⁸ Martin, R (2005) 'Did intense adverse media publicity impact on prescribing of paroxetine and the notification of suspected adverse drug reactions? Analysis of routine databases, 2001–2004', British Journal of Clinical Pharmacology, pages 224–228 (document 0572).

⁷³⁹ Tonks, A (2 February 2002) 'Withdrawal from paroxetine can be severe, warns FDA' (BMJ Volume 324) (document 0203).

⁷⁴⁰ <http://www.telegraph.co.uk/news/uknews/1432640/Seroxat-can-be-a-danger-to-under-18s-doctors-told.html>

⁷⁴¹ Martin, R (2005) 'Did intense adverse media publicity impact on prescribing of paroxetine and the notification of suspected adverse drug reactions? Analysis of routine databases, 2001–2004', British Journal of Clinical Pharmacology, pages 224–228 (document 0572).

suggesting that Cipralex was largely being prescribed to treat different conditions than paroxetine sales losses (see Figures 4.2 and 4.3). Therefore it seems likely that the fall in paroxetine sales was due to reasons other than customers switching to escitalopram.

- Despite the launch of a major new product in the same treatment area, GSK did not respond either by reducing prices or increasing its marketing spend. GSK's response was to decrease its investment in marketing⁷⁴² and to continue to price Seroxat at the same level.⁷⁴³ The decision to decrease marketing spend was not the consequence of pricing pressures, as GSK continued to sustain annual profits on paroxetine of £51 million in 2002 (see Tables 4.2 and 4.3). From this, the CMA infers that GSK perceived that the falling sales were due to factors which could not be overcome through a competitive response.

4.90 Further, the CMA notes that to the extent that the launch of escitalopram did impose any limited constraint on paroxetine, such a constraint should be considered in the context of paroxetine profits having at that time been at supra-competitive levels, and of other medicines becoming substitutes to a greater degree than they would have had prices and/or marketing of paroxetine been closer to competitive levels (see paragraph 4.19).

Entry of generic citalopram

- 4.91 As set out in paragraph 4.72, generic entry of citalopram suppliers occurred in September 2003, three months prior to independent generic entry of paroxetine suppliers in December 2003. The CMA considers that the resulting falls in paroxetine and citalopram prices are each the consequence of generic competition for each medicine respectively, and do not indicate that the generic price fall relevant to citalopram acted to constrain the prices of paroxetine.
- 4.92 Citalopram was launched in 1995, so by 2003 paroxetine and citalopram had been on the market together for at least seven years.⁷⁴⁴ There is no evidence in the evolution of prices during the period between 2000 and 2003 that paroxetine and citalopram were competing closely. Had there been effective competition between these medicines, it would not have been possible for GSK to sustain such high profits and prices prior to independent generic entry

⁷⁴² As shown in Figure 4.7, marketing spending was significantly lower in 2002 and 2003 than in 2001.

⁷⁴³ For example, the average Seroxat price (that is, 20mg and 30mg combined) remained at £0.51 per DDD from May 2002 to July 2002.

⁷⁴⁴ Lundbeck launched Cipramil in the UK in Q2 1995. See IMS diagnostics data dated 6 December 2011, supplied by GSK in response to the GSK Section 27 Notice (document 0680).

in relation to paroxetine (see paragraphs 4.78 to 4.84). This therefore makes it highly unlikely that after this time on the market together the fall in paroxetine prices observed in 2003 was as a result of the fall in the price of citalopram.

- 4.93 This is consistent with [GSK's Finance Director A's] expectation, referred to in paragraph 4.54, that *'the extent of switching from paroxetine to citalopram in the next six months is likely to be very small.'*⁷⁴⁵ One of the reasons that [GSK's Finance Director A] highlighted for expecting that the impact on paroxetine sales would be limited despite the price falls to citalopram associated with generic entry was that *'it can take a surprisingly long time for doctors to appreciate that a product which competes with the product which they usually prescribe is available generically. Also, doctors in the UK do not tend to be particularly sensitive to the cost of competing products.'*

Conclusion on quantitative analysis

- 4.94 The impact of independent generic paroxetine entry demonstrates that, prior to that event, competition from all other medicines in the treatment area had been insufficient to prevent GSK, as the only supplier of paroxetine, from sustaining prices and profits that were significantly higher than it could sustain following independent generic entry. An analysis of prior events (that of generic entry relevant to citalopram and fluoxetine, and the launch of escitalopram) suggests that other medicines constrained paroxetine prices and profits to a much lesser degree. Any constraint that other medicines did impose should therefore be considered in the context of paroxetine profits having at that time been at supra-competitive levels, and of other medicines becoming substitutes to a greater degree than they would have had prices and/or marketing of paroxetine been closer to competitive levels.

ii) The relevant geographic market

- 4.95 The definition of the relevant geographic market as national in scope is appropriate in the pharmaceutical sector because of differences in the regulatory schemes for authorising and reimbursing medicines across countries, in the marketing strategies used by pharmaceutical companies, in doctors' prescribing practices and in prices. For these same reasons, this conclusion has been reached in previous cases in the pharmaceutical sector, for example, in both the *AstraZeneca* and in the *Reckitt Benckiser*

⁷⁴⁵ [REDACTED]WS2 (GUK), Exhibit [REDACTED]6 (document 0887), paragraph 49.

decisions.⁷⁴⁶ The CMA therefore considers that the relevant geographic market is national (UK-wide) in this case.

iii) Conclusion on the relevant market

4.96 On the basis of the analysis presented above, the CMA has decided that:

- Although paroxetine was one of a number of medicines for conditions such as depression, the purchasing preferences of GPs were such that, prior to independent generic entry, GSK was able to sustain prices and profits that were significantly above the level subsequently observed.
- Consistent with this, sales of paroxetine were not materially constrained by the sales of other antidepressants, and specifically by its potential closest competitors, citalopram, escitalopram and fluoxetine.
- The CMA therefore concludes that the relevant product market is no wider than the supply of paroxetine.
- The relevant geographic market is the UK.

4.97 On this basis, the CMA finds that the relevant market in this case is no wider than the supply of paroxetine in the UK.

E. Dominance

i) Introduction

4.98 This Section considers whether, at the time the Agreements were entered into, GSK held a dominant position in the relevant market.

4.99 As set out at paragraph 4.12, when assessing whether an undertaking holds a dominant position, the CMA will consider whether that undertaking has substantial market power. Market power is defined in the relevant Commission guidelines as:⁷⁴⁷

'the ability to profitably maintain prices above competitive levels for a period of time or to profitably maintain output in terms of product

⁷⁴⁶ See Commission Decision of 15 June 2005, *AstraZeneca*, Case COMP/A. 37.507/F3a, paragraph 503 and Decision No. CA98/02/2011, *Reckitt Benckiser*, 12 April 2011, paragraphs 4.170–4.171.

⁷⁴⁷ Commission Notice: Guidelines on the applicability of Article 101 of the Treaty of the Functioning of the European Union to horizontal co-operation agreements, OJ C 11/1, 14.01.2011 ('Horizontal Guidelines'), paragraph 39.

quantities, product quality and variety or innovation below competitive levels for a period of time.'

4.100 The CMA considers that, for the reasons set out in this Section, GSK held a dominant position at least between January 1998 and November 2003. In summary, the CMA finds that:

- GSK's market share for the supply of finished product to pharmacies/wholesalers (by value) was in excess of 60% and it remained the sole manufacturer of paroxetine sold in the UK between January 1998 and November 2003 (with a market share by value or volume of 100% at the production level).
- Prior to independent generic entry, GSK was able to sustain prices and profits that were significantly higher than those observed following independent generic entry. Prices were some 90% higher and profits were around 8.5 times higher than those observed following independent generic entry.
- Barriers to expansion were significant in this market. Parallel importers were limited in their ability to expand and exercise a greater competitive constraint on GSK. The volume restrictions imposed by GSK limited the competitive constraint from the Generic Companies that supplied its product.
- GSK's patents in relation to paroxetine represented a barrier to entry and, for as long as they remained unchallenged, enabled GSK to litigate, and seek injunctions, in response to the proposed market entry of potential competitors.
- Over the Relevant Period, the NHS did not exert countervailing buyer power vis-à-vis GSK for the supply of Seroxat.

4.101 This Section is structured as follows:

- actual competition – including the market shares of GSK and its competitors in the relevant market;
- potential competition – in particular the existence, or otherwise, of significant entry barriers and the existence of other undertakings which might easily enter the market;
- buyer power – whether the NHS, as the purchaser in the relevant market, can be regarded as having had significant countervailing buyer power; and

- conclusions – the CMA's finding that GSK held a dominant position in the relevant market at least between January 1998 and November 2003.

ii) Actual competition

a) Introduction

4.102 Market shares provide valuable insights into the structure of the relevant market as well as into the relative importance of the various undertakings active on it. As a result, they are an indicator of whether an undertaking has a dominant position. Indeed the European Courts have held that very large shares (such as a market share of 50%) are, except in exceptional circumstances, in themselves evidence of the existence of a dominant position.⁷⁴⁸

4.103 The importance of market shares as an indicator of market dominance is especially relevant when the undertaking concerned has maintained a high market share over a long period of time and when its nearest competitors hold shares that are considerably lower.

4.104 As noted above (see paragraph 4.97), the CMA has concluded that the relevant market in this case is no wider than the supply of paroxetine in the UK. Accordingly, market shares presented in this Section are calculated on that basis.

b) GSK's share of the relevant market

4.105 The market shares by value of the various companies supplying paroxetine in the UK from 2001 to 2005 are shown in Table 3.4. The corresponding market shares by volume from 1998 to 2005 are presented in Table 3.5.

4.106 GSK remained the sole manufacturer of paroxetine sold in the UK between January 1998 and November 2003, with a market share by either value or volume of 100% at the production level.

4.107 GSK's market share (by value) for the supply of finished product to pharmacies/wholesalers was in excess of 60% from 2001 to 2003, that is in the years prior to and during which the Agreements were in effect and prior to independent generic entry. Similarly, GSK's market share (by volume) for the supply of finished product to pharmacies/wholesalers was above 75% in the

⁷⁴⁸ Judgment in *AKZO Chemie v Commission*, C-62/86, EU:C:1991:286, paragraph 60.

years prior to and including 2001, and fell only to 69% in 2002 and 60% in 2003.

- 4.108 It is notable that parallel importers, the only other companies supplying paroxetine prior to the Agreements, held considerably lower market shares than GSK. Taken together, the combined market share for the supply of finished product to pharmacies/wholesalers (by volume) of all the parallel importers was no more than 25% over the period presented.
- 4.109 As a consequence of the Agreements, the Generic Companies did enter the relevant market as distributors of GSK product (see paragraph 3.383). However, as explained further at paragraphs 7.25 to 7.41 (GUK), 7.76 to 7.94 (Alpharma) and B.143 to B.161 (IVAX), GSK supplied each of them with a restricted volume of product only, and this limited the market shares that they could each achieve.
- 4.110 In conclusion, given GSK's consistently high market share of over 60% (by volume) for the supply of finished product to pharmacies/wholesalers throughout the period from January 1998 to November 2003, and that rival suppliers' shares were significantly smaller and not capable of undermining GSK's leading position in the relevant market,⁷⁴⁹ this is strong evidence that GSK held a dominant position in the UK paroxetine market.

iii) Profitability

- 4.111 As set out in paragraph 4.84, prior to independent generic entry GSK was able to sustain far higher profits than was the case following independent generic entry. For example, GSK's average annual profit between 2001 and 2002 for sales of paroxetine was £49 million, compared with £6 million in 2005, indicating that profits were 8.5 times greater prior to independent generic entry. This demonstrates that, prior to the entry of generic paroxetine, the constraints exerted by other medicines were insufficient to prevent GSK, as the sole supplier of paroxetine in that period, from sustaining prices and profits that were significantly higher than those observed following independent generic entry, indicating that GSK held a dominant position in the UK paroxetine market.

⁷⁴⁹ The CMA's findings in this regard are also supported by the GC in *AstraZeneca*, which found that 'the Commission was entitled to take the view that AZ's possession of a particularly high market share and, in any event, a share which was much higher than those of its competitors, was an entirely relevant indicator of its market power, which was out of all comparison to those of the other market players' (Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 253).

iv) Barriers to expansion

4.112 The very low market share of competitors in this market, and the fact that GSK's market share for the supply of finished product to pharmacies/wholesalers in the UK remained consistently high, above 60% by volume, between 1998 and 2003 (see Table 3.5), indicates that existing competitors to GSK faced significant barriers to expansion.

4.113 Prior to the entering into of the Agreements, the only competition GSK faced in the relevant market came from suppliers of parallel imported Seroxat. However, parallel importers faced several barriers to expansion which limited the extent to which they were capable of challenging GSK's market position:

- After repackaging and relabelling, parallel importers sold the originator product which they had obtained, either directly or indirectly, from the same originator in another EU member state. As such, parallel importers were entirely dependent on whether and to what extent GSK supplied Seroxat in low-price Member States. In this regard the CMA notes that parallel importers were unable to achieve a combined market share for the supply of finished product to pharmacies/wholesalers in excess of 25% by volume in the period prior to the Agreements.
- Some pharmacies were thought to be reluctant to stock rebranded products due to a preference for UK labelled packs. For example, [GSK's Finance Director A] stated in a witness statement:⁷⁵⁰ *'In reality, the price of Distributed Paroxetine is probably slightly higher than parallel imported paroxetine. This is because purchasers of Distributed Paroxetine are willing to pay a slight premium to avoid perceived customer resistance to parallel imported products.'*

4.114 Although the Generic Companies did enter the relevant market as distributors of GSK product between December 2001 and February 2003 (see paragraph 3.383), GSK supplied each of them with a restricted volume of product only, and this limited their ability to compete effectively in the relevant market. As explained further at paragraphs 7.25 to 7.41 (GUK), 7.76 to 7.94 (Alpharma) and B.143 to B.161 (IVAX), the volume restrictions limited the Generic Companies' incentive to compete on price with GSK, and also constrained the market shares that they could each achieve.

4.115 Overall, the CMA considers that significant barriers to expansion existed in this market. Existing competitors to GSK faced significant difficulties in

⁷⁵⁰ [REDACTED]WS1 (Alpharma) (document 0241), paragraph 6.7.

expanding their supply and were limited in their ability to offer lower prices in order to compete. Market share data indicates that GSK's competitors were unsuccessful in achieving significant market shares for the supply of finished product to pharmacies/wholesalers until the advent of successful independent generic entry during 2004, from which the CMA infers that the competitive constraint they were able to impose on GSK was limited.

v) *Potential competition*

- 4.116 The CMA has also considered the existence of barriers to entry relevant to potential competition. As set out in the CMA Guidelines on the assessment of market power,⁷⁵¹ the lower the barriers to entry, the more likely it is that potential competition will prevent undertakings within the market from profitably sustaining prices above competitive levels. An undertaking with a large market share in a market protected by significant entry barriers is likely to have market power.
- 4.117 The following analysis considers the barriers to entry faced by potential competitors seeking to develop a paroxetine product. As the market has been defined at the molecule level, that is paroxetine only, this sub-section focuses on the potential introduction of generic paroxetine products.
- 4.118 Until the expiry of the Initial Patent in January 1999, there were no attempts by generic suppliers to supply generic paroxetine in the UK,⁷⁵² presumably on the basis that generic suppliers considered that their prospects of demonstrating that their product did not infringe GSK patent claims that were deemed to be valid were low and investing in product development was therefore not worthwhile.
- 4.119 In anticipation of, and following the expiry of, the Initial Patent in January 1999 and of data exclusivity in December 2000, it is apparent that a number of generic suppliers considered that, based on their assessment of GSK's patent position, it was possible to develop a non-infringing generic paroxetine product. On this basis a number of generic suppliers, including the Generic Companies, began developing generic paroxetine products that they considered did not infringe valid patent claims held by GSK.

⁷⁵¹ *Assessment of market power* (OFT415, December 2004), adopted by the CMA, paragraphs 5.2 and 5.4.

⁷⁵² The CMA notes that, in response to a question from the CMA about known generic entry at the time the IVAX-GSK Agreement was entered into, the earliest mention that GSK made about the possibility of a generic product being launched was in mid-June 2000, when GSK became aware of IVAX's intention to launch a generic. (See GSK Second Response, Part Two (document 0734), section 6B).

- 4.120 In deciding to seek to enter the market, these companies were aware that they would face significant development costs. For example, [GUK's General Manager] of GUK set out in a witness statement that:⁷⁵³ *'A great deal of time, money and effort has been invested in developing a stable product, researching quality raw material suppliers and planning to bring the product to market, including most importantly the obtaining of regulatory approval.'*
- 4.121 A key entry barrier facing any potential generic entrant related to the paroxetine patent position and the threat of litigation from GSK. Such litigation would be costly and potentially time-consuming. Its ultimate outcome was also uncertain,⁷⁵⁴ such that a potential entrant would have been aware that, had the court found in GSK's favour, it would have been unable to enter the market at all (or would have faced damages had it entered 'at risk').⁷⁵⁵ The CMA observes that while GSK's paroxetine patents were neither absolute nor insurmountable entry barriers because successful challenge was a possibility, they did nonetheless represent barriers to entry while they remained in place and prior to (any) successful challenge.
- 4.122 As set out at paragraphs 3.121 to 3.136, following their attempted market entry, GSK launched proceedings against a series of companies (including GUK and Alparma) that were seeking to bring generic paroxetine to market and, in the case of IVAX, entered into an agreement before litigation was commenced. GSK was successful in obtaining an injunction that delayed the entry of GUK pending the outcome of the relevant hearing and Alparma voluntarily provided the Alparma Undertaking, which had the same overall effect as an injunction. In each case, GSK entered into a 'settlement' agreement prior to the hearing taking place. The Agreements that were entered into with the Generic Companies are the subject of this Decision, and the likely effects of the Agreements are considered in Part 7 and paragraphs B.132 to B.189.
- 4.123 Overall, the CMA considers that there were significant barriers to entry in the relevant market. For as long as they remained unchallenged and for as long as they were deemed valid, GSK's patents in relation to paroxetine represented a barrier to entry, and enabled GSK to litigate, and seek injunctions, in response to the proposed market entry of potential competitors.

⁷⁵³ [REDACTED]WS (document 0901), paragraph 14.

⁷⁵⁴ See paragraphs B.52 (IVAX), 6.64 (GUK) and 6.82 (Alparma).

⁷⁵⁵ The CMA notes that it was not until the Apotex Interim Injunction terminated on the 18th December of 2003 that independent generic entry occurred. (*SmithKline Beecham Plc and Others v Apotex Europe Ltd and Others* [2006] EWCA Civ 658, paragraphs 8-9).

The threat of costly and uncertain litigation with GSK was substantial, as were the costs of developing a generic equivalent to GSK's product.

vi) Countervailing buyer power

4.124 In order to decide whether GSK held a dominant position in the relevant market, it is also necessary to consider the extent to which the DH/NHS exerted countervailing buyer power vis-à-vis GSK. The CMA Guidelines on the assessment of market power state that size is not sufficient for buyer power and that buyer power requires the buyer to have choice.⁷⁵⁶ Further, buyer power is most commonly found in industries where buyers and sellers negotiate.⁷⁵⁷

4.125 In this case the CMA does not consider that DH and the NHS had sufficient negotiating strength to offset GSK's market power in the period between January 1998 and November 2003, for the following reasons:⁷⁵⁸

- The overall objective of national pricing policies for medicines in the UK was generally to constrain public expenditure through the ex-factory price, reimbursement level and the frequency and conditions under which a medicine can be dispensed and used.⁷⁵⁹ Its purpose was not to control the conduct of individual suppliers.
- In the UK the PPRS, which was agreed between the DH and the ABPI, was the primary tool used by DH to control NHS branded medicine costs. However, the focus of the PPRS profit and price controls was not only portfolio-wide for each scheme member, but was also negotiated with and applied across all scheme members. Further, the initial price for an individual medicine was not constrained by the PPRS over-and-above the portfolio-wide profit cap. The PPRS does not therefore enable the NHS to constrain the pricing and conduct of manufacturers in respect of individual products.⁷⁶⁰

⁷⁵⁶ *Assessment of market power* (OFT415, December 2004), adopted by the CMA, paragraph 6.1.

⁷⁵⁷ *Assessment of market power* (OFT415, December 2004), adopted by the CMA, paragraph 6.2.

⁷⁵⁸ The CMA's view that DH could not assert countervailing buyer power is supported in general by the findings of the GC in *AstraZeneca*, which confirmed that the features of pharmaceuticals markets (which are unusual in comparison with other markets) would reinforce the market power of companies: '[T]he Commission is justified in finding ... that the health systems which characterise markets for pharmaceutical products tend to reinforce the market power of pharmaceutical companies, since costs of medicines are fully or largely covered by social security systems, which to a significant extent makes demand inelastic' (Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 262). The CJ subsequently upheld the GC's findings on appeal (Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraphs 170–182).

⁷⁵⁹ Sector Inquiry Final Report, paragraph 342.

⁷⁶⁰ The CMA's view that the PPRS does not exercise any significant constraint on GSK's ability to 'act independently' is supported by the CAT in *Genzyme Ltd v Office of Fair Trading* [2004] CAT 4. The CAT noted

- The NHS was not in fact a single, large corporate entity. Its operation is devolved to numerous executive or advisory bodies or agencies, including local bodies, such as primary care trusts (PCTs), which controlled the majority of the NHS's budget in the period between 1998 and 2005 and had responsibility for containing costs.⁷⁶¹ None of these bodies had any specific powers to require a pharmaceutical company to alter its pricing practices.⁷⁶²
- Although PCTs used various initiatives and incentives in order to influence prescribing, none of these devolved bodies themselves acted as the decision-maker with respect to the medicines that were ultimately prescribed, the decision-maker being the prescribing clinician (for example, GP). Therefore, once a prescribing physician had prescribed Serostat, the NHS did not have any choice over which product to purchase, which further undermined their ability to individually exercise buyer power.⁷⁶³

4.126 For these reasons the CMA has decided that in reality the NHS did not exert countervailing buyer power vis-à-vis GSK for the supply of Serostat.

vii) Conclusions on dominance

4.127 In light of the evidence considered by the CMA above, the CMA finds that GSK held a dominant position in the relevant market at least between January

that '[the PPRS] is not designed to control the prices of individual drugs' and goes on to cite two passages from its own judgment in *Napp*, in which it said 'As regards the issue of dominance, the effects of the PPRS are at most remote and indirect ... In our view nothing in the PPRS affects Napp's autonomous conduct in such a way as to deprive Napp of its dominant position.' *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1, at [164] and [168] (cited in *Genzyme Ltd v Office of Fair Trading* [2004] CAT 4, [262]–263)).

⁷⁶¹ Before 2000, primary care groups controlled the majority of the NHS's budget in England (some two thirds of it was controlled by these organisations in 2000). Primary care trusts (PCTs), which were free-standing NHS organisations with their own boards, staff and budget, started to be introduced in 2000. By April 2002, there were 303 of these bodies, which were responsible for controlling almost 75% of the NHS's budget in England in the Financial Year 2003/2004. See Department of Health (2000), *The NHS Plan*, a plan for investment, a plan for reform, paragraph 6.7, Department of Health (2002), HSC 2002/012 - Primary Care Trust Revenue Resource Limits 2003/04, 2004/05 & 2005/06, table 1 and 'Revolution Day for the NHS', DH, Press notice 2002/0167. The NHS in the devolved nations had different arrangements. PCTs were abolished on 31 March 2013 by the Health and Social Care Act 2012 and have been replaced by clinical commissioning groups.

⁷⁶² This point was observed by the CAT in *Genzyme Ltd v Office of Fair Trading* [2004] CAT 4, at [246]–[247]. Note that, although the CAT was referring to specific pricing practices carried out in that case, the key point may be applied more generally.

⁷⁶³ The CAT noted in *Genzyme* that '*despite the large superstructure of strategic, executive and advisory bodies [...] the clinical decision to prescribe [a medicine] for a patient suffering from [a disease] is taken locally by the responsible clinician [...] Thus, in practice, once the prescribing decision is taken by the clinician, the NHS [...] has little option but to fund the product.*' (*Genzyme Ltd v Office of Fair Trading* [2004] CAT 4, at [248]–[249]. In the current case the responsible clinician is a GP, who retains prescribing independence even when a particular prescribing decision is being recommended by his or her PCT (since 2013 PCTs have been replaced by clinical commissioning groups).

1998 and November 2003. In particular, this finding is supported by the following:

- GSK's market share for the supply of finished product to pharmacies/wholesalers (by volume) was in excess of 60% and it remained the sole manufacturer of paroxetine sold in the UK between January 1998 and November 2003 (with a market share by value or volume of 100% at the production level). Rival suppliers' shares were significantly smaller and not capable of undermining GSK's leading position in the relevant market.
- Prior to independent generic entry, GSK was able to sustain prices and profits that were significantly higher than those observed following independent generic entry. Prices were some 90% higher and profits were around 8.5 times higher than those observed following independent generic entry.
- Barriers to expansion were significant in this market. Parallel importers were limited in their ability to expand and exercise a greater competitive constraint on GSK. The volume restrictions imposed by GSK limited the competitive constraint from the Generic Companies that supplied its product.
- GSK's patents in relation to paroxetine represented a barrier to entry, and, for as long as they remained unchallenged, enabled GSK to litigate, and seek injunctions, in response to the proposed market entry of potential competitors.
- Over the Relevant Period, the NHS did not exert countervailing buyer power vis-à-vis GSK for the supply of Seroxat.

4.128 Further, as set out in Part 6 and Annex B, the only plausible rationale for the value transfers GSK made to the Generic Companies was to incentivise them to defer efforts to enter the market independently (in the case of IVAX) or in return for entry restrictions (in the case of GUK and Alparma) and to enable GSK to sustain higher profits than would have otherwise been the case. That GSK was both in a position to and did go to such lengths to protect its share in the UK paroxetine market reinforces the evidence above that GSK held a dominant position during the Relevant Period.⁷⁶⁴

⁷⁶⁴ The CAT noted in *Genzyme* that 'the very state of affairs which forms the subject matter of the present case itself indicates the ability of Genzyme to disregard the wishes of its customers and consumers.' *Genzyme Ltd v Office of Fair Trading* [2004] CAT 4, at [257].

5. UNDERTAKINGS AND AGREEMENTS

5.1 In this Part, the CMA sets out its analysis and findings in relation to the following two aspects of the legal assessment:

- whether the Parties are undertakings for the purposes of competition law; and
- whether an agreement between undertakings exists for the purposes of competition law.

A. Undertakings

5.2 The Chapter I prohibition and Article 101 TFEU apply to agreements between undertakings, decisions by associations of undertakings and concerted practices between undertakings. Furthermore, the Chapter II prohibition applies to conduct on the part of one or more undertakings.

5.3 The concept of an '*undertaking*' must be understood as designating an economic unit, even if in law that unit consists of several natural or legal persons.⁷⁶⁵ The '*undertaking*' that committed an infringement can therefore be larger than the legal entity whose representatives actually took part in the infringing activities.⁷⁶⁶

5.4 As described in Part 3, each of the Parties was, during the Relevant Period, engaged in supplying goods or services on UK pharmaceutical markets.⁷⁶⁷ The CMA therefore finds that each of the Parties was engaged in an economic activity and constitutes an undertaking for the purposes of the Act and the TFEU.

B. Agreements between undertakings

5.5 Article 101(1) TFEU prohibits agreements between undertakings, decisions by associations of undertakings and concerted practices between undertakings which may affect trade between EU Member States and have as their object or effect the prevention, restriction or distortion of competition within the EU, unless they are exempt in accordance with the provisions of Article 101(3) TFEU.

⁷⁶⁵ Judgment in *Akzo Nobel v Commission*, C-97/08 P, EU:C:2009:536, paragraph 55.

⁷⁶⁶ Judgment in *Hydrotherm*, C-170/83, EU:C:1984:271, paragraph 11; Judgment of 12 January 1995, *Viho v Commission*, T-102/92, ECR, EU:T:1995:3, paragraph 50.

⁷⁶⁷ Directly or through its subsidiaries.

5.6 Section 2(1) of the Act, which imposes the Chapter I prohibition, prohibits agreements between undertakings, decisions by association of undertakings and concerted practices between undertakings which may affect trade within the UK or a part of the UK and which have as their object or effect the prevention, restriction or distortion of competition within the UK, unless they are excluded or exempt in accordance with the provisions of Part I of the Act. The Chapter I prohibition applies only where the agreement, decision or concerted practice is, or is intended to be, implemented in the UK or part of the UK.⁷⁶⁸

5.7 As described in paragraphs 3.249 to 3.379, GSK entered into Agreements with each of GUK and Alpharma. This Section analyses whether the GUK-GSK and Alpharma-GSK Agreements, including the extensions of, and amendments to, those Agreements, are ‘*agreements between undertakings*’ within the meaning of the Chapter I prohibition and Article 101(1) TFEU.

i) *The GUK-GSK Agreement*

5.8 In respect of GUK, the CMA finds that an agreement existed between GUK and GSK for the purposes of the Chapter I prohibition and Article 101(1) TFEU, pursuant to which GSK made value transfers to GUK in return for GUK not seeking to enter the UK paroxetine market with paroxetine sourced independently of GSK (the GUK-GSK Agreement). The expressed joint intention of both GUK and GSK to that effect is clearly set out in the GUK-GSK Settlement Agreement.⁷⁶⁹

5.9 The value transfers were made directly from GSK to GUK pursuant to the GUK-GSK Settlement Agreement,⁷⁷⁰ with the following exception. The transfer of a restricted volume of paroxetine and the associated profit guarantee were made by GSK to GUK, indirectly via IVAX pursuant to the IVAX-GSK Agreement and the GUK-IVAX Agreement.⁷⁷¹ The CMA’s reasoning for its conclusion in relation to the transfer of a restricted volume of paroxetine and the associated profit guarantee is as follows: (i) the GUK-IVAX Agreement was a direct and explicit requirement of the GUK-GSK Settlement Agreement;⁷⁷² (ii) GSK was the source for the paroxetine that IVAX supplied to GUK;⁷⁷³ (iii) GSK guaranteed the product transfer and profit guarantee in

⁷⁶⁸ Sections 2(3) and 2(7) of the Act.

⁷⁶⁹ GUK-GSK Settlement Agreement (document 0995).

⁷⁷⁰ GUK-GSK Settlement Agreement (document 0995), clauses 1, 2 and 5.

⁷⁷¹ Second Addendum (document 0318) and the GUK-IVAX Agreement (document 1003), clauses 3.1 and 4.3. For the avoidance of doubt, the CMA makes no finding of infringement against IVAX in this decision.

⁷⁷² GUK-GSK Settlement Agreement (document 0995), clause 4.

⁷⁷³ Second Addendum (document 0318) and GUK-GSK Settlement Agreement (document 0995), Clause 4.

the event that IVAX was unable to fulfil its obligations under the GUK-IVAX Agreement⁷⁷⁴ and those value transfers were the result of settlement negotiations between GUK and GSK,⁷⁷⁵ (iv) if the GSK-IVAX Agreement was terminated, GSK agreed to perform IVAX's obligations to GUK under the GUK-IVAX Agreement in relation to the product transfer and profit guarantee as if those obligations were imposed directly on GSK;⁷⁷⁶ (v) the GUK-GSK Settlement Agreement provided that, upon termination of the GUK-IVAX Agreement, GSK and GUK were at liberty to restore the GUK Litigation.⁷⁷⁷

ii) The Alpha-GSK Agreement

- 5.10 In respect of Alpha, the CMA finds that an agreement existed between Alpha and GSK for the purposes of the Chapter I prohibition, pursuant to which GSK made value transfers to Alpha in return for Alpha not seeking to enter the UK paroxetine market with paroxetine sourced independently of GSK (the Alpha-GSK Agreement). The expressed joint intention of both Alpha and GSK to that effect is clearly set out in the Alpha-GSK Settlement Agreement.⁷⁷⁸
- 5.11 The value transfers were made directly from GSK to Alpha pursuant to the Alpha-GSK Settlement Agreement,⁷⁷⁹ with the following exception. The transfer of a restricted volume of paroxetine was made by GSK to Alpha, indirectly via IVAX pursuant to the IVAX-GSK Agreement and the Alpha-IVAX Agreement.⁷⁸⁰ The CMA's reasoning for its conclusion in relation to the transfer of a restricted volume of paroxetine is as follows: (i) the Alpha-IVAX Agreement was a direct and explicit requirement of the Alpha-GSK Settlement Agreement;⁷⁸¹ (ii) the evidence demonstrates that Alpha negotiated the terms of both the Alpha-GSK Settlement Agreement and the Alpha-IVAX Agreement directly with GSK, rather than negotiating the latter with IVAX⁷⁸² and, consistent with this, it was specified in Clause 2 of the Alpha-GSK Settlement Agreement that GSK would provide IVAX with the

⁷⁷⁴ Clause 5.2 of the GUK-GSK Settlement Agreement (document 0995), clause 5.2.

⁷⁷⁵ See paragraphs 3.281–3.304.

⁷⁷⁶ GUK-GSK Settlement Agreement (document 0995), clause 5.1. See also, for example, Letter from [GSK's Associate General Counsel for Europe] to [GUK's Head of Marketing] dated 20 December 2004 (document 0518).

⁷⁷⁷ GUK-GSK Settlement Agreement (document 0995), clause 11.

⁷⁷⁸ See Alpha-GSK Settlement Agreement, (document 0356).

⁷⁷⁹ Alpha-GSK Settlement Agreement (document 0356), clauses 3, 4, 5, 6. See also Alpha-GSK Settlement Agreement, (document 0356), clause 2.

⁷⁸⁰ Third Addendum (document 1807) and the Alpha-IVAX Agreement (document 1806), clauses 5 and 6. See also Alpha-GSK Settlement Agreement, (document 0356), clause 2. For the avoidance of doubt, the CMA makes no finding of infringement against IVAX in this decision.

⁷⁸¹ Alpha-GSK Settlement Agreement (document 0356), clause 2.

⁷⁸² See paragraphs 3.355–3.362.

500,000 packs that IVAX supplied to Alparma under the Alparma-IVAX Agreement; (iii) GSK was the source for the paroxetine that IVAX supplied to Alparma;⁷⁸³ (iv) the Alparma-GSK Settlement Agreement expressly recognised the prospect of subsequent litigation in relation to paroxetine hydrochloride in the UK between Alparma and GSK after termination of the Alparma-IVAX Agreement, and GSK and Alparma reserved all prospective rights and causes of action in respect of that litigation.⁷⁸⁴

⁷⁸³ Third Addendum (document 0359) and Alparma-GSK Settlement Agreement (document 0356), clause 2.

⁷⁸⁴ Alparma-GSK Settlement Agreement (document 0356), clause 9.

6. OBJECT ASSESSMENT

A. Overview

- 6.1 In analysing an agreement under Article 101(1) TFEU and the Chapter I prohibition the first step is normally to determine the 'object' of the agreement.⁷⁸⁵ If it has the object of restricting competition, these prohibitions apply, independently of any effects.
- 6.2 In this Part, the CMA sets out its assessment of the object of the GUK-GSK Agreement and the Alparma-GSK Agreement.
- 6.3 In summary, the CMA finds that the GUK-GSK Agreement and the Alparma-GSK Agreement reveal, in and of themselves, a sufficient degree of harm to competition and therefore had the object of restricting competition. GSK paid GUK and Alparma to remove the risk that they would enter the UK paroxetine market independently of GSK during a specified period, and so offer independent generic competition against GSK. GUK and Alparma accepted value transfers from GSK as compensation for their agreement to delay their independent efforts to enter the market. Those value transfers included cash payments, and the effective transfer from GSK of profit margins by means of agreements permitting the supply of restricted volumes of product to the market in place of GSK. The appointment of GUK and Alparma as distributors of GSK's paroxetine provided a means of transferring value from GSK to GUK and Alparma, with no increase in the level of competition facing GSK in the relevant market.
- 6.4 The harmful consequence to be expected from this type of coordination in the pharmaceutical sector is that the potential for effective competition against the incumbent is, in essence, 'bought off'. Instead, under the objectionable arrangement, the parties share the profits from sustained high prices, while customers and consumers are deprived of the potential benefits of substantial price decreases.
- 6.5 In more detail, the reason why it can be in the interests of an originator such as GSK to pay a potential competitor with the objective of inducing it to delay its efforts to enter the market with its generic product, can be explained as follows. For the originator, the risk of its patent being held by a court to be invalid or not infringed, multiplied by the very significant amount of profit the

⁷⁸⁵ See *Institute of Independent Insurance Brokers v Director General of Fair Trading* [2001] CAT 4 at [169] and case-law cited.

originator would lose if true generic competition were to emerge, could mean that it is commercially more attractive to pay the generic supplier to delay its efforts to launch its generic product, and in so doing share its monopoly profits with the generic supplier.⁷⁸⁶

- 6.6 If the transfers on offer from the originator are sufficient, it may also be in the interests of a potential entrant such as GUK and Alpharma to accept those transfers as compensation for its agreement to delay its efforts to launch its generic product. Putting competition law considerations to one side, such a deal will be attractive to the generic supplier to the extent that the payments or value transfers from the originator are greater than the returns that the generic supplier could achieve from continuing with its efforts to enter the market independently of the originator, multiplied by its perceived prospect of success.⁷⁸⁷
- 6.7 Under such arrangements, both competitors (this is, the originator and the generic supplier) can be better off at the same time, because the profit the generic supplier could make from entering the market will be lower (and often considerably lower) than the profit the originator would be likely to lose if independent generic entry occurred (that is to say, total profits are higher before true generic competition emerges). This is because, as set out in paragraphs 3.47 to 3.63, generic entry will tend to be quickly followed by a significant reduction in market share and/or price level of the originator product as a result of strong price competition from generic suppliers. It may thus make commercial sense for the originator to avert generic entry by making payments or otherwise transferring value up to the amount of the profit it expects to lose if generic entry were to occur. Both the originator and the generic supplier will be better off, as they share the originator's monopoly profits between themselves and defer the threat of true generic competition and the associated price declines.
- 6.8 The relevant consumers, however, are deprived of the potential to benefit from the significant price declines associated with true generic competition. The payments and value transfers serve to reallocate profits between the originator and generic supplier, but induce delays to the potential emergence of true generic competition (and the associated price declines) while failing to improve the degree of competition on the market. Such an agreement is not

⁷⁸⁶ In principle, the higher the originator estimates the chance of its patent being found invalid or not infringed, and the higher the damage to the originator resulting from successful generic entry and subsequent true generic competition, the more value it will be willing to transfer to the generic company to avoid that risk.

⁷⁸⁷ The generic supplier's 'expected returns' would represent the average of the profits associated with the potential outcomes of its entry strategy (for example, the revenue and costs associated with each outcome relevant to its strategy (such as winning or losing any litigation, and the possible timing of its entry), and the probability of each outcome.

the result of competition, but of its opposite, that is co-ordination between competitors at the expense of the consumer.

6.9 The following three Figures illustrate this situation.

Figure 6.1: The profits of the originator before generic entry

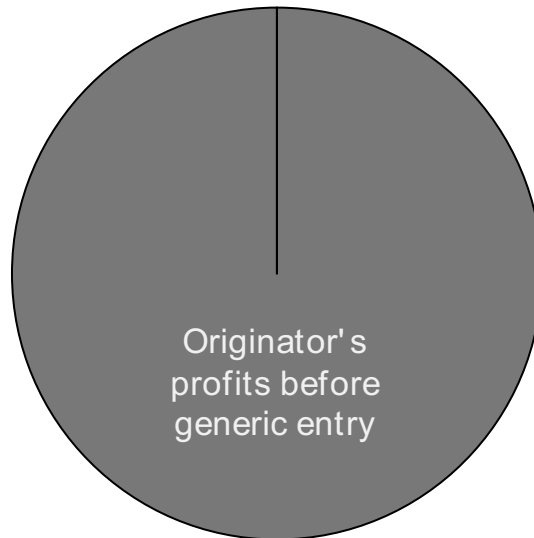


Figure 6.2: Consumer savings after generic entry

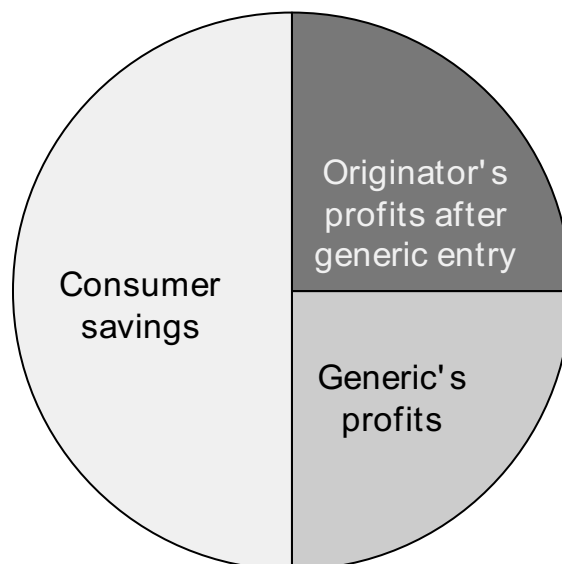
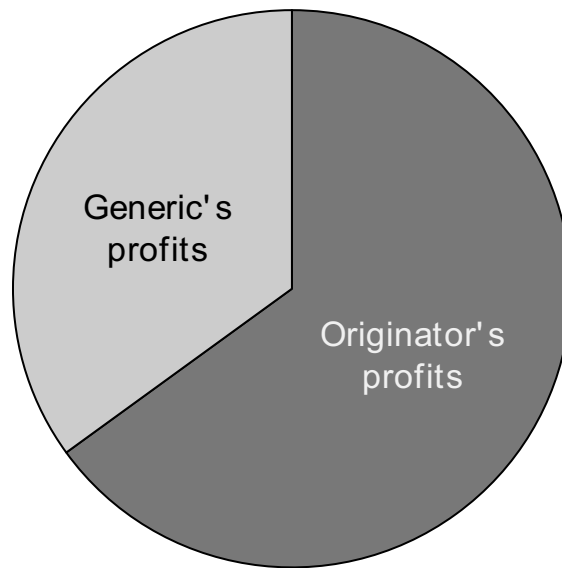


Figure 6.3: Sharing of the consumer savings by the originator and the generic supplier through an agreement with an exclusion payment



6.10 The following paragraphs of this Part are structured as follows:

- (a) Section B summarises the legal test for finding that an agreement has the object of restricting competition.
- (b) Section C sets out relevant aspects of the legal and economic context of the GUK-GSK Agreement and the Alharma-GSK Agreement that are the subject of the CMA's findings.
- (c) Section D sets out the key terms of the GUK-GSK Agreement and the Alharma-GSK Agreement, and analyses their restrictive object.

B. The legal test for an agreement which has the object of restricting competition, including potential competition

6.11 The term 'object' in Article 101(1) refers to the sense of 'purpose', 'objective', 'intent' or 'aim'.⁷⁸⁸ It is settled law that if an agreement has as its object the prevention, restriction or distortion of competition, it is not necessary to prove

⁷⁸⁸ See, for example: Judgment in *Consten & Grundig v Commission*, Joined Cases C-56/64 and 58/64, EU:C:1966:41, page 343 ("...*Since the agreement thus aims at ... it is therefore such as to distort competition...*"); Judgment in *IAZ and Others v Commission*, C-96/82, EU:C:1983:310, paragraph 25; Judgment in *Competition Authority v Beef Industry Development Society and Other*, C-209/07, EU:C:2008:643, paragraphs 32–33.

that the agreement has had, or would have, any anti-competitive effects, in order to establish an infringement.⁷⁸⁹ The restriction of competition need not be the sole purpose of the agreement: the fact that an agreement pursues other legitimate objectives, even such objectives as protecting public health or tackling an economic crisis in a sector, does not preclude it being regarded as having an object restrictive of competition.⁷⁹⁰

- 6.12 The CJ has held that certain types of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition.⁷⁹¹ The CJ characterised as the essential legal criterion for a finding of anti-competitive object that the coordination between undertakings reveals in itself ‘*a sufficient degree of harm to competition*’ that there is no need to examine its effects.⁷⁹²
- 6.13 The notion of restrictions of competition by object cannot be reduced to an exhaustive list.⁷⁹³ In order to determine whether an agreement may be considered to have the object of restricting competition, regard must be had to the content of its provisions, its objectives, and its legal and economic context.⁷⁹⁴ In assessing the context, it is also necessary to take into consideration the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market(s) in question.⁷⁹⁵ Although the parties’ intention is not a necessary factor in determining whether an agreement is restrictive, there is nothing prohibiting that factor from also being taken into account.⁷⁹⁶
- 6.14 The restriction of competition in an anti-competitive agreement may relate to existing and/or potential competition. The GC noted in *E.ON Ruhrgas* that the

⁷⁸⁹ See, for example: Judgment in *Consten and Grundig v Commission*, Joined Cases 56/64 and 58/64, EU:C:1966:41, page 342; Judgment in *Competition Authority v Beef Industry Development Society and Others*, Case C-209/07, EU:C:2008:643, paragraph 16; and Judgment in *Expedia Inc v Autorité de la concurrence and Others*, Case C-226/11, EU:C:2012:795, paragraph 35.

⁷⁹⁰ Judgment in *Competition Authority v Beef Industry Development Society and Other*, C-209/07, EU:C:2008:643, paragraph 21. Judgment in *Groupement des Cartes Bancaires v Commission*, Case C-67/13 P, EU:C:2014:2204, paragraph 70.

⁷⁹¹ Judgment in *Groupement des Cartes Bancaires v Commission*, C-67/13 P, EU:C:2014:2204, paragraph 50; recently affirmed in Judgment in *Dole v Commission*, C-286/13 P, C:2015:184, paragraph 114 and Judgment in *Toshiba v Commission*, C-373/14 P, EU:C:2016:26, paragraph 26.

⁷⁹² Judgment in *Groupement des Cartes Bancaires v Commission*, C-67/13 P, EU:C:2014:2204, paragraphs 49 and 57; recently affirmed in Judgment in *Dole v Commission*, C-286/13 P, C:2015:184, paragraph 113 and Judgment in *Toshiba v Commission*, C-373/14 P, EU:C:2016:26, paragraph 26.

⁷⁹³ See, for instance, the Opinion of Advocate-General Trstenjak delivered on 4 September 2008, C-209/07, EU:C:2008:467, in *Competition Authority v Beef Industry Development Society and Other*, paragraphs 48–49.

⁷⁹⁴ Judgment in *Groupement des Cartes Bancaires v Commission*, C-67/13 P, EU:C:2014:2204, paragraph 53, recently affirmed in Judgment in *Toshiba v Commission*, C-373/14 P, EU:C:2016:26, paragraph 27.

⁷⁹⁵ Judgment in *Groupement des Cartes Bancaires v Commission*, C-67/13 P, EU:C:2014:2204, paragraph 53; recently affirmed in Judgment in *Dole v Commission*, C-286/13 P, C:2015:184, paragraph 117.

⁷⁹⁶ Judgment in *Groupement des Cartes Bancaires v Commission*, C-67/13 P, EU:C:2014:2204, paragraph 54; recently affirmed in Judgment in *Dole v Commission*, C-286/13 P, C:2015:184, paragraph 118.

examination of conditions of competition must be based not only on existing competition between undertakings already present on the relevant market, but also on potential competition.⁷⁹⁷

- 6.15 In a case where it is contended that an agreement has the object of restricting competition from a potential new entrant, one must have regard to ‘*the structure of the market and the economic and legal context within which it functions*’, to ascertain whether there are ‘*real concrete possibilities ... for a new competitor to enter the relevant market and compete with established undertakings*’.⁷⁹⁸ This is not a hurdle requiring proof of likely effects, since otherwise the distinction between cases where an agreement has a restrictive object and cases where an agreement has - at least potentially - restrictive effects, would be eliminated. The underlying idea behind paying regard to the economic and legal context is that ‘*purely theoretical and abstract considerations*’ should not amount to infringements.⁷⁹⁹
- 6.16 The perception of the market incumbent(s) on the relevant market that there is a threat, and the response of the market incumbent(s), is relevant to the assessment whether there is a sufficiently serious threat to amount to potential competition.⁸⁰⁰ The GC stated in *Visa* that: ‘*... the essential factor is the need for the potential entry to take place with sufficient speed to form a constraint on market participants...*’⁸⁰¹
- 6.17 The very existence of an agreement under which a party undertakes to a market incumbent not to enter a market is in itself a clear indication that the market incumbent faces potential competition from that other party. The GC found in *Toshiba* that ‘*... an agreement such as [the market-sharing agreement in that case] which is designed to protect the European producers in their home territories from actual or potential competition from Japanese producers, is capable of restricting competition, unless insurmountable*

⁷⁹⁷ Judgment of 29 June 2012, *E.ON Ruhrgas v Commission*, T-360/09, ECR, EU:T:2012:332, paragraph 85. In making this finding the GC relied upon the following judgments: Judgment in *Delimitis v Henninger Brau*, C-234/89, EU:C:1991:91, paragraph 21; Judgment of 15 September 1998, *European Night Services and Others v Commission*, Joined Cases T-374/94, 375-94, 384/94 and 388/94, ECR, EU:T:1998:198, paragraph 137; Judgment of 14 April 2011, *Visa Europe v Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 68.

⁷⁹⁸ Judgment of 14 April 2011, *Visa Europe v Commission*, Case T-461/07, ECR, EU:T:2011:181, paragraph 68. Judgment of 29 June 2012, *E.ON Ruhrgas v Commission*, T-360/09, ECR, EU:T:2012:332, paragraph 85. See also paragraphs 168–169 of *Visa* which state that the essential factor is whether the undertaking has ‘*the ability to enter the market*’ and that the ‘*mere fact of its existence may give rise to competitive pressure on the undertakings currently operating in that market [...]*’.

⁷⁹⁹ See the Opinion of Advocate-General Wahl delivered on 19 June 2013, C-67/13 P, EU:C:2014:1958, in *Groupement des Cartes Bancaires v Commission*, paragraph 41.

⁸⁰⁰ Judgment of 21 May 2014, *Toshiba v Commission*, T-519/09, ECR, EU:T:2014:263, paragraph 230; recently affirmed by the CJ in Judgment in *Toshiba v Commission*, C-373/14 P, EU:C:2016:26, paragraphs 30–35. See also Judgment of 12 July 2011, *Hitachi v Commission*, T-112/07, ECR, EU:T:2011:342, paragraph 319.

⁸⁰¹ Judgment of 14 April 2011, *Visa Europe v Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 189.

barriers to entry to the European market exist which rule out any potential competition from Japanese producers.⁸⁰²

C. The legal and economic context of the Agreements that are the subject of the Decision

6.18 The CMA refers generally to the matters set out in Part 3 of this Decision, in relation to the legal and economic context of the Infringing Agreements. It draws attention in particular to the following legal and factual elements.

i) The public interest in eliminating obstacles to economic activity where patents have been granted in error

6.19 The CJ has emphasised that, as a matter of legal policy, private contractual impediments should not be put in the way of challenges to the validity of patents that may have been granted in error.⁸⁰³

6.20 Thus, the CJ ruled in *Windsurfing* in 1986 that an obligation on the licensee in a patent licensing agreement not to challenge the validity of the licensed patents:

*'...clearly does not fall within the specific subject-matter of the patent, which cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error.'*⁸⁰⁴

6.21 This principle reflects two basic considerations. The first is that the grant of a patent right involves conferring what GSK has referred to as a '*legal monopoly*'.⁸⁰⁵ The '*legal monopoly*' may allow the patent owner to charge its customers supra-competitive prices, for so long as it prevails. It is therefore

⁸⁰² Judgment of 21 May 2014, *Toshiba v Commission*, T-519/09, ECR, EU:T:2014:263, paragraph 230; affirmed by the CJ in Judgment in *Toshiba v Commission*, C-373/14 P, EU:C:2016:26, paragraphs 30–35.

⁸⁰³ Judgment in *Centrafarm and Others v Sterling Drug*, C-15/74, EU:C:1974:114, paragraph 9; Judgment in *Windsurfing International v Commission*, C-193/83, EU:C:1986:75, paragraph 45.

⁸⁰⁴ Judgment in *Windsurfing International v Commission*, C-193/83, EU:C:1986:75, paragraph 92. These principles were considered in *Knorr-Bremse Systems for Commercial Vehicles v Haldex Brake Products* [2008] EWHC 156 (Pat), paragraphs 47–51. In that case, Mr Justice Lewison of the High Court (Patents Court) stated that there was 'at the least a good arguable case' that a no-challenge clause contained in a settlement agreement was likely to distort competition and affect trade between Member States (although the case was decided on other grounds). See also Commission Notice: Guidelines on the application of Article 101 of the Treaty of the Functioning of the European Union to technology transfer agreements, OJ C 89/3, 28.3.2014, paragraph 243, which consider '*non-challenge*' clauses in the context of technology transfer and settlement agreements and state that '*non-challenge clauses in settlement agreements can under specific circumstances be anti-competitive and may be caught by Article 101(1) of the Treaty*' and '[t]he restriction of the freedom to challenge an intellectual property right is not part of the specific subject-matter of an intellectual property right and may restrict competition'.

⁸⁰⁵ GSK submission to the OFT dated 27 June 2012 (document 0746), paragraph 2.1.

important to be clear that the necessary conditions for the grant of the patent right are satisfied.

6.22 The second consideration is closely connected with the first. It is that the grant of a patent by a patent office often does not, in itself, guarantee that the necessary conditions for the grant of a legal monopoly (such as the requirement of novelty) have been met. In particular, it is only after the patent has been granted that third parties can formally oppose it.

ii) *The overall pattern of litigation and settlement in the context of challenges by generic companies in the pharmaceutical sector*

6.23 Of the patents reportedly challenged by generic companies through opposition before the EPO in the period 2000-2007, 60% were revoked and 15% were amended. Only 25% of challenged patents remained intact.⁸⁰⁶ The Sector Inquiry found for the period 2000-2007 that, whilst the vast majority of litigation cases in the EEA in the pharmaceutical sector were infringement cases initiated by originator companies against generic companies,⁸⁰⁷ generic companies in fact won 62% of all cases that resulted in a ruling.⁸⁰⁸

6.24 The CMA notes that settlement agreements that do not involve cash payments or other value transfers are common in the pharmaceutical sector. For example, in its Sector Inquiry, the Commission found that over 78% of the settlement agreements in its sample either included no restrictions on generic market entry or included some restrictions on generic entry with no value transfer being made from the originator to the generic.⁸⁰⁹

6.25 Empirical evidence from the United States supports the proposition that branded and generic companies can often settle patent litigation without using value transfers in return for entry restrictions. Although there are legal and regulatory differences between the pharmaceutical sectors in the UK and the US, the fundamental way in which competition in the sector works is sufficiently similar that this evidence is relevant. For example, in a Prepared

⁸⁰⁶ Sector Inquiry Final Report, pages 395–410. These statistics are based on responses to questionnaires sent by the Commission to various companies in relation to the Sector Inquiry; in total, 43 originator companies and 27 generic companies submitted comprehensive replies to the questionnaires. The CMA recognises that challenges are most likely in relation to those patent claims which are perceived to be 'weaker'.

⁸⁰⁷ Sector Inquiry Final Report, page 215. In the UK specifically, the majority of cases were initiated by generic companies. See also footnote 115 in paragraph 3.76.

⁸⁰⁸ Sector Inquiry Final Report, pages 223–224. There is no UK data regarding the outcome of litigation. See also footnote 115 in paragraph 3.76. The CMA recognises that challenges are most likely in relation to those patent claims which are perceived to be weaker.

⁸⁰⁹ Sector Inquiry Final Report, paragraph 743.

Statement⁸¹⁰ the FTC stated *‘the settlement data that the FTC has for the period from 2000 through 2004 indicates that parties can and do find other ways to settle cases. During that period of successful Commission enforcement, pay-for-delay settlements essentially stopped. But patent settlements – using means other than exclusion payments – continued to occur. In less than five years, there were at least as many settlement as there were in the seven years in which pharmaceutical companies were settling litigation with payments and restrictions on generic entry. Parties simply found different ways to resolve their disputes, presumably on the basis of the relative strength of their cases.’*⁸¹¹

6.26 Accordingly, it is not the case that a competition law rule prohibiting originators in the pharmaceutical sector from (in effect) paying generic rivals to delay their efforts independently to enter a market which is solely or largely supplied by a patented medicine, stands in the way of settlements of litigation as a general proposition.

iii) *Understanding the purpose of the GUK-GSK Agreement and Alpharma-GSK Agreement in the context of the lifecycle of a pharmaceutical product*

6.27 The Sector Inquiry described the lifecycle of a pharmaceutical product as constituting three main phases: (i) the R&D phase up to market launch; (ii) the period between launch and loss of exclusivity (patent expiry); and (iii) the period following the loss of exclusivity, when generic products can enter the market.

6.28 During the first phase, originator companies seek to ensure that they obtain maximum patent protection for the output of their R&D efforts.

6.29 During the second phase, following the launch of the product, the manufacturer looks to generate sufficient revenue from the medicine to cover

⁸¹⁰ Prepared Statement of The Federal Trade Commission On ‘Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs’, by Richard A. Feinstein, page 18.

⁸¹¹ A similar observation is made in the following US court documents:

- *‘[E]arlier in the last decade, when the law condemned exclusion payments, branded and generic firms entered into numerous settlements without exclusion payments’.* (FTC v. Actavis, Inc., No. 12-416, Brief of AARP, American Medical Association, National Legislative Association for Prescription Drug Prices and US Public Interest Research Groups as Amici Curiae in Support of Petitioner (677 F.3d 1298 (2012), page 17).
- US Supreme Court: *“the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point.”* (Judgment of the Supreme Court of the United States dated 17 June 2013 in *FTC v Actavis, Inc.*, 133 S. Ct. 2223 (2013), page 19).

its R&D costs and to earn a profit, before the medicine becomes subject to competitive pressure from generic equivalents. It is, therefore, often in the interests of manufacturers to prolong and maximise this phase, and to carry out strategies known as 'lifecycle management' to extend the period of market exclusivity. An example would be to carry out further R&D, known as 'incremental innovation', with a view to improving the medicine, establishing manufacturing processes for the medicine, or finding new uses for it and filing resulting associated 'secondary patent' applications.⁸¹²

- 6.30 This is described in internal GSK documents, as it relates to paroxetine, as follows:⁸¹³

'The philosophy within the group responsible for paroxetine is to patent every possible process, compound, form, aspect of the product, its production and its alternatives and derivatives which could conceivably provide some form of protection to Seroxat/Paxil. The success of this group is demonstrated by the expectation of additional years of exclusivity after basic patent expiry.'

[...]

To date patents have been filed on the compound per se, primary manufacturing processes, secondary manufacturing processes, formulations, tablet designs, and Seroxat/Paxil therapeutic uses. In future, patentable opportunities will be sought and pursued whenever additional protection can be obtained and competitive barriers raised.'

- 6.31 During this second phase, GSK engaged in legal challenges which a GSK internal document explained could be used 'to prevent/delay' generic entry.⁸¹⁴ This Decision is concerned with the lawfulness of behaviour that, understood in its context, represents one aspect of this strategy.
- 6.32 Manufacturers of generic medicines will, subject to restrictions around data exclusivity,⁸¹⁵ have the opportunity to apply for MAs⁸¹⁶ for generic equivalents of the branded medicine and, if successful, can then market them. Generic

⁸¹² See, for example, GSK's strategy to establish new indications referred to in 'Seroxat/Paxil Global 3/1 Product Plan (2001/2003)' dated April 2000 (documents 0118 and 0119).

⁸¹³ See extract from GSK internal report dated 12 March 2001 (document 0107), paragraph 4.2. This is consistent with a GSK internal paroxetine report entitled 'Integrated Project Plan, Paroxetine/Paxil/Seroxat' dated 2 August 2002 (document 0301), page 12, in which it is noted that one of GSK's stated strategies for its lifecycle management of paroxetine was to '[d]evelop line extensions and indications in order to protect the brand from generic and competitor erosion'.

⁸¹⁴ GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100).

⁸¹⁵ See paragraphs 3.90–3.92.

⁸¹⁶ See paragraphs 3.85–3.89.

medicine suppliers may develop medicines despite an originator company still retaining patents relevant to a given medicine, in particular where they consider it possible to develop a medicine that does not infringe patent claims held by the originator company and/or where it considers it possible to successfully challenge the validity of relevant patents.

6.33 In this regard, patent challenges by generic medicine suppliers are part of the overall competitive process both for generic suppliers seeking market entry for their essentially similar medicines and for originator companies that invoke process patents or other patents in an attempt to repel such market entry. In such a situation, patent litigation reflects the independent efforts of generic undertakings trying to enter the market and is also an expression of competition from the side of the originator, which is trying to defend its market position against true generic competition. Agreements that result in patent challenges being 'bought off' may therefore seriously impact the competitive process as they are frequently the very expression of potential competition in this sector.

iv) Generic competition and its impact on prices

6.34 The process of generic competition can be expected to lead to lower prices and reduced market shares for the incumbent branded supplier, in the following way:

- Where a therapeutically equivalent generic product is available, pharmacies are able to dispense either a generic or a branded product against open prescriptions.
- Where pharmacies can choose whether to dispense a branded or a generic medicine, they have a strong incentive to dispense the cheapest medicine available.
- The first generic entrant would therefore seek to lower prices by a sufficient margin to compensate pharmacies for stocking a generic product alongside the branded product. In doing so, the first generic entrant would be expected to capture a significant volume of sales from the branded supplier.⁸¹⁷

⁸¹⁷ [GSK's Finance Director A] noted in a witness statement in the GUK Litigation that a generic entrant initially makes a high volume of sales: '[i]t is well known in the industry that wholesalers and retail chains run down their stocks of branded product (including parallel imports) in anticipation of the launch of generic products, and as a result, the initial sales of generic products tend to be disproportionately high.' [§]WS2 (GUK) (document 0182), paragraph 6.4.

- Subsequent generic entrants would have an incentive to engage in strong price competition in order to encourage pharmacies to dispense their products. As a result, prices would be competed down even further, with more pharmacies switching away from the branded supplier for their supply.

6.35 On average⁸¹⁸ in the EU, about four to five generic entrants are typically present in the market one year after the loss of exclusivity, and the number of firms entering increases with the value of the product in question. Within three years of the loss of exclusivity the ratio of generic companies to originators is about 6:1. The ratio is likely to be higher in the case of high value products than it is with other lower value products.⁸¹⁹

6.36 True generic competition leads, on average, to considerable price declines both for branded and generic medicines, as demonstrated by the following examples.

- In the EU, generic medicines typically come onto the market at prices that are about 25% lower than the price of the originator product immediately prior to the loss of exclusivity.
- Generic entry also has the effect of decreasing the price of the originator product. In markets where generic entry occurs, average prices drop by almost 20% one year after the loss of exclusivity and about 40% after two years.⁸²⁰ In some cases the decrease can be as much as 80-90%.⁸²¹ Such reductions can lead to significant savings to public healthcare systems. In markets where generic medicines become available, the average EU saving to the health system (as measured by the development of a weighted price index of originator and generic products) is almost 20% one year after the first generic entry, and about 25% after two years.⁸²²
- In the UK, in the period 2000-2004 the average (weighted by sales) price reduction for a medicine in the UK one year after generic entry was 15%.⁸²³ The same report found that for the period 2004-2006, the average (weighted by sales) price reduction for a medicine in the UK one year after generic entry had risen to 42%.

⁸¹⁸ On the basis of an average weighted by product value.

⁸¹⁹ Sector Inquiry Final Report, paragraphs 201–202.

⁸²⁰ Sector Inquiry Final Report, Executive Summary, section 2.1.2.

⁸²¹ Sector Inquiry Final Report, paragraph 212.

⁸²² Sector Inquiry Final Report, Executive Summary, section 2.1.2.

⁸²³ Report entitled 'Competition in the off-patent market post generic entry', CRA International, September 2008; report prepared for Baker & McKenzie CVBA/SCRL, Page 40, Figure 16: 'The impact of generic entry 2000-2003 vs. 2004-2007 in UK' (cited data source: IMS and CRA analysis).

- 6.37 In the present case, at the time the GUK-GSK and Alparma-GSK Agreements were entered into, such outcomes in the market were expected, namely that the introduction of true generic competition would lead to substantial price decreases. In each case, at the time, independent generic entry was yet to occur, and GSK was continuing to challenge any proposed generic entry. In an expert report for GSK in the GUK Litigation in September 2001, [X] (an independent pharmaceutical consultant) put forward the opinion that the impact of generic entry on Seroxat would be ‘*serious*’, leading to significant declines in paroxetine prices and a sharp decline in GSK’s market share.
- 6.38 [GSK’s independent expert’s] expectation, based on four case studies, was that⁸²⁴ ‘*generics will probably undercut the pre-generic price of Seroxat by around 30% within 6 months of launch, by 45 to 50% after 12 months and by 60% after 24 months.*’⁸²⁵
- 6.39 Contemporaneous Alparma documents also demonstrate that Alparma expected that, were true generic competition to emerge in relation to the supply of paroxetine, the result would be significant decreases in the price of paroxetine charged to pharmacies, as generic suppliers engaged in price competition to win sales (see paragraph 3.321).
- v) *GSK’s strategy to maintain its monopolistic position, including by concluding supply agreements with third parties***
- 6.40 In April 1999, in response to the threat of generic entry, GSK established an internal project team called Project Dyke, which was tasked with defending Seroxat from generic competition and with sustaining patent protection for Seroxat. Project Dyke involved a global team from within GSK that held regular telephone conferences and meetings between 1999-2004⁸²⁶ and had two key functions of particular relevance to the issues in this Decision:
- co-ordinating the legal defence of patent rights

⁸²⁴ [X]WS (document 0143), paragraph 20.

⁸²⁵ The CMA also notes that GSK used the generic entry of fluoxetine as an example in its internal modelling of the potential impact of generic entry in relation to paroxetine anhydrate, suggesting for example that a loss in market share of 60–80% over the first few months might be observed (Email from [GSK’s Marketing Manager A for Seroxat] to [GSK Group Director (Global Market Access)], ‘Generic Competition’ dated 5 January 2001 (document 0122)).

⁸²⁶ See extract from EU Commission questionnaire dated October 2006 (document 0631), page 39, question 25 ‘In relation to “Project Dyke”, provide the following information’.

- co-ordinating GSK's entry into '*co-marketing*' agreements (see paragraphs 3.144 to 3.154).⁸²⁷

6.41 In 2001, generic companies began efforts to enter the market in certain European countries such as Denmark and Germany. GSK was aware that it would need to rely on its patent position to challenge that entry. In the presentation referred to at paragraph 3.145, [GSK's Pricing Manager for Europe] sets out the threat to Seroxat from potential generic entrants for both paroxetine anhydrate and paroxetine mesylate. In order to defend against generic entry, the presentation considers possible defence strategies for Seroxat, including:⁸²⁸

- *Maintain monopolistic position*
- *Legal challenges, court injunctions, threat of legal action.*
- *Third party supply agreement*
- *New market opportunities*
- *PLEs [Product Line Engineering] and differentiation (new doses and forms 30 mg, 10 mg strengths and new indications in GAD [General Anxiety Disorder], SAD [Seasonal Affective Disorder], PTSD [Post Traumatic Stress Disorder])*
- *OTC [Over The Counter] switch*
- *Second Fighter Brand – compete on price*
- *Marketing and promo effort*
- *Financial incentives and NSP [Net Selling Price] discounts*
- *List price cuts.'*

6.42 GSK's chosen strategy was to protect against the significant decline in prices that was expected to follow any independent generic entry. In a GSK Seroxat Brand Strategy document in December 2002, for example, GSK notes that the '*Defences undertaken to date [including co-marketing] are crucial to protect*

⁸²⁷ Extract from CNS Psychiatry- Depression and Anxiety document (document 0105); GSK document headed 'Project Dyke – Europe maintains Seroxat franchise despite generic launches!' (document 0108).

⁸²⁸ GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100).

*Seroxat prices*⁸²⁹. Connected with that, GSK recognised the possible significant loss of profit that it would potentially suffer from a reduction of Seroxat sales if generic entry occurred (as described below in some detail by [GSK's Finance Director A] in a witness statement of 20 October 2001, shortly after entering into the IVAX-GSK Agreement).⁸³⁰

6.43 On this basis, in order to '[m]aintain [GSK's] monopolistic position', GSK either needed to: (i) challenge any potential generic entrants using GSK's patent rights; or (ii) cooperate with the potential generic entrants by entering into 'supply agreement[s]' (also referred to as 'co-marketing agreements').⁸³¹

6.44 Under the supply agreement route, GSK would offer to supply potential generic entrants with paroxetine hemihydrate which the generic companies could then sell under their own name. Under the heading 'Co-marketing Strategies', the presentation continues:⁸³²

• Deals to supply paroxetine hemihydrate to generic Co [company] to be marketed under new brand name.

• Gives generic Co early access to market.

*• Avoids most price referencing, expensive legal action, risk of loss, maintains market volume.*⁸³³

6.45 In addition, GSK had identified that the supply agreement route would 'optimise market share'.⁸³⁴ GSK estimated that supply agreements could 'stabilise molecule market share of GSK compound at 70-80%'.⁸³⁵ A market share loss of 20-30% is far lower than GSK could have suffered if faced with true generic competition. For example, in relation to one of Seroxat's competitors, Prozac, the branded company, Eli Lilly, lost around 80% of its market share once generic companies entered the market in 2000.⁸³⁶

⁸²⁹ GSK presentation entitled 'Seroxat Brand Planning, Europe' by [GSK's Brand Manager (Neurosciences) Europe] dated December 2002 (document D 124).

⁸³⁰ See [REDACTED]WS2 (GUK) (document 0182), paragraphs 2.4–2.9.

⁸³¹ GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100).

⁸³² GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100). This is an extract from the slide which includes other bullet points.

⁸³³ 'Price referencing' refers to the process by which certain countries set the price (or more commonly the reimbursable price) of a medicine by referencing the price of the same product in different countries.

⁸³⁴ GSK presentation entitled 'Seroxat – Sales 2002 and future budget' dated 2002 (document 0194).

⁸³⁵ GSK presentation entitled 'How do LOC's Cope with the Generic Attack?' (document 0110).

⁸³⁶ [REDACTED]WS, Confidential exhibit [REDACTED]2 (document 0874), page 4.

6.46 Recognising the benefits of supply agreements, GSK decided during 2001 that such agreements were to be explored with third parties in the Netherlands, Denmark, Ireland, and Great Britain.⁸³⁷

vi) At the time the GUK-GSK Agreement was entered into GUK was a potential competitor to GSK

6.47 At the time the GUK-GSK Agreement was entered into, there were real concrete possibilities for GUK to supply paroxetine in the UK independently of GSK.⁸³⁸ Thus, GUK was a potential competitor. The CMA refers to the elements listed below, which are addressed in turn in the following paragraphs:

- GUK had the capability to supply into the UK generic paroxetine sourced independently of GSK. GUK had committed significant time and resources in taking steps to enable it to supply generic paroxetine in the UK. GUK's preparations had progressed to a point at which it was in possession of a marketing authorisation, and it was actually preparing to enter the market having invested in stocks of API and preparations for tableting.
- GUK continued with its preparations to enter the UK paroxetine market, despite the prospective litigation with GSK. Neither the GUK Litigation, nor the GUK Interim Injunction (which was a temporary measure pending a final adjudication of the patent issues by the court), was an insurmountable barrier to entry.
- The fact that GSK was willing to make substantial value transfers to GUK, in return for GUK agreeing not to enter the market independently of GSK, is a strong indication that GSK perceived GUK as a credible threat, and that it exerted competitive pressure on GSK. GSK was aware that if generic suppliers were successful in their efforts to enter the market prior to the expiry of its Anhydrate Patent (due in 2016), the prices and profits that GSK could have sustained in the UK paroxetine market would have decreased substantially. GSK's expected returns,⁸³⁹ taking account of the potential that its returns would be substantially lower if generic suppliers

⁸³⁷ GSK document entitled 'Seroxat patent' dated 11 May 2001 (document 0133). It also appears that such an agreement may have also been in contemplation in Australia – see email from [GSK's Senior Vice President Patents & Trademarks] to [GSK's Patent Attorney] and others dated 20 July 2001, saying that the GM of Australia favours the 'deal route' (document 0139).

⁸³⁸ With respect to both 20mg and 30mg tablets (see further paragraph 3.258).

⁸³⁹ That is, the average of its possible profits going forward, taking account of the potential revenue and costs associated with each possible outcome (for example, the success or otherwise of independent generic entry), and the likelihood associated with each.

were successful in their efforts to enter the market, were therefore lower as a result of the constraint from the threat of GUK's generic entry.

6.48 Annex D, Section B sets out and responds to the SO Addressees' main representations in relation to this Section.

a) GUK's capability

6.49 During the Relevant Period GUK was owned and controlled by Merck, a major global developer of pharmaceutical products. In 2002, GUK was one of the largest UK providers of generic medicines in the UK.⁸⁴⁰ It therefore had experience in developing and bringing generic medicines to market in the UK (and in other countries worldwide), and the general capability to develop and bring medicines such as paroxetine to market.

6.50 At the time the GUK-GSK Agreement was entered into, GUK had taken a number of steps towards enabling it to supply generic paroxetine sourced independently of GSK in the UK. As set out in paragraphs 3.249 to 3.279, GUK had:

- actively made preparations to enter the UK paroxetine market, with GUK first starting to investigate paroxetine in February 1997 with a view to supplying its own paroxetine product;
- obtained a UK MA for its paroxetine product (which was granted on 29 October 2001);
- purchased a large amount of API for the development and launch of its paroxetine product in a number of countries including the UK;
- sought and achieved (between 7 and 21 September 2001) a significant number of advance orders (approximately £5.5 million of potential sales) from customers in the UK, some for up to six months hence; and
- engaged in discussions with a number of generic suppliers about GUK supplying its paroxetine product to them;

⁸⁴⁰ Exhibit [REDACTED]1 Tab 9 to [REDACTED]WS, undated (document 0857) and [REDACTED]WS (document 0901), paragraph 8. See also [REDACTED]WS2 (document 1325), paragraphs 12 and 14: '*At present there are four major players in the generic market, namely Generics UK, Ivax, APS and Alparma. Together, they account for approximately 80% of the generics market by volume and 80% by value. ...Between them, Generics UK, Ivax and Alparma make up approximately 60% by value of the generics market.*' See also reference to GUK being '*clearly number one [in the UK] with a 20% market share*' in a letter sent by [GUK's General Manager] to a wholesaler dated 29 October 2001 (document 0921).

- contested the GSK Litigation for a period of over five months (in 2001-2002),⁸⁴¹ and until the day before the relevant trial was due to commence.

6.51 Accordingly, GUK was very close to launching the GUK Product in the UK at the time the GUK Litigation was commenced and the (temporary) GUK Interim Injunction was granted.

b) GUK's continued preparations despite the GUK Litigation and the (temporary) GUK Interim Injunction

6.52 GUK pursued the actions referred to above fully aware that GSK held a number of patents regarding paroxetine. Even prior to the initiation of the GUK Litigation, GUK was aware that it was likely to face patent infringement claims from GSK in the future.⁸⁴² Such knowledge did not stop GUK from continuing its preparations to enter the UK paroxetine market. Documents from the GUK Litigation indicate that GUK had planned to launch in the UK in November 2001.⁸⁴³

6.53 Prior to the grant of the GUK Interim Injunction on 23 October 2001, GUK would have been in a position to enter the UK paroxetine market independently of GSK.⁸⁴⁴ As [GUK's General Manager] put in his evidence to the High Court in the GUK Litigation: *'unless the injunction is granted, we [GUK] will be in a position to sell the product very shortly thereafter'*.⁸⁴⁵

6.54 Also, prior to the granting of the GUK Interim Injunction, GUK intended to enter the UK paroxetine market independently of GSK. In particular, internal

⁸⁴¹ From 18 September 2001 from the issue of the claim form by GSK to the date of settlement on 13 March 2002.

⁸⁴² In fact, GUK expected that patent infringement claims from GSK were likely: see, for example, email from [the Chief Executive of Merck Generics Group] to [Merck Generics' Head of Corporate Business Development] and [a Merck employee] dated 1 December 2000 (document 0832), set out at paragraph 3.281, in which [the Chief Executive of Merck Generics Group] explained that '[...] litigation is virtually unavoidable with SKB on paroxetine - given that we are registering in various countries a generic [with non-infringing process]'; and email from [a Research and Development employee of Merck Generics] to [Merck Generics' Finance Director], [GUK's Head of Research and Development] and [the Chief Executive of Merck Generics Group] dated 15 December 2000 (document 0835), set out at paragraph 3.282, in which [a Research and Development employee of Merck Generics] explained that *'Paroxetine tablets - this will be subject to litigation with SmithKline'*.

⁸⁴³ In an email from [the Chief Executive of Merck Generics Group] to [Merck's Chairman of the Executive Board] dated 29 May 2001 (document 0850), set out at paragraph 3.283, [the Chief Executive of Merck Generics Group] explained that he had *'taken the decision to proceed with launch in Australia and Europe - working on the basis that GSK has an invalid patent and we do not infringe'*. Further, in September 2001, GUK sought and took substantial advance orders for its product.

⁸⁴⁴ See Claimant's skeleton argument in the GUK Litigation dated 22 October 2001 (document 0907), paragraph 4. See also spreadsheet entitled *'Paroxetine - Launch analysis'* dated 11 June 2001 (document 0855), recording the *'Earliest est. launch'* for 20mg strength paroxetine in the UK as September 2001.

⁸⁴⁵ [REDACTED]WS (document 0901), paragraph 16. This is also consistent with [GSK's Finance Director A's] evidence in his first witness statement in the GUK Litigation that GUK's *'product is likely to be granted marketing authorisation in the UK imminently through the "mutual recognition" procedure'* ([REDACTED]WS1 (GUK) (document 0885), paragraph 5.3).

GUK correspondence indicates that GUK expected to be subject to litigation proceedings by GSK regarding the patent situation in the UK. However, GUK had still planned to launch its product in the UK.⁸⁴⁶ This was despite the fact that such entry would have been 'at risk' (see paragraphs 3.262 to 3.264) and, had GUK lost the GUK Litigation, it may have faced a considerable damages claim from GSK.⁸⁴⁷

6.55 Following the grant of the temporary GUK Interim Injunction on 23 October 2001, GUK continued to contest the GUK Litigation for around five months,⁸⁴⁸ and continued with its preparations for entry until it entered into the GUK-GSK Agreement and accepted value transfers from GSK (see paragraphs 6.86 to 6.141).⁸⁴⁹ GUK had turned down a series of increasingly lucrative settlement offers from GSK, before settling with GSK in March 2002. GSK's various settlement offers are set out at paragraph 3.286. The CMA notes in particular that at the end of December 2001 (less than three months before the start of the hearing in the GUK Litigation) GUK decided to turn down an offer from GSK amounting to approximately £13.3 million, and instead to continue with the GUK Litigation.⁸⁵⁰

c) *GSK's response to GUK's proposed market entry was to make value transfers to secure GUK's acceptance of entry restrictions relating to its independent market entry*

6.56 GSK's actions in response to GUK's proposed market entry support the CMA's conclusion that GUK was a potential competitor with real concrete possibilities to enter the UK paroxetine market independently of GSK.

⁸⁴⁶ In an email from [the Chief Executive of Merck Generics Group] to [Merck's Chairman of the Executive Board] dated 29 May 2001 (document 0850), set out at paragraphs 3.283 and 3.264, [the Chief Executive of Merck Generics Group] explained that he had *'taken the decision to proceed with launch in Australia and Europe - working on the basis that GSK has an invalid patent and we do not infringe'*.

⁸⁴⁷ When granting the GUK Injunction, the High Court considered that *'[t]he only thing I think I can say with some certainty is that the order of damage to the claimant [GSK] is likely to be a good deal greater than that to the defendants [GUK]'*. *SmithKline Beecham Plc v Generics (UK) Ltd*, transcript of hearing before Jacob J dated 23 October 2001 (document 0911), page 10.

⁸⁴⁸ For example, GUK informed the CMA that it *'vigorously pursued the anhydrate patent litigation in spite of this major setback [referring to the GUK Interim Injunction]'* (See GUK submission to the OFT dated 22 February 2012 (document 1214), paragraph 3.3. See also Note of meeting between the CMA and GUK on 7 February 2012 (document 1210), paragraph 13 (*'even despite GUK having good arguments on the merits of the patent'*)).

⁸⁴⁹ For example, GUK did not withdraw its application for a UK MA (which was granted on 29 Oct 2001). GUK was, as at 8 November 2001, *'in the process of varying'* its licence, and allocating 50,000 packs for supply on 'Day 1' in March 2002, in order to supply certain customers' requirements – see email chain dated 31 October 2001-8 November 2001 between [a GUK Sales and Marketing employee], [a GUK Special Projects Manager] and others (document 0927), pages 1–2. As at 12 March 2002, there were various batch numbers of stock which had been packed by Alphapharm for GUK which were either at *'freight agents waiting to come over to UK or Germany'* or *'at Alphapharm ready to come over'* – see emails beneath email from [GUK's General Manager] dated 12 March 2002 (document 0991), page 1.

⁸⁵⁰ See paragraph 3.286.

- 6.57 As explained in detail at paragraphs 6.86 to 6.141, GSK's response to the GUK Litigation was to commit to make value transfers to GUK in return for GUK's acceptance of restrictions on its ability to enter the UK paroxetine market independently of GSK. By entering into the Agreements, GSK committed to make value transfers to GUK and the other Generic Companies that totalled at least £50.9 million, including value transfers to GUK that totalled at least £21.3 million.⁸⁵¹ The average annual value that GSK committed to transfer to the Generic Companies was equivalent to 37% of its annual UK paroxetine profits.⁸⁵² These transfers were commercially rational for GSK only on the basis that they would be used to induce the Generic Companies' acceptance of entry restrictions and to delay their potential independent market entry (see also paragraphs 6.86 to 6.141 in relation to GSK's value transfers to GUK).
- 6.58 The fact that GSK chose to make substantial cash payments to GUK, and supply GUK with restricted volumes of generic paroxetine⁸⁵³ in the manner that it did, demonstrates that GSK perceived GUK's proposed entry to be credible and that GUK was a potential competitor. Had there been no real concrete possibility for GUK to enter the relevant market, there would have been no reason for GSK to enter into the GUK-GSK Agreement.
- 6.59 Consistent with this, in his witness statement in the GUK Litigation, [GUK's General Manager] said that GSK's decision to enter into a supply agreement with IVAX a full five years before patent expiry was highly unusual and was most likely to be explained by GSK's view that generic suppliers would be able to bring to market a product which did not infringe valid claims in GSK's patents.⁸⁵⁴

'In my experience of the generics market, no pharmaceutical company has ever attempted to join forces with a generics company to supply a version of its product 5 years prior to the patent on the branded product expiring. Yet that is precisely the position here, which begs the question why is SB doing this? There are only two possible reasons that I can think of. The first and most likely is that it is a reflection of SB's views on the strength of its anhydrate patent, which was granted as recent as 1997. That is to say, the reason that SB is going to start selling generic paroxetine is that it can see that generic competitors will shortly be entering the market in any event, either because the

⁸⁵¹ See paragraph B.47 for a breakdown of value transfers between the Generic Companies, and for calculations.

⁸⁵² See paragraph B.47 for a description of the calculation.

⁸⁵³ See paragraph 3.308–3.309.

⁸⁵⁴ [REDACTED]WS (document 0901), paragraph 37.

*anhydrate patent is invalid or because the competitors have a non-infringing product. The only other possible reason I can think of is the impending genericisation of Cipramil [...].*⁸⁵⁵

6.60 In its representations GSK has observed that the compromises it made on entering into the Agreements (including the GUK-GSK Agreement), such as its decision to commit to make value transfers totalling at least £21.3 million to GUK, were motivated by the uncertain litigation outcome and the threat to its patent position. For example, GSK stated that its *'rationale for settlement of the Patent Disputes was in each instance essentially the defence of its valid patent rights and their commercial value (the status quo), and for this it was prepared to compromise based on its assessment of an uncertain litigation outcome. Each Generic Company sought early entry to the UK market for a paroxetine product and each had its own particular conditions for compromise which had to be accommodated to resolve the Patent Disputes.'*⁸⁵⁶

d) *The relevance of the Parties' internal assessments as to their prospects in the GUK Litigation and of GUK entering the UK paroxetine market independently of GSK*

6.61 The CMA considers that the reasoning and evidence set out above is sufficient to demonstrate that GUK was a potential competitor to GSK in the UK paroxetine market at the time the GUK-GSK Agreement was entered into. There were real concrete possibilities for GUK to enter the market independently of GSK.

6.62 GUK submitted that the views of its staff at particular times demonstrated that GUK was not confident that it would prevail in the GUK Litigation and that there was no realistic possibility of GUK entering the market independently. In this regard, the CMA observes that the assessment of whether there were real concrete possibilities for an undertaking to enter the market is by its nature an objective assessment, and does not depend on the individual subjective perceptions of an undertaking's staff that may vary from one day to next.

⁸⁵⁵ Additionally, in an interview with the OFT [Merck's Head of Patents and Raw Material Support Group] explained *'... if an innovator is willing to settle then they must have to a certain extent a feeling ... as much as we had, you know, not necessarily a hundred percent of winning, they would have the same viewpoint, they may not have a hundred percent chance of winning, so there's a certain amount of 'leverage', so they must feel as unsecure as we feel insecure, so having got to that position where there's an insecurity on the other side, let's lever it for as much as possible'*, [REDACTED]1 (document 2330), pages 41–42.

⁸⁵⁶ GSK SO Written Response (document 2755), paragraph 4.26.

6.63 For completeness only, the CMA has nevertheless also examined the internal documents of GUK and GSK, and relevant witness evidence. This is considered in Annex E.

6.64 The Parties' internal documents confirm the analysis regarding GUK's position as a potential competitor set out above. They in fact show that there was genuine uncertainty on both sides as to their prospects in the GUK Litigation and of GUK entering the UK paroxetine market independently of GSK at the time that the GUK-GSK Agreement was entered into. They therefore confirm the conclusions from the objective evidence, considered above.

vii) *At the time the Alparma-GSK Agreement was entered into Alparma was a potential competitor to GSK*

6.65 At the time the Alparma-GSK Agreement was entered into, Alparma also had real concrete possibilities to supply paroxetine in the UK independently of GSK.⁸⁵⁷ Thus, Alparma was a potential competitor. The CMA refers to the elements listed below, which are addressed in turn in the following paragraphs:

- Alparma had the capability to supply into the UK generic paroxetine sourced independently of GSK. Alparma had committed significant time and resources in taking steps to enable it to supply generic paroxetine in the UK. Alparma's preparations had progressed to a point at which it was in possession of finished product and a marketing authorisation, and it was actually preparing to enter the market.
- Alparma continued with its preparations to enter the UK paroxetine market, despite the prospective litigation with GSK. Neither the Alparma Litigation, nor the Alparma Undertaking (which was a temporary measure pending a final adjudication of the patent issues by the court), was an insurmountable barrier to entry.
- The fact that GSK was willing to make substantial value transfers to Alparma, in return for Alparma agreeing not to enter the market independently of GSK is a strong indication that GSK perceived Alparma as a credible threat, and that it exerted competitive pressure on GSK. GSK was aware that if generic suppliers were successful in their efforts to enter the market prior to the expiry of its Anhydrate Patent (due in 2016), the prices and profits that GSK could have sustained in the UK paroxetine

⁸⁵⁷ With respect to both 20mg and 30mg tablets (see paragraphs 3.323–3.325).

market would have decreased substantially. GSK's expected returns,⁸⁵⁸ taking account of the potential that its returns would be substantially lower if generic suppliers were successful in their efforts to enter the market, were therefore lower as a result of the constraint from the threat of Alparma's generic entry.

6.66 Annex D, Section B sets out and responds to the SO Addressees' main representations in relation to this Section.

a) *Alparma's capability*

6.67 During the Relevant Period, Alparma was part of the Alparma Group and was owned and controlled by Alparma Incorporated, a major global developer of pharmaceutical products based in the US. In 2002, Alparma was one of the largest UK providers of generic medicines in the UK.⁸⁵⁹ It therefore had experience in developing and bringing generic medicines to market in the UK (and in other countries worldwide) and the general capability to develop and bring medicines such as paroxetine to market.⁸⁶⁰

6.68 At the time the Alparma-GSK Agreement was entered into, Alparma had taken a number of steps towards enabling it to supply generic paroxetine sourced independently of GSK in the UK. As set out in paragraphs 3.319 to 3.354, Alparma had:

- actively made preparations to enter the UK paroxetine market from 2000, with a view to supplying its own paroxetine product (the Alparma Product);
- obtained a UK MA for the Alparma Product (which was granted on 29 April 2002);
- ordered a significant volume of stock (almost 500,000 packs) in preparation for entering the UK paroxetine market;
- had discussions with several customers in the UK regarding supply of the Alparma Product to them; and

⁸⁵⁸ That is, the average of its possible profits going forward, taking account of the potential revenue and costs associated with each possible outcome (for example, the success or otherwise of independent generic entry), and the likelihood associated with each.

⁸⁵⁹ [REDACTED]WS1 (draft) dated (document 1318), paragraph 3 notes that '*Alparma is the largest generics drug business in the UK. We currently have over 300 products in our line producing in excess of 5.4 billion tablets a year. As a result of competitive price pressure Alparma is, I believe, the only generic company that actually manufactures in the UK. Alparma currently holds 27% of the UK generic market by volume and 23% by value.*'

⁸⁶⁰ [REDACTED]WS1 (draft) (document 1318), paragraphs 3–5.

- contested the Alparma Litigation for a period of five months, from the commencement of the Alparma Litigation in June 2002 to the date the Alparma-GSK Agreement was entered into on 12 November 2002.⁸⁶¹

6.69 Accordingly, Alparma was very close to launching the Alparma Product in the UK at the time the Alparma Litigation was commenced and the (temporary) Alparma Undertaking took effect.

b) *Alparma's continued preparations despite the Alparma Litigation and the (temporary) Alparma Undertaking*

6.70 Alparma pursued the actions referred to above fully aware that GSK held a number of patents regarding paroxetine. Even prior to the initiation of the Alparma Litigation, Alparma was aware that it was likely to face patent infringement claims from GSK in the future.⁸⁶² Such knowledge did not stop Alparma from continuing its preparations to enter the UK paroxetine market.

6.71 In an email in April 2002, [Alparma ApS's Director of Intellectual Property and Technology Affairs], in full awareness of likely litigation with GSK, agreed that Alparma should order around 500,000 packs of paroxetine from Medis, at a cost of some £3.5 million.⁸⁶³ [Alparma Ltd's Marketing Manager] confirmed that expenditure of that magnitude was '*a significant amount for Alparma to pay for stock, given that Alparma had total annual revenues of £80 million*'.⁸⁶⁴

6.72 Alparma's preparations to enter the UK paroxetine market independently of GSK were also clear from: (i) [Alparma Ltd's Director of Sales and Marketing's] statement in his draft witness statement to the High Court in the Alparma Litigation that Alparma planned to enter the UK paroxetine market '*as soon as the BASF decision ... was known*',⁸⁶⁵ and (ii) Alparma's offer to AAH Pharmaceuticals to supply them with generic paroxetine commencing on

⁸⁶¹ From 11 June 2002 from the issue of the claim form by GSK to the date of settlement on 12 November 2002.

⁸⁶² Email from [Alparma ApS's Director of Intellectual Property and Technology Affairs] to [Alparma Ltd's Marketing Manager] and others dated 29 April 2002 (document 1309) and Email chain between [Alparma ApS's Director of Intellectual Property and Technology Affairs], [Alparma Inc's President (Human Generics)], [VP New Products – FP at Alparma ApS], [Alparma Ltd's Director of Sales and Marketing], [Alparma ApS's Sales and Marketing Director], [Alparma Inc's Vice President of Intellectual Property] dated 7 June 2002, forwarded to [Alparma Ltd's Marketing Manager] on 11 June 2002 (document 1314).

⁸⁶³ Email from [Alparma ApS's Director of Intellectual Property and Technology Affairs] to [Alparma Ltd's Marketing Manager] and others dated 29 April 2002 (document 1309).

⁸⁶⁴ [redacted]WS (document 1587), paragraph 3.9.

⁸⁶⁵ [redacted]WS1 (draft) (document 1318), paragraph 7.

1 June 2002, as referred to in a [GSK's Finance Director A's] witness statement in the Alparma Litigation.⁸⁶⁶

6.73 The Alparma Undertaking of 1 August 2002 was itself manifestly only a temporary measure: the judge did not have the available evidence at that time to decide whether the Alparma Product infringed GSK's patents (specifically claim 11).⁸⁶⁷ The judge ordered a prompt trial (see paragraph 3.340).

6.74 Following the Alparma Undertaking, Alparma continued to contest the Alparma Litigation for over three months and until it entered into the Alparma-GSK Agreement and accepted value transfers from GSK (see paragraph 6.155). Moreover, the evidence at paragraphs 3.355 to 3.362 indicates that if GSK had not offered a sufficiently lucrative settlement, Alparma would have continued with its efforts to enter on an independent basis.

c) *GSK's response to Alparma's proposed market entry was to make value transfers to secure Alparma's acceptance of entry restrictions relating to its independent market entry*

6.75 GSK's actions in response to Alparma's proposed market entry support the CMA's conclusion that Alparma was a potential competitor with real concrete possibilities to enter the UK paroxetine market independently of GSK.

6.76 As explained at paragraph 3.325, the warning letter which GSK's lawyers sent to Alparma on 27 May 2002 noted that GSK expected Alparma to launch on 1 June 2002.⁸⁶⁸

6.77 It is notable that GSK substantially altered its defensive position during the Alparma Litigation, and ended by abandoning the specified allegations of infringement that were the original focus of its action. GSK discontinued its claim against Alparma for infringement of the Hemihydrate Patent on 1 August 2002.⁸⁶⁹ GSK also stated that the patent position regarding the

⁸⁶⁶ [REDACTED]WS1 (document 0241), paragraphs 7.1–7.2.

⁸⁶⁷ See, in this regard, the discussion in the email chain between [Alparma ApS's Sales and Marketing Director], [Patent Specialist and Patent Manager at Alparma ApS], [Alparma ApS's patent attorney], [Alparma Inc's Vice President of Intellectual Property], [Alparma's Head of Purchasing], [Alparma Ltd's Director of Sales and Marketing], [VP New Products – FP at Alparma ApS], [Alparma Inc's Chief Legal Officer], [Alparma's external lawyer] of [external law firm] dated 1 to 2 August 2002 (document 1331). It was reported that: *'The judge was of the opinion that he did not [have] to reach [a decision on] the evidence presented [to] him on this case because a simple plant inspection would end the matter on whether there was a displacement step in the process.'*

⁸⁶⁸ Letter from [GSK's external lawyers] to the Directors of Alparma Limited dated 27 May 2002 (documents D185, D186 and D187).

⁸⁶⁹ GSK Second Response, Part Two (document 0734), paragraph 7.4.

Anhydrate Patent had become more ‘*complicated*’⁸⁷⁰ following the judgment in the BASF Litigation⁸⁷¹, which was handed down on 12 July 2002. In that judgment, Mr Justice Pumfrey had found the majority of claims in the Anhydrate Patent to be invalid, and he upheld only claims 10a and 11 (see paragraphs 3.332 to 3.334). GSK’s claim for patent infringement against Alparma had hitherto focused on claims 1 and 3 of the Anhydrate Patent (which were found invalid by Mr Justice Pumfrey). This meant that GSK had to substantially amend its claim at a late stage in order to rely on process claim 11 (which it had not originally relied upon).

6.78 As explained in detail at paragraphs 6.150 to 6.205, GSK’s response to the Alparma Litigation was to commit to make value transfers to Alparma in return for Alparma’s acceptance of restrictions on its ability to enter the UK paroxetine market independently of GSK. The CMA refers to the points made above in relation to GUK, at paragraphs 6.57 to 6.60, which apply equally here.

d) The relevance of the Parties’ internal assessments as to their prospects in the Alparma Litigation and of Alparma entering the UK paroxetine market independently of GSK

6.79 The CMA considers that the reasoning and evidence set out above is sufficient to demonstrate that Alparma was a potential competitor to GSK in the UK paroxetine market at the time the Alparma-GSK Agreement was entered into. There were real concrete possibilities for Alparma to enter the market independently of GSK.

6.80 Actavis submitted, and Xellia and Zoetis jointly (‘Xellia-Zoetis’) submitted, that the views of staff at particular times demonstrated that Alparma was not confident that it would prevail in the Alparma Litigation and that there was no realistic possibility of Alparma entering the market independently. In this regard, the CMA observes that the assessment of whether there were real concrete possibilities for an undertaking to enter the market is by its nature an objective assessment, and should not depend on the individual subjective perceptions of an undertaking’s staff that may vary from one day to next.

6.81 For completeness only, the CMA has nevertheless also examined the internal documents of Alparma and GSK, and relevant witness evidence. This is considered in Annex G.

⁸⁷⁰ GSK Second Response, Part Two (document 0734), paragraphs 4.3 and 4.30.

⁸⁷¹ *BASF AG v SmithKline Beecham plc* [2002] EWHC 1373 (Pat)

6.82 The Parties' internal documents confirm the analysis regarding Alparma's position as a potential competitor set out above. They in fact show that there was genuine uncertainty on both sides as to their prospects in the Alparma Litigation and of Alparma entering the UK paroxetine market independently of GSK at the time that the Alparma-GSK Agreement was entered into. They therefore confirm the conclusions from the objective evidence, considered above.

D. The content of the GUK-GSK Agreement

6.83 As explained in paragraphs 3.305 to 3.310, the GUK-GSK Settlement Agreement came into force on 13 March 2002, the day before the substantive hearing on the patent infringement issues was due to commence. That agreement had a three-year term, but was terminated with effect from 1 July 2004, nine months before it was due to expire. The associated GUK-IVAX Agreement, entry into which was a condition precedent to the GUK-GSK Settlement Agreement, came into force on 14 March 2002 and also had a three-year term. The GUK-IVAX Agreement was terminated on 25 June 2004, at around the same time as the GUK-GSK Settlement Agreement was terminated (and likewise nine months before the GUK-IVAX Agreement was due to expire).

6.84 The GUK-GSK Settlement Agreement included the following provisions:

- Stock purchase: GSK agreed to purchase GUK's stock of paroxetine hydrochloride anhydrate for US\$12.5 million, payable on a quarterly basis over three years (clause 1).
- Marketing allowance: GSK agreed to pay GUK an annual '*marketing allowance*' of £1.65 million for three years, commencing in March 2002 (clause 2).
- Discharge: the Parties agreed to a Consent Order that the GUK Litigation be stayed, and the GUK Interim Injunction (and GSK's cross undertaking in damages) be discharged (clause 13).
- As a condition precedent, GUK agreed to enter into a sub-distribution agreement with IVAX (clause 4).
- Legal costs: GSK agreed to pay 50% of GUK's legal costs incurred in the litigation (whether billed or unbilled), up to a maximum of £500,000 payable on 31 March 2002 (clause 3).

- IVAX obligations: if the IVAX-GSK Agreement was terminated, GSK agreed to perform certain of IVAX's obligations, namely the delivery of paroxetine to GUK and the obligations to maintain '*GUK's minimum level of profit over the term of the*' GUK-IVAX Agreement, as if those obligations were imposed directly on GSK (clause 5.1). If IVAX was unable to fulfil its obligations under the GUK-IVAX Agreement, GSK agreed to guarantee those of IVAX's obligations set out above (clause 5.2).
- Restriction on entry: during the term of the GUK-IVAX Agreement, GUK (or any member of the Merck Generics Group) agreed not to '*make, import, supply or offer to supply paroxetine hydrochloride in the United Kingdom*' save as purchased from IVAX or otherwise manufactured or marketed by GSK or with GSK's consent (clause 8(i) and (ii)).
- GUK agreed not to assign or transfer its MA for three years (clause 8(iii)).
- Other markets: the Parties agreed to discuss the supply by GSK of paroxetine to GUK/Merck Generics Group in other European markets (clause 9).
- On termination of the GUK-IVAX Agreement (set out below) whether by effluxion of time or otherwise, both GSK and GUK were at liberty to restore the GUK Litigation (clause 11).

6.85 As a condition precedent to the GUK-GSK Settlement Agreement, a sub-distribution agreement between GUK and IVAX, the GUK-IVAX Agreement, was concluded on 14 March 2002.⁸⁷² This was reflected in the Second Addendum to IVAX's supply agreement with GSK, which amended the original IVAX-GSK Agreement as necessary (see paragraph 3.224).⁸⁷³ Both the GUK-GSK Settlement Agreement and the GUK-IVAX Agreement were to be for three years, save as set out below. The other relevant obligations included in the GUK-IVAX Agreement were as follows:

- Restriction on entry: GUK agreed not to '*manufacture, import or distribute*' paroxetine hydrochloride in Great Britain, Northern Ireland, the Channel Islands and the Isle of Man during the term of the GUK-IVAX Agreement (clause 2.2). This clause replicated an equivalent clause in the GUK-GSK Settlement Agreement.

⁸⁷² See GUK-GSK Settlement Agreement (document 0995), clause 4, signed by both Parties.

⁸⁷³ GUK-IVAX Agreement (documents 1003 and 1765). See also Heads of Agreement between GSK and IVAX (document 0217) and Second Addendum (document 0318).

- Product: the product was defined as paroxetine hydrochloride. 'Packs' were defined as 30 x 20mg patient packs, with paroxetine hydrochloride as the active substance (clause 1.1).
- IVAX appointed GUK as a non-exclusive sub-distributor for paroxetine hydrochloride for Great Britain, Northern Ireland, the Channel Islands and the Isle of Man (clause 1.1).
- Volume: *'Unless GUK notifies IVAX otherwise ... GUK shall order and IVAX shall supply'* 750,000 packs for each year of the agreement (clause 3.1). Clause 3.3 stated that *'GUK shall be entitled to vary quantities ordered ... PROVIDED THAT it is recognised that IVAX shall not be obliged to deliver Products in excess of the amount set out in clause 3.1 (first sentence) although it shall, where requested, use reasonable endeavours to comply with any order for such excess'*.⁸⁷⁴ In short, GUK was not obliged to order its full quantity (750,000 packs) and IVAX was not obliged to supply any quantities in excess of that set out in the agreement.
- Initial delivery: Clause 3.1 recognised that for *'regulatory reasons'* IVAX may face an initial delay in supplying product to GUK. Accordingly, it allowed for IVAX, in lieu of supply in the first two months of the GUK-IVAX Agreement, to pay GUK £237,500 (excluding VAT) per month. This clause was, in fact, invoked.⁸⁷⁵
- Duration and termination: the GUK-IVAX Agreement was specified as being for three years (clause 11.1). However the contract could be terminated if the Market Price per pack fell below £8.45 for at least three consecutive months in the third year of the contract, or any time after that (clause 4.4).
- Profit Guarantee: should the average selling price of a pack of 30 tablets fall below £12.25 per pack, IVAX provided GUK with a profit guarantee, agreeing to pay GUK the shortfall, to ensure that GUK's profits would not fall below £2.85 million per year (excluding VAT) (clause 4.3). £2.85 million was the amount that GUK would make if it sold all its allocated packs of paroxetine (750,000) at £12.25 less the cost of the packs at £8.45 per

⁸⁷⁴ Indeed, to do so, IVAX would need to obtain additional supplies from GSK (or otherwise supply less paroxetine itself). Additional supply from GSK would have been inconsistent with the Second Addendum (document 0318), clause 2.6.

⁸⁷⁵ See email from [a GUK Sales and Marketing employee] to [IVAX's Sales and Marketing Manager] dated 6 March 2003 (document 1112) entitled 'Paroxetine yr 1 reconciliation [sic]' attaching spreadsheet entitled 'Norton/GUK Paroxetine Deal 2002/3' (document 1108). See also email from [X] of IVAX to [X] of IVAX dated 13 May 2002 (document 1774).

pack. The profit guarantee therefore only covered the loss of profit incurred between £12.25 and £8.45 (that is, £3.80 per pack) and not any losses generally incurred by GUK for selling below the supply price of £8.45.⁸⁷⁶

- Price: the price for the product per pack was £8.45 (clauses 1.1 and 4.1).⁸⁷⁷

E. The restrictive object of the GUK-GSK Agreement

6.86 Under the GUK-GSK Agreement, GSK made cash payments and other value transfers in return for GUK's acceptance of entry restrictions. The CMA finds that the objective aim of the GUK-GSK Agreement was to restrict competition, on the following basis:

- GUK accepted restrictions on its competitive behaviour;
- GSK made cash payments and other value transfers to GUK;
- The objective aim of the value transfers was to induce GUK's acceptance of the entry restrictions:
 - under the terms of the GUK-GSK Agreement those value transfers were conditional on GUK not entering the market independently of GSK during the term of the GUK-GSK Agreement; and
 - the decision to make the value transfers cannot be explained on the basis of the stated purposes of the transfers, nor on any basis that was not anti-competitive, which the Parties have suggested or that the CMA can discern.

⁸⁷⁶ GUK invoked this clause in both 2002 and 2003. In relation to 2002, see email from [a GUK Sales and Marketing employee] to [IVAX's Sales and Marketing Manager] dated 6 March 2003 (document 1112) entitled 'Paroxetine yr 1 reconciliation [sic]' attaching spreadsheet entitled 'Norton/GUK Paroxetine Deal 2002/3' (document 1108). In relation to 2003, see email from [a GUK Sales and Marketing employee] to [IVAX's Sales and Marketing Manager] dated 16 March 2004 (document 1130) entitled 'Paroxetine reconciliation [sic]' attaching spreadsheet entitled 'Norton/GUK Paroxetine Deal 2003/4' (document 1129) (a revised version of the relevant spreadsheet was emailed to IVAX on 21 May 2004 which provided revised selling prices for January and February 2004, see email from [GUK's Head of Marketing] to [IVAX's Sales and Marketing Manager] dated 21 May 2004 (document 1137) attaching spreadsheets entitled 'Norton/GUK Paroxetine Deal 2002/3' and 'Norton/GUK Paroxetine Deal 2003/4' (documents 1136).

⁸⁷⁷ This price is then consistently shown in GUK internal documents: see internal reconciliations, spreadsheet entitled 'Norton/ GUK Paroxetine Deal 2002/3 (document 1109) and spreadsheet entitled 'Norton/ GUK Paroxetine Deal 2003/4 (document 1136).

6.87 These elements are discussed in the section below. Annexes D and F set out and respond to the Parties' representations in relation to the object of the GUK-GSK Agreement.

i) *The restrictions accepted by GUK on its competitive behaviour*

6.88 GUK accepted an express obligation to refrain from entering and competing in the UK paroxetine market independently of GSK.⁸⁷⁸

6.89 The restriction was absolute: it allowed for no competition from GUK as a supplier of paroxetine sourced independently of GSK,⁸⁷⁹ and it extended beyond GUK to include both: (i) any company that was part of the Merck Generics Group;⁸⁸⁰ and (ii) any other company that sought to licence GUK's MA in order to supply paroxetine in the UK⁸⁸¹ or to purchase GUK's paroxetine product to resell within the UK.

6.90 Moreover, while the preamble of the GUK-GSK Agreement explained that GUK and GSK had agreed to '*the settlement of the Litigation*',⁸⁸² the GUK-GSK Agreement did not resolve the patent dispute between GUK and GSK. It only deferred it. There was no counterpart to GUK limiting its conduct in the form of any commitment from GSK that it would refrain from patent infringement proceedings if GUK entered the UK paroxetine market after the expiry of the GUK-GSK Agreement. Further, there is no attempt in the GUK-GSK Agreement to agree to take further steps to resolve the patent issue, or to agree a date from which GUK could have entered the UK paroxetine market with its own generic product. Instead, the GUK-GSK Agreement specifically provided that GSK (and GUK) would be free to '*restore the Litigation*' upon termination of the GUK-IVAX Agreement.⁸⁸³

⁸⁷⁸ Specifically, for the term of the GUK-IVAX Agreement.

⁸⁷⁹ GUK-GSK Settlement Agreement (document 0995), clause 8(i). This restriction was broadly replicated in the GUK-IVAX Agreement (document 1003), clause 2.2: '*GUK shall not manufacture, import or distribute Products in the Territory [Great Britain, Northern Ireland, the Channel Islands and the Isle of Man] during the term of this Agreement except pursuant to this Agreement (save where such Products are manufactured or marketed by SKB (or with SKB or any member of its Group's consent))*'.

⁸⁸⁰ GUK-GSK Settlement Agreement (document 0995), clauses 8(i) and 8(ii).

⁸⁸¹ See GUK-GSK Settlement Agreement (document 0995), clause 8(iii).

⁸⁸² GUK-GSK Settlement Agreement (document 0995).

⁸⁸³ GUK-GSK Settlement Agreement (document 0995), clause 11. Termination of the GUK-IVAX Agreement (document 1003) was either through expiry or material breach. GUK offering for sale in the UK any paroxetine product sourced independent of GSK would have been a material breach.

ii) The value transferred by GSK to GUK under the GUK-GSK Agreement

6.91 In total, under the GUK-GSK Agreement, GSK agreed to make cash payments and other value transfers to GUK of at least £21.3 million over its three year term.⁸⁸⁴ The value transfers were as follows:

- an annual ‘marketing allowance’ payment of £1.65 million, totalling £4.95 million over the term of the GUK-GSK Agreement;⁸⁸⁵
- the purchase of GUK’s stock of paroxetine (designated for sale in the UK) for £8.8 million, paid on a quarterly basis over the term of the GUK-GSK Agreement;⁸⁸⁶ and
- a restricted volume of paroxetine, in relation to which GSK sacrificed its profit margin, and instead transferred this margin to GUK. Over the three year term of the Agreement, GSK stood to sacrifice at least £7.5 million.⁸⁸⁷ As a consequence of the profit guarantee clause⁸⁸⁸ the margin GUK received was guaranteed and amounted to £2.85 million per year.⁸⁸⁹

6.92 As set out at paragraph 5.9, the CMA finds that the value transfers were made directly from GSK to GUK pursuant to the GUK-GSK Settlement

⁸⁸⁴ This assumes that the GUK-GSK Agreement was not terminated early. This includes £13.7 million in cash payments for marketing allowances and stock purchases (calculated as: $(12,500,000/1.4225)+(1,650,000 \times 3)$), where 1.4225 is the average monthly US dollars into pounds sterling exchange rate according to the Bank of England for March 2002) and between £7.5 million to £11.8 million in the transfer of the distribution margin on the restricted volume supplied by GSK (see paragraph 6.103).

The CMA has calculated that the approximate amount GSK did in fact sacrifice in making value transfers to GUK was between £17.9 million and £20.3 million in total. (Calculated as: $(12,500,000/1.4225)+(1,650,000 \times 3)+((750,000/12)*20*([price]-8.45))$), where 1.4225 is the average monthly US dollars into pounds sterling exchange rate according to the Bank of England for March 2002, 20 is the number of months which the GUK-GSK Agreement lasted prior to generic entry (between March 2002 – November 2003) and the [price] was either £11.80 (an estimate of the price per pack of parallel imported paroxetine which GSK’s UK subsidiary would have been credited with, see footnote 1713), or £13.70 (the weighted average Seroxat 20mg pack price between January to March 2002). The CMA notes that the actual value of the stock purchase may have differed due to exchange rate fluctuation and that GUK also received payments in respect of the profit guarantee clause beyond November 2003.

⁸⁸⁵ GUK-GSK Settlement Agreement (document 0995), clause 2.

⁸⁸⁶ GUK-GSK Settlement Agreement (document 0995), clause 1.3. The stock purchase payments in the GUK-GSK Agreement were stated as US\$12.5 million. In GSK Second Response, Part Two (document 0734), GSK suggested at paragraph 10.12 that \$12.5 million equated to £7.5 million. GSK based this calculation on the ‘average of the annual average rates for 2002-2004 (the period over which payments were made) from the ECB’s Statistical Data Warehouse’, see (document 0734), footnote 52. The CMA considers that the appropriate figure is that agreed between GSK and GUK at the time of entering into the GUK-GSK Agreement as that is the appropriate reference period for assessing the objective aim of that Agreement. Accordingly, the CMA has used the Bank of England’s monthly average exchange rates for March 2002 in order to express this payment in pounds sterling for consistency and ease of comparison with the other payments.

⁸⁸⁷ See paragraph 6.104 for calculation.

⁸⁸⁸ GUK-IVAX Agreement (document 1003), clause 4.3.

⁸⁸⁹ GUK-GSK Settlement Agreement (document 0995), clauses 5.1 and 5.2. Although this guarantee was from IVAX to GUK, GSK guaranteed that transfer under the GUK-GSK Settlement Agreement (see GUK-GSK Settlement Agreement (document 0995), clauses 5.1 and 5.2).

Agreement,⁸⁹⁰ with the following exception. The transfer of a restricted volume of paroxetine and the associated profit guarantee were made by GSK to GUK, indirectly via IVAX pursuant to the IVAX-GSK Agreement and the GUK-IVAX Agreement.⁸⁹¹

iii) The value transfers were conditional on GUK agreeing not to enter the UK paroxetine market independently of GSK

6.93 Under the terms of the GUK-GSK Agreement, the value transfers from GSK to GUK were each contractually linked to GUK not entering the UK paroxetine market independently of GSK during the term of the GUK-GSK Agreement:⁸⁹²

- The transfer referred to as the ‘*marketing allowances*’ was conditional on GUK not entering the UK paroxetine market independently of GSK for the term of the GUK-GSK Agreement. The GUK-GSK Settlement Agreement specified that in the event of a repudiatory breach no further marketing allowances would be payable by GSK to GUK.⁸⁹³ GUK entering the UK paroxetine market with a product sourced from a company other than GSK would have constituted such a repudiatory breach.⁸⁹⁴
- GSK’s value transfer for GUK’s paroxetine stock was conditional on GUK not entering the UK paroxetine market independently of GSK for the term of the GUK-GSK Agreement.⁸⁹⁵ The GUK-GSK Settlement Agreement specified that in the event of a breach no further sums would be payable for GUK’s paroxetine stock.⁸⁹⁶
- The transfer of a restricted volume of paroxetine from GSK to GUK, and the associated profit guarantee, was conditional on GUK not entering the UK paroxetine market independently of GSK for the term of the GUK-GSK Agreement.⁸⁹⁷ The GUK-IVAX Agreement specified that GUK must not

⁸⁹⁰ GUK-GSK Settlement Agreement (document 0995), clauses 1, 2 and 5.

⁸⁹¹ Second Addendum (document 0318) and the GUK-IVAX Agreement (document 1003), clauses 3.1 and 4.3.

⁸⁹² Specifically, for the term of the GUK-IVAX Agreement.

⁸⁹³ See GUK-GSK Settlement Agreement (document 0995), clause 6.

⁸⁹⁴ Specifically, such action by GUK would have been a breach of clause 8 of the GUK-GSK Settlement Agreement (document 0995). In addition to adhering to the entry restrictions, GUK’s obligations under the GUK-Settlement Agreement (document 0995) included: (i) retaining stocks identified for eventual delivery to SB (see clause 1.2 of the GUK-GSK Settlement Agreement); (ii) entering into a sub-distribution agreement with IVAX as a condition precedent (see clause 4 of the GUK-GSK Settlement Agreement).

⁸⁹⁵ See GUK-GSK Settlement Agreement (document 0995), clause 6.

⁸⁹⁶ GUK-GSK Settlement Agreement (document 0995), clause 6.

⁸⁹⁷ Specifically, for the term of the GUK-IVAX Agreement.

supply any product other than GSK's⁸⁹⁸ and stipulated that any such breach would enable the other party to terminate the agreement.⁸⁹⁹

iv) GSK's decision to make each of the value transfers to GUK cannot be explained on the basis of their stated purpose

a) The 'marketing allowances'

6.94 During the period of the GUK-GSK Agreement, GSK agreed to pay GUK a supposed 'marketing allowance' of £1.65 million per year for three years (totalling £4.95 million in the three year period commencing 31 March 2002).⁹⁰⁰

6.95 For the reasons set out below, the CMA does not accept that the purpose of the marketing allowance was to fund marketing expenditure to be carried out by GUK:

- There was no link between the marketing allowance and the sale of product: GSK made the payments in question irrespective of whether GUK sold any of the paroxetine supplied to it by GSK.
- Despite the scale of the marketing allowance that GSK paid to GUK, GSK has confirmed that it did not monitor or control spending by GUK on marketing and promotion.⁹⁰¹
- In a meeting with the OFT in December 2011, [GSK's Finance Director A] stated that generic suppliers were not expected to engage in marketing and promotional activity in order to sell generic medicines.⁹⁰²

⁸⁹⁸ GUK-IVAX Agreement (document 1003), clause 2.2.

⁸⁹⁹ GUK-IVAX Agreement (document 1003), clause 11.2.

⁹⁰⁰ GSK, in fact, paid GUK marketing allowances that totalled £3,877,500 in the period 28 March 2002 to 2 April 2004, see the response dated 17 October 2011 to the Section 26 Notice dated 12 August 2011 sent to GUK (document 1195), paragraph 5 and Annex 1 – table of settlement payments dated 17 October 2011 (document 1196).

⁹⁰¹ See GSK Second Response, Part Two (document 0734), paragraph 10.6.

GSK submitted that it is not reasonable to expect GSK to monitor the use of its marketing expenditure, as GSK was entitled to confine the use of its resources to settling its litigation, which was its overriding aim (GSK SO Written Response (document 2755), paragraph 6.146). The CMA considers that GSK's lack of interest in monitoring the use of the marketing allowances is relevant to an assessment of their real purpose and GSK's decision not to monitor the allowances' use is consistent with their purpose being nothing other than to induce GUK's acceptance of the entry restrictions described above.

⁹⁰² See Note of Meeting between GSK and the OFT dated 19 December 2011 (document 0688), paragraph 34.

- GUK had no need to market generic paroxetine as it could rely on the substantial marketing investment made by GSK, as outlined by GSK in the GUK Litigation.⁹⁰³
- The ‘*marketing allowances*’ (£1.65 million per year) were far higher than GUK’s annual marketing budget (£400,000 per year) for its entire range of products.⁹⁰⁴
- GUK was unable to confirm how it used the marketing allowances.⁹⁰⁵
- Under the terms of the GUK-GSK Agreement, GUK was subject to a volume restriction (see paragraph 6.103). Given the resulting limits on GUK’s ability to meet increases in demand, GUK had no incentive to spend the marketing allowance on the marketing of paroxetine.
- GUK did not interpret the marketing allowance as being for marketing and instead treated it as increased revenues and profits. For example, an internal GUK email on 27 November 2001 from [GUK’s General Manager] considered the ‘*marketing payment*’ to be part of the profit that GUK would achieve under GSK’s offer at the time.⁹⁰⁶

6.96 Moreover, in the economic context of the pharmaceutical sector, the payment of marketing allowances by GSK to GUK could not in any case have been expected to generate value to GSK, other than as part of an anti-competitive strategy. For example, to the extent that GUK did use such transfers to market the paroxetine supplied to it by GSK to wholesalers and pharmacies (of which there is no evidence to suggest that it did: see paragraph 6.95), the

⁹⁰³ See exhibit [REDACTED]6 to [REDACTED]WS2 (GUK) (document 0887), paragraph 10. See also skeleton argument of claimant (GSK) for the GUK Interim Injunction, dated 23 October 2001 (document 0910), recitals 39–40, and Note of Meeting between GSK and the OFT dated 19 December 2011 (document 0688), paragraph 34, in which [GSK’s Finance Director A] stated that generic companies (or distributors) were not expected to engage in marketing and promotional activity in order to sell generic drugs.

⁹⁰⁴ [REDACTED]WS (document 0901), paragraph 10.

⁹⁰⁵ Part one of the response dated 30 April 2012 to the Section 26 Notice dated 23 March 2012 sent to GUK, added to on 5 April 2012 (document 1232), page 5.

⁹⁰⁶ Email chain between [GUK’s General Manager], [GUK’s Managing Director] and [the Chief Executive of Merck Generics Group] dated 27 November 2001 (document 0937). See also an email chain between [GUK’s General Manager], [GUK’s Managing Director], [GUK’s external lawyer] of [external law firm], [the Chief Executive of Merck Generics Group] and [Merck’s Head of Patents and Raw Material Support Group] entitled ‘*Improved Glaxo offer*’ dated 23 to 26 November 2001 (document 0936), in which [GUK’s Managing Director] explained that GSK’s ‘*offer equates to £6.53 per pack*’ and that that was ‘*still short of my £6.00 target for 600,000 packs*’. GSK’s ‘*offer*’ at this time was ‘*520k packs PA @ £8.45/pack + £1m PA for “marketing support”*’. It is clear from this that [GUK’s Managing Director] took the marketing allowance into account when he referred to the cost per pack equating to £6.53. See also the email from [GUK’s General Manager] to [the Chief Executive of Merck Generics Group] and [GUK’s Managing Director] dated 22 December 2001 (document 0953) and the email chain between [GUK’s General Manager], [GUK’s Managing Director], [the Chief Executive of Merck Generics Group], [Merck’s Head of Patents and Raw Material Support Group] dated 27 November 2001 (document 0938).

result would have been a decrease in GSK's sales of Seroxat, but no increase to GSK's overall sales of paroxetine (see paragraph 3.57):⁹⁰⁷

- GUK would have had little incentive to invest its marketing allowance in marketing to GPs. Such expenditure may have generated more paroxetine prescriptions, but GUK's ability to generate sales of its product would have relied on its ability to convince pharmacies to dispense its product rather than GSK's branded Seroxat.
- To the extent that GUK instead used its marketing allowance to promote sales of its product to wholesalers and pharmacies, this would have had no impact on the overall sales of paroxetine, which would only be increased if more GPs could be persuaded to prescribe it more frequently.
- Marketing to wholesalers/pharmacies would therefore impact only on the proportion of paroxetine that was dispensed as generic paroxetine rather than as branded Seroxat. For example, where a pharmacy receives a prescription for paroxetine, such marketing may in principle make them more likely to dispense paroxetine supplied by GUK than Seroxat supplied by GSK.
- On that basis, the effect of any marketing of paroxetine by GUK would be to increase sales of paroxetine supplied by GUK at the expense of Seroxat supplied by GSK. Rather than generate value to GSK, such marketing would in fact decrease GSK's sales of Seroxat, to its detriment.
- Consistent with this, GSK has confirmed that it did not expect GUK to market for the benefit of GSK.⁹⁰⁸

6.97 The CMA also does not accept that the purpose of the marketing allowance was to fund price discounts. Although [GSK's Finance Director A] and [the Chief Executive of Merck Generics Group]⁹⁰⁹ have stated that the marketing

⁹⁰⁷ This is consistent with a statement made by [GSK's independent expert], see footnote 81.

⁹⁰⁸ See GSK Second Response, Part Two (document 0734), paragraphs 10.1–10.6.

⁹⁰⁹ GSK SO Written Response (document 2755), paragraphs 6.148–6.149, with reference to [the Chief Executive of Merck Generics Group] Transcript dated 17 December 2012, page 39 (doc 2335). [the Chief Executive of Merck Generics Group] stated that the marketing allowance could have been used to fund discounts. See also the witness statement of [GSK's Finance Director A] dated 1 August 2013 (document A 0059), paragraph 4.5. (Annex 2 to GSK SO Written Response (document 2755)). See also GSK SO Written Response (document 2755), paragraphs 7.93 and 7.95, with reference to paragraphs 5.124 and 5.125. In this regard, GSK refers to [IVAX's Commercial Director's] statement that IVAX's finance team allowed him to regard the allowance as lowering the relevant cost of goods sold, the need for IVAX to compete with parallel imports of Seroxat, and to [GSK's Finance Director A's] witness statement as follows: *'I recall [that] the marketing and promotional payments were ultimately for IVAX, and indeed all the Generic Companies, to use as they saw fit. Indeed, once each of the Agreements was reached it was for the Generic Companies to decide what they wanted to use the funds for – whether for example as marketing funds to target particular kinds of pharmacies or as extra margin to allow price discounting'*. GSK SO Written Response (document 2755), paragraph 5.125.

allowance could be used for that purpose, there can have been no expectation that the marketing allowance would in practice have been used to fund discounts and/or provide for a lower supply price, as the promotional allowance was a fixed sum that came without any connection to the quantity of paroxetine sold by GUK. As a result, once the Agreement was made, this sum was economically indistinguishable from any other cash available to GUK. Unlike a lower supply price, the promotional allowance would have had no potential to increase GUK's incentives to compete with GSK. Further:

- Under the terms of the GUK-GSK Agreement, GUK was subject to a volume restriction (see paragraph 6.103). Given the resulting limits on GUK's ability to meet increases in demand, GUK had no incentive to use the marketing allowance to fund discounts below its supply price.
- Consistent with this, the CMA observes that GUK charged prices that were materially above the supply price of £8.45, such that it did not use the marketing allowance to fund discounts below its supply price of £8.45,⁹¹⁰ and the marketing allowances instead contributed to GUK's profits during the period of the Agreement.
- It is evident from GUK's negotiation of the GUK-GSK Agreement that it assumed that the payments would be a source of profit, and would not be used to fund discounts. For example, an internal GUK email on 27 November 2001 from [GUK's General Manager] considered the '*marketing payment*' to be part of the profit that GUK would achieve under GSK's offer at the time.⁹¹¹
- Had GUK used the marketing allowance to fund discounts below its supply price, it would have made less profit from supplying paroxetine than had it made no sales and retained the marketing allowance.⁹¹²

⁹¹⁰ In particular, GUK's weighted average selling price for paroxetine 20mg was £13.38 per pack between May 2002 and November 2003.

⁹¹¹ Email chain between [GUK's General Manager], [GUK's Managing Director] and [the Chief Executive of Merck Generics Group] dated 27 November 2001 (document 0937). See also an email chain between [GUK's General Manager], [GUK's Managing Director], [GUK's external lawyer] of [external law firm], [the Chief Executive of Merck Generics Group] and [Merck's Head of Patents and Raw Material Support Group] entitled 'Improved Glaxo offer' dated 23 to 26 November 2001 (document 0936), in which [GUK's Managing Director] explained that GSK's '*offer equates to £6.53 per pack*' and that that was '*still short of my £6.00 target for 600,000 packs*'. GSK's '*offer*' at this time was '*520k packs PA @ £8.45/pack + £1m PA for "marketing support"*.' It is clear from this that [GUK's Managing Director] took the marketing allowance into account when he referred to the cost per pack equating to £6.53. See also the email from [GUK's General Manager] to [the Chief Executive of Merck Generics Group] and [GUK's Managing Director] dated 22 December 2001 (document 0953) and the email chain between [GUK's General Manager], [GUK's Managing Director], [the Chief Executive of Merck Generics Group], [Merck's Head of Patents and Raw Material Support Group] dated 27 November 2001 (document 0938).

⁹¹² For example, for each unit of product that was sold below the supply price of £8.45, an incremental loss would be suffered and less of the marketing allowance would be retained. In such a scenario, paroxetine profits would be higher if no further sales were made and the marketing allowance was retained.

6.98 On the basis of the evidence analysed above, the CMA finds that the objective aim of the marketing allowance could not have been to fund marketing to be carried out by GUK, or to fund discounts to its resale price. There were no legitimate benefits to GSK of transferring the marketing allowance to GUK, and GUK had no reason to use the marketing allowances for marketing or for discounting. GUK accepted the marketing payments as one of the value transfers it received in return for its acceptance of the entry restrictions.

b) The stock purchase

6.99 GSK agreed to purchase the stock that GUK had designated for the UK that was in GUK's possession or under its control at the time that the GUK-GSK Agreement came into force (13 March 2002). GSK agreed to pay GUK £8.8 million⁹¹³ for that stock, paid quarterly over a three year period, commencing with a first payment on 31 March 2002. From GSK's perspective, making such payments for GUK's stock of paroxetine could not have been expected to be profitable for GSK, except in relation to the benefits to be derived from restricting competition:

- The GUK-GSK Agreement did not allow for GUK's MA to be assigned or transferred to GSK,⁹¹⁴ so GSK would not have been able to sell GUK's stock.
- Once received, GSK destroyed GUK's product; GSK has explained that *[t]his was always the intention*.⁹¹⁵
- GUK's approach to delivering its stock to GSK shows that GUK's primary concern was to deliver stock on time rather than to deliver finished product. In an internal GUK email on 27 March 2002 regarding arranging delivery of the first batch of GUK paroxetine stock to GSK, [GUK's Commercial Director] explained that the stock should be sent *'in whatever form, raw material or bulk or packed'* was available.⁹¹⁶ If GUK's product was of value to GSK (beyond ensuring that GUK's product was not resold)

⁹¹³ The stock purchase payment in clause 1.3 of the GUK-GSK Settlement Agreement (document 0995) was stated as US\$12.5 million. The CMA has used the Bank of England monthly average exchange rate for March 2002 (1.4225) in order to express this value transfer in pounds sterling for consistency and ease of comparison with the other value transfers (see also paragraph 6.102).

⁹¹⁴ In fact, the GUK-GSK Settlement Agreement (document 0995) explicitly prevented GUK from assigning or transferring its UK MA to **any** company during the term of the Agreement, see clause 8(iii).

⁹¹⁵ See GSK Second Response, Part Two dated (document 0734), paragraph 10.15.

⁹¹⁶ Email from [GUK's Commercial Director] to [GUK's Materials Manager] and others dated 27 March 2002 (document 1028).

then it would have been expected that GUK would have been concerned with the quality and form of the product that it supplied to GSK.

- GSK agreed to the amount that it would pay GUK for its stocks of paroxetine without actually being aware of the amount of stock that it was purchasing. It is only after the GUK-GSK Agreement came into force that GUK wrote to GSK to inform GSK of the volume of stock GUK had purchased.⁹¹⁷

6.100 GSK submitted that the purpose of the stock purchase was *‘to confirm, in accordance with the settlement agreement, that it would not be supplied on the market’*.⁹¹⁸ GSK’s submission therefore recognises that the value that GSK attached to the stock purchase was precisely the benefit GSK received from ensuring that GUK did not supply its paroxetine product in the UK independently.

6.101 For GUK, the payments for stock were one aspect of the compensation that GUK received in return for its acceptance of the entry restrictions. In this regard, GSK submitted to the OFT/CMA during the Investigation that *‘GUK sought in the negotiations to be compensated for its estimated market value of the stock’* and that *‘GUK had tableted and packaged the stock by the time of the settlement and therefore wished to be compensated for this’*.⁹¹⁹ GUK rejected GSK’s initial offers because GUK considered that those offers were not sufficient.⁹²⁰

6.102 On the basis of the payments that GSK made to GUK for its stock, and on the basis of GUK’s internal documents, it is apparent that GUK was successful in

⁹¹⁷ On 26 March 2002 (13 days after the GUK-GSK Agreement had come into force), [GUK’s General Manager] wrote to [GSK’s Finance Director A]: *‘We have now established our stock holding of paroxetine and confirm that the quantity of product designated for the UK amounts to 474.75kg. This quantity is made up of active raw material, bulk product, finished product, samples taken and product lost in manufacture’* (Letter from [GUK’s General Manager] to [GSK’s Finance Director A] dated 26 March 2002 (document 1004)).

⁹¹⁸ See GSK Second Response, Part Two (document 0734), paragraph 10.15.

⁹¹⁹ See GSK Second Response, Part Two (document 0734), paragraph 10.12. An email from [GUK’s Commercial Director] to [GUK’s Materials Manager] and others dated 27 March 2002 (document 1028) in fact suggests that GUK was not as advanced with tableting and packing its product as GSK has suggested.

⁹²⁰ For example, in an email on 22 December 2001 to [the Chief Executive of Merck Generics Group], [GUK’s General Manager] set out GSK’s latest offer and concluded that *‘this is a poor return given the level of investment’*, a view that [the Chief Executive of Merck Generics Group] shared (email from [GUK’s General Manager] to [the Chief Executive of Merck Generics Group] and [GUK’s Managing Director] dated 22 December 2001 (document 0953)). It is informative that GSK’s settlement offer at that time did not include any payment for GUK’s paroxetine stock. This is a point that [GUK’s General Manager] recognised in an email he sent to [Merck’s Head of Patents and Raw Material Support Group], [GUK’s Managing Director] and [the Chief Executive of Merck Generics Group] on 31 December 2001, in which he explained that GSK’s offer at the time *‘does not include recovery of active and any damage such an action may have with Sumika’* (email between [Merck’s Head of Patents and Raw Material Support Group], [the Chief Executive of Merck Generics Group], [GUK’s General Manager], [GUK’s Head of Research and Development], [Head of Merck Operation in Canada], [the Head of Merck Operation in Australia] and [GUK’s Managing Director] dated 31 December 2001 (document 0955)).

negotiating transfers that went well beyond GUK's stock purchase costs,⁹²¹ and provided GUK with profits that would also enable it to provide compensation to its own supplier, Alphapharm, for the lost sales that it would suffer as a consequence of GUK's decision to enter into the GUK-GSK Agreement.⁹²²

⁹²¹ The CMA observes that GSK's value transfer was in excess of GUK's costs of production for that stock:

- On 26 March 2002, [GUK's General Manager] sent a letter to [GSK's Finance Director A] confirming that *'the quantity of product designated for the UK amounts to 474.75kg'*. (Letter from [GUK's General Manager] to [GSK's Finance Director A] dated 26 March 2002 (document 1004)). In total, the GUK stock designated for the UK and purchased by GSK under the GUK-GSK Settlement Agreement amounted to 23,737,500 tablets (calculated as $(474.75 \times 50000) / 30$) or 791,250 packs. While the CMA does not have an exact conversion rate between kilograms and number of tablets/packs, the evidence indicates that one kilogram of API equated to approximately 50,000 tablets (see email chain between Sumika and GUK dated 23 May 2001 attaching a spreadsheet of forecasted paroxetine requirements (documents 0848 and 0847)). An email from [GUK's Finance Director B] to [GUK's Commercial Director] dated 19 April 2002 (document 1046) indicates a different conversion rate of 1kg = 43,000 tablets. Under this alternative conversion rate, the stock purchased by GSK amounted to 20,414,250 tablets or 680,475 packs ($(474.75 \times 43000) / 30$).
- The effective price per pack that GSK paid GUK was £11.12 (calculated as $8,800,000 / 791,250$). Under Bank of England monthly average exchange rate for March 2002 (1.4225), \$12.5 million equated to approximately £8.8 million. Under the alternative conversion rate, the effective price GSK paid was £12.94 per pack. The CMA notes that the price of £11.12 is very close to the price that GUK had offered to its customers for initial sales of its own product - around £11.50 per pack. ([X]WS (document 0901), paragraph 54: *'parallel imports are currently trading at £11.50 per pack [...] We have offered customers a generic paroxetine product at a similar price'*).
- The effective price per pack that GSK paid to GUK (£11.12) for GUK's product was significantly greater than the cost that GUK was paying per pack (£4.63) to Alphapharm for GUK's product. See for example, email from [GUK's Finance Director B] to [GUK's Commercial Director] dated 19 April 2002 (document 1046). This figure is recorded in GUK documents as US\$6.69. The CMA has converted this figure into pounds sterling (see footnote 886). That cost price covered both the cost of API and provided Alphapharm with a *'markup of 20% on active cost'*.

⁹²² Internal GUK documents subsequent to the GUK-GSK Agreement being finalised demonstrate that GUK understood that GSK's stock purchase included a profit for GUK. In particular, internal GUK discussions in March and April 2002 show that GUK sought to calculate *'the "profits" from API sold to GSK'*. (Email from [the Chief Executive of Merck Generics Group] to [GUK's Commercial Director] dated 22 March 2002 (document 1039)). It is not clear from the evidence on the CMA's file what final payments were agreed as between GUK, Alphapharm and Sumika. Nonetheless, GUK's internal considerations are informative in showing that GUK was seeking to apportion payments to both cover the costs of production and provide a profit. Those considerations included:

- the cost of the API purchased from Sumika and designated for GUK in the UK (purchased at £5,272 per kg); This figure is recorded in GUK documents as US\$7,500 per kg. The CMA has converted this to pounds sterling (see footnote 886).
- a notional cost of production for Alphapharm (proposed to be 20%, a price of £4.70 per pack charged by Alphapharm to GUK); This figure is recorded in GUK documents as US\$6.69. The CMA has converted this to pounds sterling (see footnote 886).
- a *'fair number'* for the R&D that Alphapharm had carried out (initially proposed to be 10%). See email chain between [the Chief Executive of Merck Generics Group], [the Head of Merck Operation in Australia], [GUK's Managing Director] [and other GUK employees] dated 20 March 2002 to 12 April 2002 (document 1039) and email chain between [GUK's Commercial Director], [GUK's Managing Director], [GUK's Finance Director B], [the Chief Executive of Merck Generics Group], [the Head of Merck Operation in Australia] dated 19 to 24 April 2002 (document 1053). In an email on 25 April 2002 to [the Head of Merck Operation in Australia], [the Chief Executive of Merck Generics Group] set out what GUK proposed to pay Alphapharm - the price included a *'cost +25%'* (that is, a 25% mark up on the API cost). (Email from [GUK's Managing Director] to [the Head of Merck Operation in Australia] dated 25 April 2002 (document 1058)).

c) *The effective transfer from GSK of profit margins by means of agreements permitting the supply by GUK of restricted volumes of product to the market in place of GSK*

6.103 The arrangement permitting GUK to supply a limited volume of GSK's product, giving GUK a predictable (and indeed guaranteed) margin, also falls to be regarded as a form of value transfer.⁹²³ This arrangement, in the relevant commercial context, was not a normal supply agreement, intended to bring about legitimate benefits to GSK (for example, lower distribution costs or an increase in the number of customers that could be supplied). The distribution margin earned by GUK on the restricted volume of product was, in reality, a mechanism for achieving a value transfer from GSK to GUK. As described in detail below, the CMA considers that this value transfer was made in return for the restrictions.⁹²⁴

6.104 This transfer of a restricted volume of paroxetine amounted to a 'value transfer' because, as a consequence of the volume restriction described at clause 3.1 of the GUK-IVAX Agreement (and the impact this would have on prevailing prices in the market), GSK was, in practice, simply transferring to GUK the margin that it would have otherwise earned on such volumes. In the same way as a payment, GSK was able to use this mechanism to make a transfer to GUK through a means that would not result in a meaningful increase in the price competition it was facing on the market:

- As set out in further detail in paragraph 6.106, GSK was already able to distribute the product throughout the UK, and the GUK-GSK Agreement did not provide for any opportunities to increase supply or to lower its distribution costs.
- As such, in committing to transfer a restricted volume of paroxetine from GSK to GUK, GSK committed to sacrifice a profit margin on the sales of the product transferred from GSK to GUK in the range of £7.5 million to £11.8 million, (depending on the proportion of sales that GUK made that

⁹²³ Whilst the product transfer and profit guarantee clauses were set out in the GUK-IVAX Agreement (document 1003), clauses 3.1 and 4.3, the CMA finds that these value transfers were made indirectly from GSK to GUK (via IVAX, pursuant to the IVAX-GSK Agreement and the GUK-IVAX Agreement) (see paragraph 6.92).

⁹²⁴ It is evident that the volume restriction did in fact bind GUK's sales volumes. For example, during negotiations of the GUK-GSK Agreement, GUK sought substantially higher product volumes. In a letter from [GUK's General Manager] to [IVAX's Commercial Director] dated 24 January 2002 (document 0965), [GUK's General Manager] stated that '*one of the principle sticking points has been that GlaxoSmithKline, through yourselves, has been unwilling to meet our required demand of 1 million packs per year*'. Furthermore, the relevant sales data demonstrates that volume restriction did constrain the purchases that GUK could make from GSK (see paragraph 7.29). It is also relevant that the same volume limitations were also included in GSK's Agreements with each of IVAX and Alpha, and in those cases the evidence likewise demonstrates the relevant clauses represented volume restrictions (see paragraphs B.69–B.79 (IVAX) and 6.163 (Alpha)).

were at the expense of imported GSK product or products sold by GSK UK).⁹²⁵

- For GUK, the returns associated with this value transfer could be forecast with near certainty because, as a consequence of the volume restriction, GUK would have no incentive to set a price that was materially below prevailing levels. That is because if GUK had adopted price levels that were materially below the market level, the volume restriction would have left it unable to satisfy the resulting increase in demand. GUK could therefore be expected to price at prevailing market levels, and to earn the resulting margin across the maximum 750,000 packs of paroxetine per year that GSK agreed to transfer to GUK (see paragraph 3.309).
- Consistent with this, GUK's entry onto the market had no discernible impact on market prices (see paragraph 3.387). Further, when assessing the expected profitability of the GUK-GSK Agreement, GUK assumed that it would be able to maintain prices at prevailing market levels.⁹²⁶

6.105 Moreover, under the GUK-GSK Agreement, GUK was in any case guaranteed a minimum distribution margin of £2.85 million per year. This is because, in the event that GUK's average selling price was below £12.25, it was agreed that that compensation would be paid to GUK to ensure that it would generate returns of at least £2.85 million per year, irrespective of the volume of sales that GUK achieved.⁹²⁷

⁹²⁵ Calculated as: $750,000 \times 3 \times ([\text{price}] - 8.45)$, where the [price] was either £11.80 (an estimate of the price per pack of parallel imported paroxetine which GSK's UK subsidiary would have been credited with, see footnote 1713), or £13.70 (the weighted average Seroxat 20mg pack price between January to March 2002). This assumes that the GUK-GSK Agreement would not be terminated early.

⁹²⁶ When contemplating GSK's settlement offers, it is evident that GUK considered that prices would remain at or close to prevailing levels. For example, the volumes of packs offered and the corresponding gross sales estimates presented in paragraph 6.108 imply GUK's selling prices to be in the region of £11.92 to £12.50.

⁹²⁷ GUK-IVAX Agreement (document 1003), clause 4.3. See also an email from [GUK's General Manager] to [GUK's Managing Director] and [the Chief Executive of Merck Generics Group] dated 12 March 2002 (document 0989), setting out GSK's latest settlement offer and explaining that *'[i]n the event that G[UK] cannot achieve a selling price over £12.20 then a rebate will be paid to G[UK] to achieve the agreed profit figure'*. The minimum profit guarantee was invoked by GUK in relation to its sales of paroxetine in the UK in both the first contract year (2002-03) and the second contract year (2003-04). In relation to 2002-3, see email from [a GUK Sales and Marketing employee] to [IVAX's Sales and Marketing Manager] and others entitled 'Paroxetine yr 1 reconciliation [sic]' dated 6 March 2003 (document 1112), attaching spreadsheet of reconciliation for first year of contract entitled 'Paroxetine yr 1 shortfall.xls' dated 5 March 2003 (document 1108). In relation to 2003-04, see email from [a GUK Sales and Marketing employee] to [IVAX's Sales and Marketing Manager] and others entitled 'Paroxetine reconciliation [sic]' dated 16 March 2004 (document 1130), attaching spreadsheet for reconciliation for contract for 2003 dated 15 March 2004 (document 1129) (a revised version of the relevant spreadsheet was emailed to IVAX on 21 May 2004 which provided revised selling prices for January and February 2004, see email chain between [GUK's Head of Marketing], [IVAX's Sales and Marketing Manager], [a GUK Sales and Marketing employee], [GUK's Financial Controller], [GUK's Finance Director A] dated 21 May 2004 (document 1137), attaching spreadsheet of revised paroxetine schedule for 2003 dated 21 May 2004 (document 1136)).

6.106 The transfer of a restricted volume of paroxetine could not have been expected to generate legitimate benefits for GSK:

- at the time the GUK-GSK Agreement was entered into, GSK was already able to distribute its products (including Seroxat) throughout the UK. The additional sub-distribution agreement with GUK therefore did not provide for opportunities to increase supply or to lower GSK's distribution costs;⁹²⁸
- any strategy aimed at increasing the supply of paroxetine was reliant on persuading GPs to issue more prescriptions for paroxetine, and could not be achieved by entering into a supply agreement with GUK; and
- consistent with this, it is clear that, by imposing volume restrictions on the purchases that GUK could make from GSK, the intention was not to encourage the development of a supply channel involving GUK.

6.107 Consistent with the analysis outlined above⁹²⁹ the CMA observes that the volume restriction was in practice effective in constraining GUK's market share (see paragraph 7.29). Further, the transfer of a restricted volume of paroxetine did in practice provide for a means to remunerate GUK that did not result in an increase in the competitive constraints faced by GSK and a material decrease in paroxetine prices to pharmacies following GUK's market entry with GSK product (see paragraph 3.387).⁹³⁰

6.108 GUK's internal documents support the findings outlined above, and indicate that the transfer of a restricted volume of paroxetine was an element of the compensation that GUK received in return for its acceptance of the entry

⁹²⁸ GSK documents that refer to entry into sub-distribution agreements make no reference to efficiencies or gains to be made through increased distribution, but rather, focus on the need to protect GSK's price and patent position. See, for example, GSK presentation entitled 'Seroxat Patent Challenge' by [GSK's Finance Director A] and [GSK's Head of Regulatory Affairs] dated 5 February 2001 (document 0123), and [redacted]WS2 (GUK) (document 0182) / [redacted]WS2 (Alpharma) (document 0289).

⁹²⁹ GSK SO Written Response (document 2755) paragraph 6.119.

⁹³⁰ Further, the CMA observes that the payments that GSK made to GUK in relation to the minimum profit guarantee were limited, which is consistent with GUK not having sold paroxetine at levels significantly below market prices. In relation to 2002-03, GUK claimed £260,914 for a profit shortfall, and as explained at footnote 932, this can partly be attributed to GUK having sold less than the total volume of product it had ordered, rather than having sold at prices below market prices (email from [a GUK Sales and Marketing employee] to [IVAX's Sales and Marketing Manager] and others entitled 'Paroxetine yr 1 reconciliation [sic]' dated 6 March 2003 (document 1112), attaching spreadsheet of reconciliation for first year of contract entitled 'Paroxetine yr 1 shortfall.xls' dated 5 March 2003 (document 1108)). In relation to 2003-04, GUK claimed a higher payment of £1,468,010 which the CMA considers is due to the onset of true generic competition which began in December 2003 (see email chain between [GUK's Head of Marketing], [IVAX's Sales and Marketing Manager], [a GUK Sales and Marketing employee], [GUK's Financial Controller], [GUK's Finance Director A] dated 21 May 2004 (document 1137), attaching spreadsheet of revised paroxetine schedule for 2003 dated 21 May 2004 (document 1136)).

restrictions, and that GUK anticipated that it would earn margins consistent with prevailing price levels and that were in any case guaranteed:

- The contemporaneous GUK documents show that when contemplating GSK's settlement offers, GUK worked on the basis that both the volume it would be able to sell and the price it would achieve would be unaffected over the term of the GUK-IVAX Agreement.⁹³¹
- In the event that GUK's average selling price was below £12.25, the minimum profit guarantee was paid to GUK irrespective of the volume of sales that GUK achieved. This is demonstrated by the fact that the '*shortfall*' that GUK claimed from IVAX for its sales in 2003-04 was for sales that were less than GUK's total volume under the GUK-IVAX Agreement (750,000 packs).⁹³²

6.109 The CMA has considered GSK's submission that the above analysis would imply that any supply agreement would involve a value transfer.⁹³³ The CMA considers that a key distinction between the GUK-GSK Agreement and a potentially pro-competitive supply agreement is the volume restriction (confining supply to a limited amount of product) within the economic context of the present case, specifically where (a) GSK was already in a position to distribute the product throughout the UK, (b) there were no legitimate economic advantages to GSK from the arrangement, and (c) there were no incentives on GUK to compete on price or otherwise to do more than substitute - to the extent permitted - for sales by GSK. For the reasons

⁹³¹ For example, (i) in an email on 23 November 2001 to [GUK's Managing Director], [GUK's General Manager] set out the current offer ('520k packs PA @ £8.45/pack + £1m PA for "marketing support"') and explained that this would give GUK 'gross sales of £6.5m with a £3m profit' (Email chain between [GUK's General Manager], [GUK's Managing Director], [GUK's external lawyer] of [external law firm], [the Chief Executive of Merck Generics Group] and [Merck's Head of Patents and Raw Material Support Group] entitled 'Improved Glaxo offer' dated 23 to 26 November 2001 (document 0936)), (ii) in a further email on 27 November 2001, [GUK's General Manager] set out a revised offer including '520,000 packs @ £8.25 + £1.5m marketing payment (£6.2m gross + £3.5m profit)' (Email chain from [GUK's General Manager] to [GUK's Managing Director] and [the Chief Executive of Merck Generics Group] dated 27 November 2001 (document 0937)), and (iii) in an email on 22 December 2001, [GUK's General Manager] set out the latest offer including '520k Packs at £8.85 cogs (this will give gross sales of £6.2m and nett [sic] profit of £1.63m)' (Email from [GUK's General Manager] to [the Chief Executive of Merck Generics Group] and [GUK's Managing Director] dated 22 December 2001 (document 0953)). See also paragraph 3.315.

⁹³² Although GUK ordered the full quantity of packs available to it in the second contract year (March 2003 to February 2004) of the GUK-GSK Agreement (see paragraph 8.85 in Part 8, Section B for a discussion of whether the volume restriction in the GUK-GSK Agreement was binding), GUK's sales in that year were 713,171 packs, which was 36,829 packs less than its total volume under the GUK-IVAX Agreement. However, GUK claimed payment to ensure that it achieved the minimum profit of £2.85 million provided for by Clause 3.1 of the GUK-IVAX Agreement, see paragraph 6.107. See email entitled 'Paroxetine reconciliation [sic]' dated 16 March 2004 attaching spreadsheet (documents 1129 and 1130) (a revised version of the relevant spreadsheet was emailed to IVAX on 21 May 2004 which provided revised selling prices for January and February 2004, see email from [GUK's Head of Marketing] to [IVAX's Sales and Marketing Manager] dated 21 May 2004 attaching spreadsheet, (documents 1137 and 1136)).

⁹³³ GSK SO Written Response (document 2755), paragraph 6.170; see also GUK SO Written Response (document 2752), Section B.

outlined above, the volume restriction ensured that in this context the transfer of GSK's product was essentially the same as a cash payment from GSK to GUK, in that it provided a means by which GSK could transfer value to GUK, but without providing for meaningful increases in the actual competitive constraints that GSK faced in the relevant market.

6.110 In contrast, had the GUK-GSK Agreement not included the volume restriction, GUK would have had some scope to choose how much paroxetine to purchase and sell in order to maximise its profits and would have had an increased incentive to compete on price to do so. Under such a scenario, it would have been open to GUK to offer price decreases as a means of increasing its sales to maximise its profits, and the returns it would earn would be a function of how effectively it competed with GSK. In such a scenario, the losses suffered by GSK could have been far greater than the losses it made by transferring a restricted volume of product to GUK as: (i) additional supplies to GUK would have resulted in further margin losses on those sales; and (ii) the resulting competition would have been expected to result in materially lower prices (and profit margins) on those sales that GSK did retain. Under such a scenario, the margin would not simply be transferred from GSK to GUK. Rather, GSK would have been expected to suffer sales losses and margin decreases that would have been associated with more effective competition and lower prices, and purchasing wholesalers and pharmacies would have benefited from more effective competition and the material price decreases that would have been expected to follow. The associated returns generated by GUK would have been derived from its efforts to compete meaningfully on the market (albeit with GSK product) without the constraint of restricted volumes.

v) ***The overall level of the value transfers cannot be explained on any other commercial basis that was not anti-competitive, and the value transfers were commercially rational only on the basis that they would induce GUK's acceptance of entry restrictions and delay its potential independent market entry***

6.111 There are no other bases (which the Parties have suggested in response to the Investigation, or otherwise that the CMA can discern) on which the GUK-GSK Agreement could legitimately have involved value transfers totalling at least £21.3 million from a market incumbent to a potential competitor.

6.112 As set out below, the CMA finds that the avoidance of costs associated with the litigation (including both the costs of the litigation itself and those relating to the settlement of the cross-undertaking in damages that existed in relation to the injunction that was in place pending the litigations outcome) cannot

plausibly explain the level of value transfers made by GSK under the terms of the GUK-GSK Agreement.

6.113 From GSK's perspective, its decision to make value transfers totalling at least £21.3 million can only be explained by its desire to induce GUK's acceptance of the entry restrictions and to delay its potential independent generic entry. In carrying out this assessment, it is important to recall, in particular, that:

- because the GUK-GSK Agreement deferred rather than resolved the underlying questions of patent validity and infringement, the value transfers that GSK made during the term of the GUK-GSK Agreement did not enable GSK to avoid the costs associated with their litigation, but only to defer them. Although the conduct and outcomes of future litigation could not be forecast with certainty, the three year GUK-GSK Agreement left the contested issues unresolved and this meant that the costs and damages exposure associated with their litigation would either be deferred to subsequent litigation during the term of those Agreements or, failing that, would be deferred to subsequent litigation with GUK. In order to avoid those costs, GSK and GUK would have needed to enter into a subsequent agreement, for a duration as long as the patents under dispute, but their avoidance would not be achieved by the GUK-GSK Agreement and the value transfers it included.
- GSK has not submitted that its decision to commit to the value transfers can, objectively, be explained solely by a desire to avoid the costs and exposure relevant to the GUK Litigation. For example, in its representations, GSK stated that *'its rationale for settlement of the Patent Disputes was in each instance essentially the defence of its valid patent rights and their commercial value (the status quo), and for this it was prepared to compromise based on its assessment of an uncertain litigation outcome. Each Generic Company sought early entry to the UK market for a paroxetine product and each had its own particular conditions for compromise which had to be accommodated to resolve the Patent Disputes.'*⁹³⁴

6.114 From GUK's perspective, its actions demonstrate that it had determined the value transfers would provide it with sufficient compensation for its acceptance of the entry restrictions. It can be inferred that GUK considered that the GUK-GSK Agreement provided it with expected returns⁹³⁵ that were

⁹³⁴ GSK Written SO response (document 2755), paragraph 4.26.

⁹³⁵ GUK's 'expected returns' would represent the average of the profits associated with the potential outcomes of its entry strategy (for example, the revenue and costs associated with each outcome relevant to its strategy (such as winning or losing any litigation, and the possible timing of its entry), and the probability of each outcome.

higher than those associated with continuing with its efforts to enter the market independently of GSK. As outlined above, each of the value transfers was not for its stated purpose. As outlined below, the CMA does not consider that GUK's acceptance of the value transfers can be explained by the cross-undertaking in damages.

a) *The value transfers cannot be explained by the avoidance of the costs and disruption of litigation*

- 6.115 GSK submitted that its expected litigation costs put *'the sums paid under the settlements into proportion'*.⁹³⁶ In the context of the GUK-GSK Agreement, GSK has estimated that it would have incurred further litigation costs of £2.2 million had it pursued litigation in response to GUK's potential independent market entry.⁹³⁷
- 6.116 The CMA notes that even on the basis of GSK's own estimate, the value transfers of at least £21.3 million that GSK committed to transfer to GUK was significantly more than the estimated legal costs of £2.2 million, such that avoiding those costs cannot explain the value transfers that GSK made to GUK. Moreover, at the time the GUK-GSK Agreement was entered into, GSK had already committed to make payments to IVAX totalling at least £17.9 million,⁹³⁸ which meant that on entering into the GUK-GSK Agreement, GSK had agreed to make value transfers to IVAX and GUK totalling at least £39.2 million,⁹³⁹ compared to the £5.75 million of litigation costs that GSK submitted were avoided by entering into those Agreements.
- 6.117 Further, the litigation costs estimated by GSK are a significant overstatement of the litigation costs that GSK avoided by entering into the GUK-GSK Agreement.
- 6.118 First, the CMA emphasises that the GUK-GSK Agreement did not relieve GSK of the burden of litigating the patent issues, because the GUK-GSK Agreement could not and did not prevent other generic suppliers from litigating against them in the future; nor did GSK even resolve its dispute with GUK by, for example, committing not to contest GUK's independent generic entry at a specified future date. The estimated GUK litigation costs were not

⁹³⁶ GSK Second Response, Part Two (document 0734), paragraph 5.3(b).

⁹³⁷ GSK Second Response, Part Two (document 0734), paragraphs 5.1–5.16.

⁹³⁸ See paragraph B.63 for calculation.

⁹³⁹ This is made up of £17.9 million to IVAX and £21.3 million to GUK, and has been calculated on the basis that neither of the Agreements was terminated early, and sales by the Generic Companies substituted for sales by parallel importers. Had the Generic Companies' sales instead substituted for GSK's own sales in the UK, the value that GSK committed to transfer to IVAX and GUK was instead £47.8 million (made up of £22.3 million to IVAX and £25.5 million to GUK). For the calculations see paragraph B.63 for IVAX and 6.91 for GUK.

therefore avoided as a consequence of the GUK-GSK Agreement, but merely deferred (see also paragraph 6.113).

- 6.119 Second, although GSK was committed to making value transfers totalling at least £21.3 million on entering into the GUK-GSK Agreement, the litigation costs that it deferred were unlikely to include all of the costs that GSK has estimated that it would have incurred in relation to the GUK and IVAX disputes. This is because, as was ultimately the case following GSK's dispute with Apotex, one concluded case was likely to have provided clarity as to whether and on what terms generic entry was possible without infringing valid patent claims, and had the potential to prompt the widespread generic entry that would have disincentivised GSK from pursuing further litigation.⁹⁴⁰
- 6.120 Had GSK been confident in its patent position, as it submitted to the CMA during the Investigation, it would have expected to prevail before the Courts and recover at least a significant proportion of its litigation costs. Although it would also have had to take into account the (*ex hypothesi* lower) risk of being unsuccessful and paying a proportion of GUK's litigation costs, the net effect of the English rule⁹⁴¹ on costs should have been to reduce GSK's expected litigation costs if it had been confident in its case.
- 6.121 GSK also submitted, in general terms, that *'[l]itigation is a burden to the business in terms of costs and a distraction of management and scientists' time from the daily running of the business'*.⁹⁴² GSK stated that as well as direct costs, litigation also diverts scientist, patent attorney and management time which can be disruptive to the business, and that GSK *'needs to focus its*

⁹⁴⁰ Although a judgment may have related only to whether GUK's product infringed valid patent claims, a judgment in GUK's favour was likely to prompt further entry and to substantially limit GSK's incentive to pursue further litigation against other parties. For example, GUK's entry was very likely to have led to entry by Ratiopharm and Novartis (to whom GUK has agreed to sub-license its product (see paragraph 3.261)). Their independent generic entry would have been expected to result in the substantial price declines that GSK was seeking to avoid by pursuing litigation, limiting GSK's incentive to pursue further litigation in response to further entry. Other generic suppliers would also have been more likely to enter 'at risk', particularly if the decision was taken that the risks and exposure to damages had been reduced by the favourable judgment and subsequent entry (indeed Actavis stated it was the level of risk and exposure to damages which was the key consideration for Alpharma in determining whether to launch (Actavis SO Written Response (document 2754), paragraphs 10.20–10.23)). Conversely, had GSK prevailed in litigation, this had the potential to disincentivise other generic companies from pursuing independent entry. This is consistent with the views of [GSK's Finance Director A], who explained that: *'[t]he market could continue as it was if GSK won litigation but if it lost the patent then everything would go. There would be intense competition from the generics in the near future. GSK therefore decided, to provide for some period of certainty, to enter into supply agreements* (Note of meeting between the OFT and GSK dated 19 December 2011 (document 0688), paragraphs 18 and 20). Similarly, a note in which IVAX considered its options for the launch of paroxetine, dated 14 March 2001, states that one benefit of entering into an agreement along the lines of the IVAX-GSK Agreement is that *'every one [sic] else has to start again'*. In contrast if it did choose to test the patent *'[p]rinciples will be established for all'* ('Seroxat (paroxetine): 14th March 2001' dated 14 March 2001 (document 1699)).

⁹⁴¹ Under the English rule, the law which governs the allocation of court costs and attorney fees, the losing party in litigation bears the costs of both parties.

⁹⁴² GSK Second Response, Part Two (document 0734), paragraph 8.1(d).

resources on its business operations' in determining its approach.⁹⁴³ GSK has explained that '[i]t is impossible to quantify in verifiable figures the huge diversion in management time and the general disruptiveness of litigation to the company as a whole'.⁹⁴⁴

- 6.122 There is no indication from the contemporaneous evidence that this general assertion was a relevant factor in GSK's decision-making at the time of entering into the Agreements, or that it could plausibly explain the value transfers.
- 6.123 To the contrary, in those documents that explain GSK's rationale, the focus is on preventing true generic competition (see, for example, paragraphs 6.134 to 6.139). In his explanations of the rationale for the Agreements, [GSK's Finance Director A] did not mention that an assessment of these factors was made, nor that GSK considered that, having quantified them, such factors justified a commitment to make value transfers totalling at least £21.3 million.
- 6.124 Further, at the time when GSK entered into the GUK-GSK Agreement, the litigation had already progressed such that the necessary submissions, experiments and testing would have been largely completed (see paragraph 3.305). Those were to that extent sunk costs which could not be avoided by the GUK-GSK Agreement.
- 6.125 In any case, as with the litigation costs themselves, any '*disruption*' was not avoided by the GUK-GSK Agreement, but simply deferred until the fundamental issues concerning GSK's patent position became the subject of subsequent litigation.
- 6.126 The cost and disruption of prospective litigation cannot therefore explain GSK's decision to commit to making value transfers to GUK of at least £21.3 million, or more generally its decision to make value transfers totalling at least £50.9 million to the Generic Companies.

b) The value transfers cannot be explained by the cross-undertaking in damages

- 6.127 GUK submitted that the GUK-GSK Agreement does not contain a reverse payment⁹⁴⁵ because, having been injuncted, it had potentially a large claim for damages against GSK. It submitted that this explained the value transfers.

⁹⁴³ GSK Second Response, Part Two (document 0734), paragraph 8.10.

⁹⁴⁴ GSK Second Response, Part Two (document 0734), paragraph 5.4.

⁹⁴⁵ GUK Response dated 31 July 2013 to the SO ('GUK SO Written Response') (document 2752), paragraph 3.50.

6.128 In this connection, GUK notes that as part of the settlement, GUK and GSK agreed that the proceedings between them be stayed with GSK being discharged from its cross-undertaking in damages. GUK then set out the potential extent of damages that GSK would have faced, describing the costs that it had incurred in preparing to launch, and the potential revenues that it could have achieved had it entered the market independently of GSK.⁹⁴⁶ As a consequence, GUK stated the value transfers made by GSK could have been expected to provide for benefits to GSK beyond those associated with eliminating the threat of independent generic entry and that GUK was not therefore compensated in return for agreeing entry restrictions.⁹⁴⁷

6.129 The CMA does not accept that the value transfers can be explained by GSK's desire to avoid a potential exposure to damages under the cross-undertaking.

6.130 First, the proposition that the value transfers were attributable to the extinguishment of GSK's liability under the cross-undertaking is not supported by the terms of the Agreement, by the contemporaneous documents, nor by GSK's submissions in the Investigation:

- The value transfers considered above were in fact all conditional on GUK's ongoing commitment to refrain from entering the market with generic paroxetine over a period of 3 years (and potentially longer had the GUK-GSK Agreement been renewed), as set out in paragraph 6.93.
- The GUK-GSK Agreement did not include any payments that referred to the cross-undertaking, and the only one-off payment for costs in the GUK-GSK Agreement (which was relevant to the period of the GUK Litigation) was a payment for 50% of GUK's legal costs incurred in the GUK Litigation up to a maximum of £500,000.⁹⁴⁸
- GSK has not suggested that the cross-undertaking can explain the level of value transfers it made to GUK or to the Generic Companies more generally. GSK submitted, for example, that the stock purchase was

⁹⁴⁶ GUK stated that GSK's potential damages exposure to GUK would need to take into account the stock GUK had purchased for its UK launch (a value of \$6 million), £5.5 million in advance orders which GUK was unable to fulfil due to the injunction, lost total sales in the first six months amounting to £35 million, and the loss of reputation potentially suffered by GUK because it had been unable to fulfil orders, including the loss of customers and orders on other products. See GUK SO Written Response (document 2752), paragraph 3.51. GUK estimated that GUK's lost profits over the 6-month period beginning in October 2001 would have been around £20.5 million, though noted that this figure did not include loss of reputation with its customers as that would be hard to value. GUK suggested that if GSK had a very good chance (say, 80%) of prevailing in the event of continued litigation, the value to GSK of being discharged from the cross undertaking in damages would be £4.1 million. See Annex 1 of GUK SO Written Response (document 2753), section 3.1.3.

⁹⁴⁷ GUK SO Written Response (document 2752), paragraph 3.52.

⁹⁴⁸ See GUK-GSK Settlement Agreement (document 0995), clause 3.

insisted on by GUK, and accepted by GSK as a means of ensuring that GUK would remain off the market (see paragraphs 6.99 to 6.102). GSK stated that the promotional allowances were part of its ongoing supply arrangements with GUK, and that it was open to GUK (and IVAX and Alpharma) to use such payments to fund discounts below the supply price of £8.45 (see paragraph 6.97). Moreover, GSK submitted that its '*confidence in the validity of its patents at the time was strong*'⁹⁴⁹, on which basis it would have considered there was a small chance of it being ordered to pay damages to GUK and no reason to pay to GUK a substantial proportion of GUK's possible claim.

- There are no contemporaneous documents which indicate that this was the rationale for the payments. GUK's submission is at odds with its own internal discussion, in which it considered whether the value transfers provided it with sufficient compensation for its Agreement not to enter the market independently of GSK for a period of 3 years, as opposed to its willingness to discharge GSK from its potential damages liability (see paragraphs 6.136 to 6.138).

6.131 Second, the CMA does not consider that GSK's exposure to a damages claim is in any case capable of explaining the value transfers it committed to make to GUK:

- Although the GUK-GSK Agreement did extinguish GSK's liability in relation to the litigation that existed at the time, the GUK-GSK Agreement only deferred litigation of the contested issues, and the associated costs (see paragraphs 6.90 and 6.113). By way of illustration, had GUK sought to enter the market after the expiry of the GUK-GSK Agreement (or had another entrant sought to do so during its term), GSK was highly likely to commence litigation again and to have faced again the damages associated with a cross-undertaking.⁹⁵⁰ Because a cross-undertaking related to potential damages suffered by GUK during the period between the date of an undertaking to the date of the associated judgment, this deferred damages exposure would be likely to be approximately the same as the damages exposure that GSK would have faced if GUK had continued with the litigation instead of entering into the GUK-GSK Agreement. For that reason, under the terms of the Agreement, the value transfers did not in practice materially decrease the total damages

⁹⁴⁹ GSK Second Response, Part Two (document 0734), paragraph 4.22.

⁹⁵⁰ The exposure would be comparable if GUK had been permitted to enter the market 'at risk'. In that case, GSK would have been expected to suffer losses during the period of the litigation, but could have sought damages had it prevailed in the litigation.

exposure that GSK faced in relation to the litigation of the contested issues and, as a consequence, the avoidance of an exposure to damages cannot explain GSK's decision to make value transfers.⁹⁵¹ Similarly, GUK's acceptance of value transfers related to its commitment to defer its proposed entry (and the resulting litigation process), rather than to final compensation for a claim and not to the settlement of claim that was likely to have been restored had GUK sought to enter the market at the end of the GUK-GSK Agreement.

- On the basis of GUK's own estimate of the damages that GSK avoided from GUK not entering the market independently, which totalled £4.1 million (see footnote 946 for the component parts of the calculation), the expected value of the damages faced by GSK does not explain GSK's decision to commit to make value transfers to GUK of at least £21.3 million over the initial three year term of the Agreement. In any case, the CMA also notes that GUK's analysis ignores the fact that these damages were likely to be deferred rather than avoided (see above), and considers that the lost profits estimate on which GUK based its potential damages estimate (of £4.1 million, see paragraph 6.128) significantly overstates GUK's potential lost profits when compared with the documentary evidence.⁹⁵²

⁹⁵¹ Had another generic supplier sought to enter the market during the term of the GUK-GSK Agreement, it would also be the case that GSK would not have made value transfers that had enabled it to defer the costs exposure associated with the period of litigation. For example, the litigation concerning the central question of whether generic entry was permissible would have simply been deferred as a consequence of the GUK-GSK Agreement, as would the associated litigation costs and the damages exposure relevant to the period of the litigation. On this basis also, therefore, the expected costs of a damages claim would not have been avoided as a consequence of the GUK-GSK Agreement, and were likely only to have been deferred.

⁹⁵² For example, the CMA considers that GUK's lost profits figure of £20.5 million over six months is not reliable because:

- it exceeds the value of GSK's own profits on paroxetine 20mg over 6 months in 2001 (see Table 5.2 which sets out GSK's profits of £34.3 million in 2001, implying profits of not more than £17.15 million over a 6 month period). It is implausible that such generic entry could result in sales values and profits greater than those of the originator;
- GUK did not account for out-licensed supply in its lost profits figure, and instead treated the full value of sales as though it would have earned the higher profits available on sales to wholesalers and pharmacies (see email chain between [a GUK Sales and Marketing employee], [a GUK Special Projects Manager], [GUK's Head of Contract Sales], [GUK's General Manager] and [GUK's Sales and Marketing Director] dated 31 October to 9 November 2001 (document 0927) and email chain between [a GUK Sales and Marketing employee], [GUK's General Manager], [GUK's Sales and Marketing Director] and [GUK's Head of Contract Sales] dated 30 October 2001 (document 0923), which indicates that GUK was considering out-licensing stock to other generic companies). Had GUK out-licensed stock to other generic companies it would have received a price below prevailing market prices on this stock (for example, in distribution contracts between GUK and Biochemie and between GUK and Ratiopharm in Europe, GUK could expect to receive an initial supply price of £4.70 per pack). The CMA notes that the contracts referred to are final, but unsigned versions. See email from [Commercial Director of Merck Generics] to [a Merck employee] and [the Chief Executive of Merck Generics Group] dated 19 April 2002 (document 1049), attaching Ratiopharm distribution agreement dated 28 June 2001 (document 0856) and Biochemie distribution agreement dated 20 August 2001 (document 0864). The Biochemie distribution contract specified a 'Floor price' of EUR 0.25 per tablet, which is EUR 7.50 per pack of 30 tablets. This is £4.70 when converted into GBP at a rate of 1.5955 (Source: Bank of

- 6.132 More generally, the CMA observes that any argument that a substantial proportion of the value transfers was made to settle damages exposure by GSK would inexorably imply that GSK considered its patent position to be assailable and likely to fail in court.
- 6.133 Had that been the case, any settlement agreement would be expected to be on terms that allowed for a much greater (and meaningful) degree of competition in the paroxetine market than was the case resulting from the GUK-GSK Agreement. Such an argument cannot be reconciled with the terms of the GUK-GSK Agreement, pursuant to which (i) GUK entered the market with GSK's product on terms that could not be expected to have any meaningful impact on market prices; (ii) GUK's proposed entry was deferred for a period of three years, after which point GSK remained free to challenge any attempts by GUK to enter the market on the expiry of the GUK-GSK Agreement; and (iii) GSK committed to make significant payments on the condition that GUK refrained from entering the market.
- vi) *The evidence of the Parties' subjective intentions supports the objective evidence that the objective aim of the GUK-GSK Agreement was to restrict competition***

- 6.134 GSK's internal documents demonstrate that in its negotiations with GUK (and the other Generic Companies), its strategy was to use payments and other value transfers to induce GUK to accept the restrictions described above. For example, [X](GSK's Finance Director [B]) wrote in a manuscript note of a conversation with GSK's Associate General Counsel, that took place around August or September 2003 (see paragraph 3.240), that the Agreements (including the GUK-GSK Agreement) '*were mechanisms for paying a certain amt*' and that '*We then devised mechanisms*'. [GSK's Finance Director B]

England, August 2001). This is similar to the 'floor price' in the Ratiopharm contract of DM 0.49 per tablet, which is DM 14.70 per pack of 30 tablets. This is £4.57 when converted into GBP at a rate of 3.2141 (Source: Bank of England, June 2001). (See Ratiopharm distribution agreement dated 28 June 2001 (document 0856) and Biochemie distribution agreement dated 20 August 2001 (document 0864), Schedule 2). The CMA notes that this price is consistent with a discussion in a later email chain dated 8 May 2002, in which Ratiopharm requests a lower floor price and GUK colleagues discuss internally that a floor price of £4.70 gives a very reasonable margin for the UK market. See email chain between [Merck employee], [Merck's Strategic Sourcing Specialist], [the Chief Executive of Merck Generics Group], [Merck employee], [Merck employee] and [Commercial Director of Merck Generics] dated 3 to 8 May 2002 (document 1063).

(iii) Furthermore, GUK contemporaneous documents suggest that GUK expected to earn profits of £6 million in the year first after generic entry (and therefore £3 million over 6 months), which is further evidence that GUK has significantly overstated the potential damages faced by GSK (email from between [Merck's Head of Patents and Raw Material Support Group], [the Chief Executive of Merck Generics Group], [GUK's General Manager], [GUK's Head of Research and Development], [Head of Merck Operation in Canada], [the Head of Merck Operation in Australia], [GUK's Managing Director] dated 31 December 2001 (document 0955)).

noted that as a result [the Generic suppliers were] *stopped [from] entering the market*.⁹⁵³

6.135 [GSK's Finance Director B's] description is consistent with that provided by [GSK's Finance Director A] during a meeting with the OFT dated 19 December 2011 and in a later witness interview with the CMA.⁹⁵⁴ [GSK's Finance Director A] has explained that GSK's rationale for entering into the Agreements (including the GUK-GSK Agreement) was to reduce uncertainty, and to enable the relevant team to meet pre-existing financial targets that had been produced on the basis of no generic competition emerging prior to patent expiry.⁹⁵⁵ In negotiating agreements that would provide for that certainty, GSK was willing to provide compensation to the Generic Companies, including GUK.⁹⁵⁶ The relevant meeting note (as approved by GSK) records [GSK's Finance Director A's] comments as follows:⁹⁵⁷

'The market could continue as it was if GSK won litigation but if it lost the patent then everything would go. There would be intense competition from the generics in the near future. GSK therefore decided, to provide for some period of certainty, to enter into supply agreements.

[...]

[redacted] [[GSK's Finance Director A]] said that there had been negotiation between the parties in relation to the payments made by GSK in the context of the settlement agreements. This was to provide compensation for costs incurred by the generics. He [GSK's Finance

⁹⁵³ See [GSK's Finance Director B's] electronic transcribed note and handwritten original note contained in 'Non-confidential 3rd questionnaire response - seroxat financial information', undated (document 0081). In a later witness statement dated 23 July 2014, [GSK's Finance Director B] explained that '*mechanisms*' was likely to mean something like '*ways of*' and that '*stopped [from] entering the market*' was her summary of a conversation that she recalls having with GSK's in-house lawyer, [redacted] ([redacted]WS2 (document 3180)).

⁹⁵⁴ See Note of the meeting between the OFT and GSK held on 19 December 2011 (document 0688) and signed transcript of post-SSO witness interview with [GSK's Finance Director A] ([redacted]1') (document 4008R).

⁹⁵⁵ See paragraph 30 of the Note of the meeting between the OFT and GSK held on 19 December 2011 (document 0688), paragraph 30. [GSK's Finance Director A] explained that '*when planning, at a management team level, there was a need to deliver and there was a need for certainty in relation to sales projections [...]. [redacted] said that making a deal with the generics ensured that the management team would be able to deliver next year's numbers*'. In a post-SSO witness interview, [GSK's Finance Director A] stated that his reference to '*next year's numbers*' was a reference to a budget agreed over a three-year planning horizon ([redacted]1 (document 4008R), pages 15–16). [GSK's Finance Director A] stated that GSK was not anticipating multiple generics entering the market and competing on price for several years, and it sought to maintain that position of some level of certainty (see pages 15-16). This is consistent with [Alpharma ApS's Sales and Marketing Director's] account of a meeting between Alpharma and GSK on 11 October 2002 in which [GSK's Finance Director A] reportedly stated a key issue for GSK was '*Maintaining stability and predictability*' (See document 1361).

⁹⁵⁶ See also [redacted]WS1 (document 0241), paragraph 9.2 and [redacted]WS2 (GUK) (document 0182), paragraph 2.4.

⁹⁵⁷ Note of meeting between the OFT and GSK on 19 December 2011 (document 0688), paragraphs 18 and 20. See also [redacted]WS1 (document 0241), paragraph 9.2 and [redacted]WS2 (GUK) (document 0182), paragraph 2.4.

Director A] noted that the payments were agreed following a "straight negotiation in commercial terms".'

- 6.136 GUK's internal documents demonstrate that, during its negotiations with GSK, its intention was to maximise the profits that it would receive from GSK, to ensure that it received returns that it deemed sufficient given the costs it had already incurred, and that would provide for sufficient compensation (in the form of value transfers) for its agreement to delay its potential independent entry into the UK paroxetine market.
- 6.137 Evidence concerning the negotiation of the GUK-GSK Agreement confirms that GUK determined whether the value transfers offered by GSK would provide it with sufficient profits by comparing them to the expected returns of pursuing its efforts to enter the market independently of GSK. For example, in an email dated 31 December 2001, [GUK's General Manager] commented that the offer that GSK had made to GUK would enable it to earn profits that were comparable with those that it expected to earn by entering the UK paroxetine market independently of GSK. [GUK's General Manager] noted that the GSK offer '*would deliver a similar bottom line (£5.6m v's £6m)*', although still reached the conclusion that the offer was insufficient to deter GUK from continuing with the GUK Litigation at that stage.⁹⁵⁸
- 6.138 Similarly, the CMA observes that unless GSK committed to make high enough value transfers to GUK, GUK was otherwise unwilling to agree to the restrictions described above. Both prior to and during the course of the GUK Litigation, GSK made various increasingly lucrative offers to GUK. All of GSK's offers were rejected by GUK until it was ultimately satisfied with GSK's offer. This is demonstrated by Table 3.2, which records the various settlement offers GSK made to GUK during the course of the GUK Litigation. For example, GUK was not prepared to agree to limit its entry into the UK paroxetine market unless it was sufficiently '*compensated*' and would receive value transfers that would provide a sufficient '*profit*'.⁹⁵⁹ Similarly:
- In an email on 27 July 2001, in the context of discussing a possible settlement between GSK and Alphapharm, [the Chief Executive of Merck

⁹⁵⁸ Email chain between [Merck's Head of Patents and Raw Material Support Group], [the Chief Executive of Merck Generics Group], [GUK's General Manager], [GUK's Head of Research and Development], [Head of Merck Operation in Canada], [the Head of Merck Operation in Australia] and [GUK's Managing Director] dated 31 December 2001 (document 0955).

⁹⁵⁹ See, for example, an email from [GUK's Managing Director] to [the Chief Executive of Merck Generics Group] dated 22 March 2002 (document 1056), referring to the '*profit*' that would be made from the GSK stock purchase. An email from [the Head of Merck Operation in Australia] to [the Chief Executive of Merck Generics Group] dated 14 March 2002 (document 1001) records that '*The GSK deal must indirectly compensate us [Alphapharm] in some way for this*'.

Generics Group] explained that GSK's offer to GUK '*was simply an offer to license GUK to give a reasonable returnbut not good enough for us to avoid the patent risks and launch*'.⁹⁶⁰

- In an email to [the Chief Executive of Merck Generics Group] on 27 November 2001, in relation to an earlier offer from GSK, [GUK's Managing Director] considered that GSK's '*offer is now better than my minimum*'.⁹⁶¹
- In an email on 22 December 2001 from [GUK's General Manager] to [the Chief Executive of Merck Generics Group], regarding the latest offer GSK had made to GUK was as follows,⁹⁶² [GUK's General Manager] stated that '*I am inclined to agree with your [the Chief Executive of Merck Generics Group's] view that this is a poor return given the level of investment*'.
- In an email on 31 December 2001 [the Chief Executive of Merck Generics Group] explained that if GUK remained '*confident*' of winning the Patent Dispute it should '*push for the best deal we can*'.⁹⁶³ It is clear that at the time he considered that such a '*deal*' should provide GUK with sufficient profit ('*we need the API covered - plus a decent profit*').
- In a separate email to [the Head of Merck Operation in Australia] on 12 March 2002, [the Chief Executive of Merck Generics Group] provided an update on discussions between GUK and GSK and explained that GUK had '*a real concern that we may not prevail in the patent case - so a settlement and local distribution agreement seem to be the best way to go - provided the numbers are right*'.⁹⁶⁴ While this indicates that at that time the GUK-GSK Agreement seemed to be GUK's preferred approach, it also shows that GUK's agreement to defer its efforts to enter the UK paroxetine market independently of GSK was conditional on GUK being adequately compensated ('*provided the numbers are right*'). The implication from this is that if the '*numbers*' were not '*right*' then GUK would not agree to the restrictions ultimately set out in the GUK-GSK Agreement.⁹⁶⁵ GUK's alternative approach absent the GUK-GSK Agreement was to continue to

⁹⁶⁰ Email chain between [the Chief Executive of Merck Generics Group] and [the Head of Merck Operation in Australia] dated 27 July 2001 (document 0859).

⁹⁶¹ Email chain between [GUK's General Manager], [GUK's Managing Director] and others dated 27 November 2001 (document 0937).

⁹⁶² Email from [GUK's General Manager] to [the Chief Executive of Merck Generics Group] and [GUK's Managing Director] dated 22 December 2001 (document 0953).

⁹⁶³ Email chain between [Merck's Head of Patents and Raw Material Support Group], [the Chief Executive of Merck Generics Group] and others dated 31 December 2001 (document 0954).

⁹⁶⁴ Email from [the Chief Executive of Merck Generics Group] to [the Head of Merck Operation in Australia] dated 12 March 2002 (document 0990).

⁹⁶⁵ The fact that GUK agreed to the GUK-GSK Settlement Agreement the following day (13 March 2002) shows that GUK considered that the '*numbers*' were '*right*'.

pursue its efforts to enter the UK paroxetine market independently of GSK.⁹⁶⁶

- In an email to [Merck's Head of Patents and Raw Material Support Group], on 31 December 2001, [the Chief Executive of Merck Generics Group] explained that GSK's *'final offer was still not acceptable'* and suggested that:⁹⁶⁷

*[...] as long as you remain confident of winning [although there are no guarantees] we must push for the best deal we can and that means [under scenario 2 - which is the option under discussion] that we need the API covered - plus a decent profit - **otherwise we should push [sic] on with the case for ultimate launch.**'* (emphasis added)

6.139 Taken together, the evidence regarding intentions confirms the CMA's analysis of the objective aim of the GUK-GSK Agreement set out above. It confirms that GSK's intention was to use the value transfers as a means of securing entry restrictions and deferring the threat of generic entry. It also confirms that GUK's intention was to accept the value transfers on the basis that they provided sufficient compensation for its acceptance of the entry restrictions.

vii) Conclusion on restriction of competition by object

6.140 Under the GUK-GSK Agreement, GSK made cash payments and other value transfers in return for GUK's acceptance of entry restrictions. The CMA finds that the objective aim of the GUK-GSK Agreement was to restrict competition. The value transfers were conditional on GUK not entering the UK paroxetine market independently of GSK during the term of the GUK-GSK Agreement. Further, the value transfers cannot be explained by legitimate commercial objectives, as submitted by the Parties, or which the CMA can discern; they only made commercial sense on the basis that GSK would benefit from delays to GUK's potential independent entry and they were accepted by GUK as compensation for its acceptance of the entry restrictions.

6.141 The CMA finds that the GUK-GSK Agreement – viewed in its legal and economic context - was, by its very nature, restrictive of competition. It

⁹⁶⁶ See, in particular, an email from [the Chief Executive of Merck Generics Group] to [Merck's Head of Patents and Raw Material Support Group] and others dated 31 December 2001 (document 0954): *'otherwise we should push [sic] on with the case for ultimate launch'*.

⁹⁶⁷ Email from [the Chief Executive of Merck Generics Group] to [Merck's Head of Patents and Raw Material Support Group] and others dated 31 December 2001 (document 0954).

reveals, in and of itself, a sufficient degree of harm to competition and therefore had the object of restricting competition.

6.142 In view of all of the foregoing (and the other aspects of the legal assessment set out at Part 10), the CMA finds that GSK and GUK infringed the Chapter I prohibition and/or Article 101 TFEU, by participating in an agreement (the GUK-GSK Agreement) that had as its object the prevention, restriction or distortion of competition.

F. The content of the Alparma-GSK Agreement

6.143 The Alparma-GSK Agreement is described at paragraphs 3.363 to 3.367. The terms of the contracts comprising the Alparma-GSK Agreement are summarised below.

6.144 The Alparma-GSK Settlement Agreement was entered into on 12 November 2002 and had an initial one year term which was subsequently extended to 30 November 2004. That agreement was terminated on 13 February 2004, some eight months before it was due to expire. The associated Alparma-IVAX Agreement, entry into which was a condition precedent to the Alparma-GSK Settlement Agreement, was entered into on 20 November 2002 and also had an initial one year term, which was subsequently extended in line with the re-negotiation of the Alparma-GSK Settlement Agreement. The Alparma-IVAX Agreement terminated at the same time as the Alparma-GSK Settlement Agreement (13 February 2004), also some eight months before it was due to expire.

6.145 GSK and Alparma agreed that the proceedings between them in relation to the Anhydrate Patent be dismissed, with both Parties discharged from their respective undertakings, which for Alparma was to refrain from selling paroxetine and for GSK a cross undertaking in damages.⁹⁶⁸ In clause 1 of the Alparma-GSK Settlement Agreement, GSK and Alparma agreed to:

‘consent to an Order in the form of the draft Minute of Order annexed to this Agreement’.

6.146 The relevant parts of this Order read as follows:⁹⁶⁹

⁹⁶⁸ Alparma-GSK Settlement Agreement (document 0356), draft minute of order.

⁹⁶⁹ Alparma-GSK Settlement Agreement (document 0356), see confidential schedule, clause 5 and draft minute of order.

'each party shall reserve all rights and causes of action they may have [...]

and that:

'all further proceedings in this claim be dismissed'.

6.147 The remaining provisions of the Alparma-GSK Settlement Agreement were as follows:

- *'Alparma shall forthwith and during the currency of the Ivax Supply Agreement discontinue all participation in the oppositions to the amendment of UK Patent GB 2,297,550 [...] and GSK and Alparma agree to instruct their solicitors to consent to whatever Order is necessary to this effect.'*⁹⁷⁰
- *'Alparma shall as a condition precedent to this agreement becoming legally binding, enter into a sub-distribution agreement with GSK's exclusive sub-distributor Ivax Pharmaceuticals UK [...] ("the Ivax Supply Agreement") for supply to Alparma of paroxetine with effect from 1 December 2002. GSK shall ensure that it provides Ivax with 500,000 (five hundred thousand) 30x20mg packs of "Product" [...] to allow Ivax to supply Alparma under that agreement'.*⁹⁷¹
- *'GSK shall pay to Alparma the sum of £3,000,000 (three million pounds) in respect of the production and preparation costs for launch in the UK market by Alparma of paroxetine hydrochloride anhydrate.'*⁹⁷²
- *'GSK shall contribute £500,000 (five hundred thousand pounds) towards Alparma's legal costs incurred in the above litigation.'*⁹⁷³
- *'GSK shall pay a marketing allowance to Alparma of £100,000 per month (for a maximum of 12 months) during the term of the Ivax Supply Agreement. In the event of a breach of the terms of this Agreement or in the event of termination of the Ivax Supply Agreement pursuant to Alparma's breach or insolvency the payment of the marketing allowance shall cease with immediate effect (provided that any partial month shall be paid in a pro rata amount). However, if Alparma terminates the Agreement due to Ivax's breach or insolvency, the payments shall continue*

⁹⁷⁰ Alparma-GSK Settlement Agreement (document 0356), clause 1.

⁹⁷¹ Alparma-GSK Settlement Agreement (document 0356), clause 2.

⁹⁷² Alparma-GSK Settlement Agreement (document 0356), clause 3.

⁹⁷³ Alparma-GSK Settlement Agreement (document 0356), clause 4.

*for a maximum of 12 months from commencement of the Ivax Supply Agreement in such circumstances.*⁹⁷⁴

- *'GSK shall provide immediate access under signature of a confidentiality agreement to Alparma of information relating to GSK's products in three therapeutic areas (cardiac; antibiotics and neuro-muscular blockers) being candidates for divestment in the UK by GSK. Alparma shall have an exclusive period of three months from the date of this Agreement to evaluate such products to indicate its interest and sign a Heads of Agreement for the potential purchase of such product(s). Such potential purchase shall ensure the transfer to Alparma of value in an amount of at least £500,000 (five hundred thousand pounds) failing which an alternative means to achieve such transfer would be agreed.'*⁹⁷⁵

- *'(i) During the currency of the Ivax Supply Agreement Alparma shall not make, import, supply or offer to supply paroxetine hydrochloride in the United Kingdom save as purchased from Ivax pursuant to the Ivax Supply Agreement or otherwise manufactured or marketed by GSK (or with GSK's consent) in the EU*

(ii) Alparma is authorised to undertake on behalf of each member in the Alparma group that no such group member shall make, import, supply or offer to supply paroxetine in the United Kingdom during the currency of the Ivax Supply Agreement save in respect of paroxetine hydrochloride manufactured or marketed by GSK (or with GSK's consent) in the EU.

*(iii) Alparma shall not assign or transfer its UK marketing authorisation for paroxetine during the currency of the supply period under the Ivax Supply Agreement.'*⁹⁷⁶

6.148 Following an approval granted on 18 November 2002 by the Executive and Finance Committee of Alparma Inc's Board of Directors,⁹⁷⁷ the Alparma-

⁹⁷⁴ Alparma-GSK Settlement Agreement (document 0356), clause 5.

⁹⁷⁵ Alparma-GSK Settlement Agreement (document 0356), clause 6.

⁹⁷⁶ Alparma-GSK Settlement Agreement (document 0356), clause 7.

⁹⁷⁷ See Minutes of meeting with the Executive and Finance Committee of the Board of Directors of Alparma Inc. on 18 November 2002 (documents D 211 and D 212). See also email from [Alparma Inc's Vice President of Intellectual Property] to [Alparma ApS's Sales and Marketing Director], [Alparma Ltd's Director of Sales and Marketing] and [Secretary of Alparma] dated 18 November 2002 (document A 0055): '[Alparma Ltd's Director of Sales and Marketing] and [Alparma ApS's Sales and Marketing Director]: *Please do not sign the Ivax document until I let you know that we have board approval. This contract is greater than US\$5 million so we need board approval. We have an executive committee meeting this afternoon and [Alparma Inc's Chief Legal Advisor] will be seeking approval, which we expect to be granted.*' See also [REDACTED]WS (document 3172, paragraph 3.6): '*...[T]he direct involvement for the actual settlement agreement with GSK came from senior management – [Alparma Inc's President (Human Generics)], [Alparma Inc's Chief Legal Officer] and [Alparma Inc's Chief Financial Officer]. This contract had to go to the Board of Alparma Inc. for approval.*' See also Alparma

IVAX Agreement was entered into on 20 November 2002.⁹⁷⁸ Conclusion of the Alpharma-IVAX Agreement was a condition precedent to the Alpharma-GSK Settlement Agreement becoming legally binding.⁹⁷⁹ GSK and IVAX also entered into the Third Addendum, reflecting the amendments necessary for the Alpharma-IVAX Agreement, on 20 November 2002.⁹⁸⁰ The key obligations and definitions included in the Alpharma-IVAX Agreement are set out below:

- Product: the product was defined as paroxetine hydrochloride 20mg tablets. 'Packs' were defined as 30 x 20mg patient packs, with paroxetine hydrochloride as its active substance.⁹⁸¹
- IVAX appointed Alpharma as a non-exclusive sub-distributor for paroxetine hydrochloride for Great Britain, Northern Ireland, the Channel Islands and the Isle of Man.⁹⁸²
- Compensation for initial delay in supply: IVAX agreed to compensate Alpharma £200,000 per month for up to three months in the event that there was an initial delay in supply after the effective date of the agreement.⁹⁸³
- Volume: IVAX committed to supply Alpharma during the term of the agreement with five hundred thousand (500,000) packs pursuant to Alpharma purchase orders.⁹⁸⁴
- Price: the price for the product per pack was set at £8.45.⁹⁸⁵
- Duration, termination and loss minimisation: the Alpharma-IVAX Agreement was specified as being for a term of one year.⁹⁸⁶ However, this was subject to the following:⁹⁸⁷

'Alpharma shall be permitted to terminate this Agreement upon one (1) month's written notice to IVAX upon formation of the Generic Market or upon demise (whether by invalidation, surrender, abandonment or otherwise) of current claim 11 of UK Patent GB 2,297,550 or equivalent

document entitled 'Contract Policy' dated 6 June 2002 (document A 0026, pages 1–3). See also paragraph 3.368.

⁹⁷⁸ Alpharma-IVAX Agreement (document 1806).

⁹⁷⁹ Alpharma-GSK Settlement Agreement (document 0356), clause 2.

⁹⁸⁰ Third Addendum (document 0359).

⁹⁸¹ Alpharma-IVAX Agreement (document 1806), clauses 1.8-1.9 and First Schedule.

⁹⁸² Alpharma-IVAX Agreement (document 1806), clause 1.11.

⁹⁸³ Alpharma-IVAX Agreement (document 1806), clause 5.1.

⁹⁸⁴ Alpharma-IVAX Agreement (document 1806), clause 5.2.

⁹⁸⁵ Alpharma-IVAX Agreement (document 1806), clause 6.1.

⁹⁸⁶ Alpharma-IVAX Agreement (document 1806), clause 11.1.

⁹⁸⁷ Alpharma-IVAX Agreement (document 1806), clause 11.3.

claim. In the event that ALPHARMA terminates its supply agreement with IVAX due to the Market Price (as defined below) of a pack of paroxetine 20mg thirty (30) tablets falling below £8.45 per pack, IVAX will reimburse Alpharma the difference between the Market Price and £8.45 up to a maximum of two hundred thousand pounds sterling (£200,000) per calendar month for a maximum of two (2) calendar months. For the purposes of this clause 11.3 Market Price shall mean the average selling price for the Product in the Territory as determined by calculating the average price for the month following the notice to terminate served by Alpharma upon IVAX calculated for all companies offering such products for sale in the Territory but excluding products sold by SB under the trade mark "SEROXAT".'

6.149 In the context of the termination clause, 'Generic Market' was defined as meaning: '*when a monthly average price for the Product (in thirty (30) tablets) sold by any company in the Territory (not including SB and Alpharma) falls below nine pounds and fifty pence (£9.50) per Pack or when a paroxetine 20 mg product is sold other than under SB's marketing authorisation*'.⁹⁸⁸

G. The restrictive object of the Alpharma-GSK Agreement

6.150 Under the Alpharma-GSK Agreement, GSK made value transfers in return for Alpharma's acceptance of entry restrictions. The CMA finds that the objective aim of the Alpharma-GSK Agreement was to restrict competition, on the following basis:

- Alpharma accepted restrictions on its competitive behaviour;
- GSK made cash payments and other value transfers to Alpharma;
- The objective aim of the value transfers was to induce Alpharma's acceptance of the entry restrictions:
 - under the terms of the Alpharma-GSK Agreement those value transfers were conditional on Alpharma not entering the market independently of GSK during the term of the Alpharma-GSK Agreement; and
 - the decision to make the value transfers cannot be explained on the basis of the stated purposes of the transfers, nor on any basis that

⁹⁸⁸ Alpharma-IVAX Agreement (document 1806), clause 1.5.

was not anti-competitive, which the Parties have suggested or that the CMA can discern.

6.151 These elements are discussed in the section below. Annexes D and H set out and respond to representations in relation to the object of the Alparma-GSK Agreement.

i) *The restrictions accepted by Alparma on its competitive behaviour*

6.152 Alparma accepted an express obligation to refrain from entering the UK paroxetine market independently of GSK.⁹⁸⁹

6.153 That restriction was absolute: it allowed for no competition from Alparma as a supplier of paroxetine sourced independently of GSK, and it extended beyond Alparma to include both: (i) any company that was part of the Alparma group;⁹⁹⁰ and (ii) any other company that sought to licence Alparma's UK MA in order to supply paroxetine in the UK or purchase the Alparma Product to resell within the UK.⁹⁹¹

6.154 The Alparma-GSK Agreement did not resolve the patent dispute between Alparma and GSK. It only deferred it. There was no counterpart to Alparma limiting its conduct in the form of any commitment from GSK that it would refrain from patent infringement proceedings if Alparma entered the UK paroxetine market after the expiry of the Alparma-GSK Agreement. If Alparma sought to enter the market independently of GSK following the expiry of the Alparma-GSK Agreement, it would have continued to face the threat of litigation from GSK. Further, there is no attempt in the Alparma-GSK Agreement to agree to take further steps to resolve the patent issue, or to agree a date from which Alparma could have entered the UK paroxetine market. Instead, the Alparma-GSK Agreement specifically provided that: '*GSK and Alparma reserve all prospective rights and causes of action in respect of Alparma's product that is involved in the Litigation [...].*'⁹⁹²

⁹⁸⁹ Specifically, for the term of the Alparma-IVAX Agreement. See Alparma-GSK Settlement Agreement (document 0356), clause 7(i).

⁹⁹⁰ Alparma-GSK Settlement Agreement (document 0356), clause 7(ii).

⁹⁹¹ Alparma-GSK Settlement Agreement (document 0356), clause 7(iii).

⁹⁹² Alparma-GSK Settlement Agreement (document 0356), clause 9.

ii) The value transferred by GSK to Alparma under the Alparma-GSK Agreement

6.155 In total, under the Alparma-GSK Agreement, GSK agreed to make cash payments and other value transfers to Alparma of £11.8 million over its two year term.⁹⁹³ The value transfers were as follows:

- a 'marketing allowance' payment of £100,000 per month;⁹⁹⁴
- £3 million in respect of Alparma's production and preparation costs for launch in the UK market of paroxetine;⁹⁹⁵
- £500,000 as a contribution towards Alparma's legal costs;⁹⁹⁶
- a value of £500,000 to be achieved through GSK providing access to Alparma to a potential purchase of three products (cardiac, antibiotics, and neuro-muscular blockers), failing which an alternative means of achieving such a transfer of value was to be agreed;⁹⁹⁷ and
- a restricted volume of paroxetine, in relation to which GSK sacrificed its profit margin, and instead transferred this margin to Alparma.⁹⁹⁸ Over the two year term of the Agreement, GSK stood to sacrifice £5.9 million.⁹⁹⁹

6.156 As set out at paragraph 5.11, the CMA finds that the value transfers were made directly from GSK to Alparma, pursuant to the Alparma-GSK

⁹⁹³ This assumes that the Alparma-GSK Agreement was not terminated early. This includes £5.9 million in cash payments for marketing allowances, production and preparation costs, and legal costs (calculated as: 3,000,000 + 500,000 + (100,000 x 24)) and £5.9 million in the form of the transfer of the distribution margin on the restricted volume supplied by GSK (see paragraphs 6.163 and 6.164). The CMA has calculated that the approximate amount GSK in fact sacrificed in making value transfers to Alparma was around £7.2 million in total. (Calculated as: 3,000,000 + 500,000 + (100,000 x 13) + ((500,000/12)*11) x (13.7 - 8.45)), where 13 is the number of months which Alparma received a marketing allowance payment during the term of the Alparma-GSK Agreement, 11 is the number of months which the Alparma-GSK Agreement was in effect prior to generic entry (between December 2002 - November 2003) and £13.70 is the weighted average Seroxat 20mg pack price between January to March 2002.

⁹⁹⁴ See clause 5 of the Alparma-GSK Settlement Agreement, (document 0356).

⁹⁹⁵ See clause 3 of the Alparma-GSK Settlement Agreement, (document 0356).

⁹⁹⁶ See pursuant to Alparma-GSK Settlement Agreement, (document 0356), clause 4.

⁹⁹⁷ Alparma-GSK Settlement Agreement (document 0356), clause 6. The CMA notes that the £500,000 of value, in relation to Alparma's potential purchase of three products from GSK, was not initially transferred to Alparma because no agreement in relation to these products could be reached. However, as described further at paragraph 6.165, it was subsequently agreed (during renegotiation of the deal) that Alparma would receive this value by increasing its annual purchase volumes. This was consistent with clause 6 of the Alparma-GSK Settlement Agreement that should it not be possible to secure the transfer of £500,000 value from GSK to Alparma through the transfer of the products, then an alternative means was to be agreed.

⁹⁹⁸ Alparma-GSK Settlement Agreement (document 0356), clause 6. See also Alparma-IVAX Agreement (document 1806), clauses 5-6.

⁹⁹⁹ See paragraph 6.164 for calculation.

Settlement Agreement,¹⁰⁰⁰ with the following exception. The transfer of a restricted volume of paroxetine was made by GSK to Alparma, indirectly via IVAX pursuant to the IVAX-GSK Agreement and the Alparma-IVAX Agreement.¹⁰⁰¹

iii) *The value transfers were conditional on Alparma agreeing not to enter the UK paroxetine market independently of GSK*

6.157 Under the terms of the Alparma-GSK Agreement the value transfers from GSK to Alparma were each contractually linked to Alparma not entering the UK paroxetine market independently of GSK during the term of the Agreement:¹⁰⁰²

- The transfer of the ‘*marketing allowance*’ was conditional on Alparma not entering the UK paroxetine market independently of GSK for the term of the Alparma-GSK Agreement. This is clear from the Alparma-GSK Settlement Agreement which specified that in the event of a breach of the Alparma-GSK Agreement no further marketing allowance would be payable by GSK to Alparma.¹⁰⁰³ Alparma entering the UK paroxetine market with a product sourced from a company other than GSK would have constituted such a breach.¹⁰⁰⁴
- The transfer of a restricted volume of paroxetine from GSK to Alparma was conditional on Alparma not entering the UK paroxetine market independently of GSK for the term of the Alparma-GSK Agreement. This is clear from the Alparma-GSK Settlement Agreement (see paragraph 6.147) which specified that Alparma must enter into a sub-distribution agreement with IVAX (the Alparma-IVAX Agreement),¹⁰⁰⁵ and that Alparma must not supply any product other than GSK’s for the term of the Alparma-IVAX Agreement.¹⁰⁰⁶ Further the Alparma-GSK Settlement Agreement stated that GSK shall provide IVAX with 500,000 packs of paroxetine to allow IVAX to supply Alparma under the Alparma-IVAX Agreement.¹⁰⁰⁷

¹⁰⁰⁰ Alparma-GSK Settlement Agreement (document 0356), clauses 3–6. See also Alparma-GSK Settlement Agreement (document 0356), clause 2.

¹⁰⁰¹ Third Addendum (document 0359) and the Alparma-IVAX Agreement (document 1806), clauses 5–6. See also Alparma-GSK Settlement Agreement (document 0356), clause 2.

¹⁰⁰² Specifically, for the term of the Alparma-IVAX Agreement.

¹⁰⁰³ See Alparma-GSK Settlement Agreement (document 0356), clause 5.

¹⁰⁰⁴ Specifically, such action by Alparma would have been a breach of clause 7 of the Alparma-GSK Settlement Agreement (document 0356).

¹⁰⁰⁵ Alparma-GSK Settlement Agreement (document 0356), clause 2.

¹⁰⁰⁶ Alparma-GSK Settlement Agreement (document 0356), clause 7.

¹⁰⁰⁷ Alparma-GSK Settlement Agreement (document 0356), clause 2.

- The contribution to legal, production and preparation costs was conditional on Alparma not entering the UK paroxetine market independently of GSK for the term of the Alparma-GSK Agreement. This is clear from the Alparma-GSK Settlement Agreement (see paragraph 6.147) which provided for the payment of the contributions to production and preparation costs¹⁰⁰⁸ and to legal costs,¹⁰⁰⁹ and specified that Alparma must not supply any product other than GSK's.¹⁰¹⁰

iv) GSK's decision to make each of the value transfers to Alparma cannot be explained on the basis of their stated purpose

a) The 'marketing allowance'

6.158 During the period of the Alparma-GSK Agreement, GSK committed to pay Alparma a supposed 'marketing allowance' of £100,000 per month.¹⁰¹¹

6.159 For the reasons set out below, the CMA does not accept that the purpose of the marketing allowance was to fund marketing expenditure carried out by Alparma:

- There was no link between the marketing allowance and the sale of product: GSK made the payments in question irrespective of whether Alparma purchased or sold any paroxetine supplied to it by GSK.¹⁰¹²
- Despite the scale of the marketing allowance that GSK paid to Alparma, GSK has confirmed that it did not monitor or control spending by the Alparma on marketing and promotion.¹⁰¹³

¹⁰⁰⁸ Alparma-GSK Settlement Agreement (document 0356), clause 3.

¹⁰⁰⁹ Alparma-GSK Settlement Agreement (document 0356), clause 4.

¹⁰¹⁰ Alparma-GSK Settlement Agreement (document 0356), clause 7.

¹⁰¹¹ Alparma-GSK Settlement Agreement (document 0356), clause 5.

¹⁰¹² Under clause 5 of the Alparma-GSK Settlement Agreement (document 0356), the allowance was paid for the duration of the Alparma-IVAX Agreement, until the Alparma-IVAX Agreement was terminated or breached. Under clause 5.2 of the Alparma-IVAX Agreement, IVAX agreed to supply Alparma with 500,000 packs pursuant to Alparma purchase orders. However, there was no contractual imperative for Alparma to submit purchase orders. Alparma-IVAX Agreement dated 20 November 2002 (document 1806) contains a number of undertakings (at clause 4) but no contractual obligation concerning Alparma's submission of purchase orders.

¹⁰¹³ See GSK Second Response, Part Two (document 0734), paragraph 10.6.

GSK submitted that it is not reasonable to expect GSK to monitor the use of its marketing expenditure, as GSK was entitled to confine the use of its resources to settling its litigation, which was its overriding aim (GSK SO Written Response (document 2755), paragraph 7.93). The CMA considers that GSK's decision not to monitor the allowance's use is consistent with its purpose being nothing other than to induce Alparma's acceptance of the entry restrictions described above.

- In a meeting with the OFT in December 2011, [GSK's Finance Director A] stated that generic suppliers were not expected to engage in marketing and promotional activity in order to sell generic medicines.¹⁰¹⁴
- Actavis has confirmed that GSK made no attempt to ascertain that Alparma was using the allowance to market generic paroxetine.¹⁰¹⁵
- Alparma had no need to market generic paroxetine as it could rely on the substantial marketing investment made by GSK, as outlined by GSK in the GUK Litigation.¹⁰¹⁶
- Under the terms of the Alparma-GSK Agreement, Alparma was subject to a volume restriction (see paragraph 6.163). Given the resulting limits on Alparma's ability to meet increases in demand, Alparma was not incentivised to spend the marketing allowance on marketing paroxetine.
- In discussions between Alparma and GSK regarding a prospective settlement, GSK is reported as offering a lump sum and/or monthly payment '*which can be turned into either a cross undertaking as part of the settlement or a promotional fee*'. The fact that Alparma considered that this payment could be described in multiple ways, including in ways that did not relate to marketing, also indicates that it was not intended to be used for marketing purposes.

6.160 Moreover, in the economic context of the pharmaceutical sector, the payment of marketing allowances by GSK to Alparma could not in any case have been expected to generate value to GSK, other than as part of an anti-competitive strategy. For example, to the extent that Alparma did use such transfers to market the paroxetine supplied to it by GSK to wholesalers and pharmacies (of which there is no evidence that it did: see paragraph 6.159), the result would have been a decrease in GSK's sales of Seroxat, but no increase to GSK's overall sales of paroxetine (see paragraph 3.57):¹⁰¹⁷

- Alparma would have had little incentive to invest its marketing allowance in marketing to GPs. Such expenditure may have generated more paroxetine prescriptions, but Alparma's ability to generate sales of its own

¹⁰¹⁴ See Note of meeting between the OFT and GSK on 19 December 2011 (document 0688), paragraph 34.

¹⁰¹⁵ Part two of the Actavis response dated 30 April 2012 to the Section 26 Notice dated 23 March 2012 sent to Actavis, added to on 5 April 2012 (document 1539), paragraph 2.10.

¹⁰¹⁶ See exhibit [redacted]6 to [redacted]WS2 (GUK) (document 0887), paragraph 10. See also skeleton argument of claimant (GSK) for the GUK Interim Injunction dated 23 October 2001 (document 0910), recitals 39–40.

¹⁰¹⁷ This is consistent with a statement made by [GSK's independent expert], see footnote 81.

product would have relied on its ability to convince pharmacies to dispense its product rather than GSK's branded Seroxat.

- To the extent that Alparma instead used its marketing allowance to promote sales of its product to wholesalers and pharmacies, this would have had no impact on the overall sales of paroxetine, which would only be increased if more GPs could be persuaded to prescribe it more frequently.
- Marketing to wholesalers/pharmacies would therefore impact only on the proportion of paroxetine that was dispensed as generic paroxetine rather than as branded Seroxat. For example, where a pharmacy receives a prescription for paroxetine, such marketing may in principle make them more likely to dispense paroxetine supplied by Alparma than Seroxat supplied by GSK.
- On that basis, the effect of any marketing by Alparma for paroxetine would be to increase sales of paroxetine supplied by Alparma at the expense of Seroxat supplied by GSK. Rather than generate value to GSK, such marketing would in fact decrease GSK's sales of Seroxat, to its detriment.
- Consistent with this, GSK has confirmed that it did not expect Alparma to market for the benefit of GSK.¹⁰¹⁸

6.161 The CMA also does not accept that the purpose of the marketing allowance was to fund price discounts. Although [GSK's Finance Director A]¹⁰¹⁹ and Actavis¹⁰²⁰ have stated that the marketing allowance could be used for that

¹⁰¹⁸ GSK Second Response, Part Two (document 0734), paragraphs 10.1–10.6.

¹⁰¹⁹ [GSK's Finance Director A] stated that the Generic Companies could use the promotional allowance 'as they saw fit'. See witness statement of [GSK's Finance Director A] dated 1 August 2013 (document A 0059), paragraph 4.5. See also GSK SO Written Response (document 2755), paragraph 6.146, with reference to paragraphs 5.124 and 5.125. In this regard, GSK refers to [IVAX's Commercial Director's] statement that IVAX's finance team allowed him to regard the allowance as lowering the relevant cost of goods sold, the need for IVAX to compete with parallel imports of Seroxat, and to [GSK's Finance Director A's] witness statement as follows: '*I recall [that] the marketing and promotional payments were ultimately for IVAX, and indeed all the Generic Companies, to use as they saw fit. Indeed, once each of the Agreements was reached it was for the Generic Companies to decide what they wanted to use the funds for – whether for example as marketing funds to target particular kinds of pharmacies or as extra margin to allow price discounting*' (paragraph 5.125).

¹⁰²⁰ Actavis stated that it believes that Alparma treated the marketing allowance as a discount to the cost price of the product sourced from GSK (Actavis SO Written Response (document 2754), paragraph 8.6). In this regard, Actavis refers to an email that was requesting a comparison of the profitability of the Alparma-GSK Agreement when compared with sourcing product from Delta, in which the recipient is asked to '*[l]ook at the cost price from Delta vs cost price from GSK with and without the £100k contribution*' (see email chain between [Alparma Ltd's Managing Director], [Alparma Ltd's Marketing Manager], [Alparma's Head of Sales & Marketing] and others dated 23–26 June 2003 (document 1428)).

purpose, there can have been no expectation that the marketing allowance would in practice have been used to fund discounts and/or provide for a lower supply price, as the promotional allowance was a fixed sum that came without any connection to the quantity of paroxetine sold by Alpharma. As a result, once the Agreements were made, those sums were economically indistinguishable from any other cash available to Alpharma. Unlike a lower supply price, the promotional allowance would have had no potential to increase Alpharma's incentives to compete with GSK.¹⁰²¹ Further:

- Under the terms of the Alpharma-GSK Agreement, Alpharma was subject to a volume restriction (see paragraph 6.163). Given the resulting limits on Alpharma's ability to meet increases in demand, Alpharma had no incentive to use the marketing allowance to fund discounts below its supply price.
- Consistent with this, the CMA observes that Alpharma charged prices that were materially above the supply price of £8.45, such that it did not use the marketing allowance to fund discounts below its supply price of £8.45,¹⁰²² and the marketing allowances instead contributed to Alpharma's profits during the period of the Agreement.
- It is evident from Alpharma's negotiation of the Alpharma-GSK Agreement that it assumed that the marketing payments would not be used to fund discounts. For example, Alpharma was assessing the profitability of GSK's offer on the basis that it would be able to price its allocated volume of paroxetine at prevailing market prices (see paragraphs 3.359 and 3.360).
- Had Alpharma used the marketing allowance to fund discounts below its supply price, it would have made less profit from supplying paroxetine than had it made no sales and retained the marketing allowance.¹⁰²³

GSK has also submitted that the promotional allowance could be used either for discounting or for marketing to facilitate Alpharma's ability to compete through non-transparent price competition (GSK SO Written Response (document 2755), paragraphs 7.97–7.98, with reference to [X]WS (document 1587), paragraph 3.14).

¹⁰²¹ The CMA observes that while Alpharma may well have considered the relative profitability of the Alpharma-GSK Agreement by considering what impact the marketing allowance would have on its average supply cost, the marketing allowance cannot therefore have been expected to increase Alpharma's incentives to market its restricted product volumes at a lower price. This is consistent with the witness evidence of [Alpharma Ltd's Director of Sales and Marketing], who thought that the marketing allowance was '*just added to the Profit and Loss account as a contribution to the bottom line*': witness statement of [Alpharma Ltd's Director of Sales and Marketing], signed on 27 August 2014 (document 3232), paragraph 8.5 and also with Alpharma's decision not to use the marketing allowance to fund market prices that were below the supply price of £8.45.

¹⁰²² In particular, Alpharma's weighted average selling price for paroxetine 20mg was £12.30 per pack between February 2003 and November 2003.

¹⁰²³ For example, for each unit of product that was sold below the supply price of £8.45, an incremental loss would be suffered and less of the marketing allowance would be retained. In such a scenario, paroxetine profits would be higher if no further sales were made and the marketing allowance was retained.

6.162 On the basis of the evidence analysed above, the CMA finds that the objective aim of the marketing allowance could not have been to fund marketing to be carried out by AlphaPharma, or to fund discounts to its resale price. There were no legitimate benefits to GSK of transferring the marketing allowance to AlphaPharma, and AlphaPharma had no reason to use the marketing allowances for marketing or for discounting. AlphaPharma accepted the marketing payments as one of the value transfers it received in return its acceptance of the entry restrictions described above.

b) *The effective transfer from GSK of profit margins by means of agreements permitting supply by AlphaPharma of restricted volumes of product to the market in place of GSK*

6.163 The arrangement permitting AlphaPharma to supply a limited volume of GSK's product, giving AlphaPharma a predictable margin, also falls to be regarded as a form of value transfer.¹⁰²⁴ This arrangement, in the relevant commercial context, was not a normal supply agreement, intended to bring about legitimate benefits to GSK (for example, lower distribution costs or an increase in the number of customers that could be supplied). The distribution margin earned by AlphaPharma on the restricted volume of product was, in reality, a mechanism for achieving a value transfer from GSK to AlphaPharma. As described in detail below, the CMA considers that this value transfer was made in return for the restrictions.¹⁰²⁵

6.164 This transfer of a restricted volume of paroxetine amounted to a 'value transfer' because, as a consequence of the volume restriction (and the impact

¹⁰²⁴ Whilst the product transfer clause was set out in the AlphaPharma-IVAX Agreement (document 1806), clause 5, the CMA finds that this value transfer was made indirectly from GSK to AlphaPharma (via IVAX, pursuant to the IVAX-GSK Agreement and the AlphaPharma-IVAX Agreement) (see paragraph 6.164).

¹⁰²⁵ It is evident that the volume restriction did in fact bind AlphaPharma's sales volumes. For example, in an email from [AlphaPharma Ltd's Managing Director] to [AlphaPharma's Distribution Manager] dated 20 May 2005, [AlphaPharma Ltd's Managing Director] states: '*Paroxetine, we won't get any more at this stage – GSK are 'quite happy' with limiting the market – but we should be getting our agreed share*'. In a subsequent email in the same email chain, [AlphaPharma Ltd's Managing Director] states: '*Paroxetine – we could sell double the monthly allowance we have from IVAX/GSK*' (see internal AlphaPharma email chain between [AlphaPharma Ltd's Managing Director], [AlphaPharma Ltd's Marketing Manager], [AlphaPharma's Distribution Manager], [AlphaPharma's Product Sourcing Manager], [a Third Party Planner of AlphaPharma], [AlphaPharma's Finance Director] and [AlphaPharma's Sales Support Supervisor] dated 20–22 May 2003 (document 1424). In an email from [AlphaPharma Ltd's Managing Director] to [AlphaPharma Ltd's Marketing Manager] (and others) dated 25 June 2003 (document 1428), [AlphaPharma Ltd's Managing Director] requested that [AlphaPharma Ltd's Marketing Manager] considered what volumes AlphaPharma could supply under an agreement with Delta rather than with GSK and '*if not restricted*'. Furthermore, the relevant sales data demonstrates that the volume restriction did constrain the purchases that AlphaPharma could make from GSK (see paragraph 7.80–7.82). See also the email from [AlphaPharma Ltd's Director of Sales and Marketing] to [AlphaPharma ApS's Sales and Marketing Director] and others dated 14 October 2002 (document 1361), in which [AlphaPharma Ltd's Director of Sales and Marketing] refers to an '*Annual supply quota of 500000 packs of 20mg*' (emphasis added). It is also relevant that the same volume limitations were also included in GSK's Agreements with each of IVAX and GUK, and in those cases the evidence likewise demonstrates the relevant clauses represented volume restrictions (see paragraphs 6.103 to 6.110 (GUK) and B.69–B.79 (IVAX)).

this would have on prevailing prices in the market), GSK was, in practice, simply transferring to Alharma the margin that it would have otherwise earned on such volumes. In the same way as a payment, GSK was able to use this mechanism to make a transfer to Alharma through a means that would not result in a meaningful increase in the price competition it was facing on the market:

- As set out in further detail in paragraph 6.167, GSK was already able to distribute the product throughout the UK, and the Alharma-GSK Agreement did not provide for any opportunities to increase supply or to lower its distribution costs.
- As such, in committing to transfer a restricted volume of paroxetine from GSK to Alharma, GSK committed to sacrifice a profit margin on the sales of the product transferred from GSK to Alharma of £5.9 million (based on the sales that Alharma made being at the expense of product sold by GSK UK).¹⁰²⁶
- For Alharma, the returns associated with this value transfer could be forecast with near certainty because, as a consequence of the volume restriction, Alharma would have no incentive to set a price that was materially below prevailing levels.¹⁰²⁷ That is because if Alharma had adopted price levels that were materially below the market level, the volume restriction would have left it unable to satisfy the resulting increase in demand. Alharma could therefore be expected to price at prevailing market levels, and to earn the resulting margin across the maximum 500,000 packs of paroxetine per year that GSK agreed to transfer to Alharma in the first year of the Alharma-GSK Agreement and across the maximum 620,000 packs of paroxetine per year that GSK agreed to transfer to Alharma in the second year of the Agreement (see paragraphs 3.368 to 3.374).

¹⁰²⁶ Calculated as: $(500,000+620,000) \times (13.7 - 8.45)$, where the £13.70 is the weighted average Seroxat 20mg pack price between January to March 2002. This assumes that the Agreement would not be terminated early. The CMA considers that sales by Alharma substituted for GSK's own sales in the UK rather than for sales by parallel importers, because, as set out in Part 2, Section G, parallel import sales were minimal by January 2003, and Alharma did not begin supplying paroxetine pursuant to the Alharma-GSK Agreement until February 2003.

¹⁰²⁷ Consistent with this, in his Witness Statement [Alharma ApS's Sales and Marketing Director] noted that: *'Being supplied with a fixed, limited, volume of stock of 500,000 packs would have affected Alharma's incentives to discount the GSK-sourced product or the retail price. For some UK customers, to win business you would have to offer a very low price. Clearly, given that only a limited supply of product was available, Alharma was not in a position to compete for these customers, as GSK would have known well. It therefore would have been better from GSK's perspective to pay a higher lump sum to Alharma to cover all of Alharma's upfront costs, and effectively buy off some of our risk, rather than supplying more packs to Alharma'* ([§]WS (document 3172), paragraph 8.14).

- Consistent with this, Alparma's entry onto the market had no discernible impact on market prices (see paragraph 3.387). Further, when assessing the expected profitability of the Alparma-GSK Agreement, Alparma assumed that it would be able to maintain prices at prevailing market levels.

6.165 The use of product as a value transfer was further illustrated by the decision by Alparma to accept an increase in its purchase volume allowance in relation to clause 2 of the Alparma-GSK Agreement. Clause 6 obliged GSK to provide Alparma with product rights that were worth at least £500,000 or, if this value was not realised by Alparma purchasing suitable products from GSK, then '*an alternative means to achieve such a transfer shall be agreed*'.¹⁰²⁸ Alparma declined to purchase the product rights offered by GSK, and it was agreed that the '*alternative means*' to achieve the transfer of £500,000 transfers would be an increase in the annual purchase volumes that Alparma would be allowed to make from GSK, and the associated profit margin.¹⁰²⁹ The fact that Alparma and GSK treated the transfer of additional purchase volumes as extinguishing the outstanding £500,000 value owed by GSK demonstrates very clearly that both perceived the transfer of restricted volumes of paroxetine product to be a form of value transfer.¹⁰³⁰

6.166 Furthermore, an internal email from [Alparma ApS's Sales and Marketing Director] to [Alparma Ltd's Director of Sales and Marketing], [Alparma ApS's patent attorney] and others dated 24 October 2002 confirms the 'value' that Alparma considered that it would receive as a consequence of the transfer of a restricted volume of product:¹⁰³¹

'1. [...].

2. *An MA for the "2nd image" of the GSK product (ie. a version without GSK imprints on tablet etc.). GSK will supply bulk for IVAX to pack in Alparma packs. Launch around December 1st, 2002. **They will be ready to offer 500,000 packs of the 20 mg 30 tabs pack at a transfer price of £8.45. The value of this offer is app. £2.5 m on a 12 month basis. We will receive profit compensation for any delays***

¹⁰²⁸ See Alparma-GSK Settlement Agreement (document 0356), clause 6.

¹⁰²⁹ Specifically, it was agreed on 14 November 2003 that, to achieve the £500,000 value transfer articulated at clause 6, Alparma would be allowed to purchase 120,000 more packs, bringing the total to 620,000 (see Alparma-GSK Settlement Agreement amendment dated 14 November 2003 (document 0441)).

¹⁰³⁰ It is also noted that Alparma's acceptance of 120,000 packs of paroxetine (in place of the £500,000 it was otherwise due) suggests that it considers that it could earn a margin of over £4 on each pack sold. Such margins would necessitate Alparma remaining able to sell paroxetine at prevailing market prices.

¹⁰³¹ Email from [Alparma ApS's Sales and Marketing Director] to [Alparma Ltd's Director of Sales and Marketing] and others entitled 'Quick note on UK settlement for Paroxetine – meeting October 23 2002' dated 24 October 2002 (document 1364).

after December 1st, as time is short for artwork, packing, logistics etc.'
(emphasis added)

6.167 The transfer of a restricted volume of paroxetine could not have been expected to generate legitimate benefits for GSK:

- At the time the Alharma-GSK Agreement was entered into, GSK was already able to distribute its products (including Seroxat) throughout the UK. The additional sub-distribution agreement with Alharma therefore did not provide for opportunities to increase supply or to lower GSK's distribution costs.¹⁰³²
- any strategy aimed at increasing the supply of paroxetine was reliant on persuading GPs to issue more prescriptions for paroxetine, and could not be achieved by entering into a supply agreement with Alharma; and
- consistent with this, it is clear that, by imposing volume restrictions on the purchases that Alharma could make from GSK, the intention was not to encourage the development of a supply channel involving Alharma.

6.168 Consistent with the analysis outlined above, and contrary to the Parties' submissions that the Alharma-GSK Agreement accelerated generic entry and contributed to price declines,¹⁰³³ the CMA observes that the volume restriction was in practice effective in constraining Alharma's market share (see paragraphs 7.80 to 7.82). Further, the transfer of a restricted volume of paroxetine did in practice provide for a means to remunerate Alharma that did not result in an increase in the competitive constraints faced by GSK and a material decrease in paroxetine prices to pharmacies following Alharma's market entry with GSK product (see paragraph 3.387).

6.169 Alharma's internal documents support the findings outlined above, and indicate that the transfer of a restricted volume of paroxetine was an element of the compensation that Alharma received in return for its acceptance of the entry restrictions, and that Alharma anticipated that it would earn margins consistent with prevailing price levels:

¹⁰³² GSK documents that discuss entry into sub-distribution agreements make no reference to efficiencies or gains to be made through increased distribution, but rather, focus on the need to protect GSK's price and patent position. See, for example, GSK presentation entitled 'Seroxat Patent Challenge' by [GSK's Finance Director A] and [GSK's Head of Regulatory Affairs] dated 5 February 2001 (document 0123), and [redacted] WS2 (GUK) (document 0182) / [redacted] WS2 (Alharma) (document 0289).

¹⁰³³ Actavis SO Written Response (document 2754), paragraphs 1.47, 4.14 and 11.1, Xellia-Zoetis Response dated 7 August 2013 to the SO ('Xellia-Zoetis SO Written Response') (document 2767), paragraph 269, GSK SO Written Response (document 2755), page 142, paragraphs 4.6, 4.15, page 158, paragraphs 6.111, 6.119, page 257 summary box and paragraph 8.58.

- As can be seen from the emails set out at paragraphs 3.359 and 3.360, Alparma was aware that its sales of paroxetine would give it a fixed sum, which, together with the '*lump sum[s]*' constituted its compensation for agreeing to stay out of the UK paroxetine market.
- The value transfer which was achieved through the transfer of the capped volumes at a fixed transfer price was an additional value transfer made in return for Alparma entering into an Agreement that included the restrictions described above. This is illustrated in paragraph 6.165, which describes how GSK's obligation to ensure a value transfer of at least £500,000 to Alparma was extinguished in return for an increase in the volume cap (from 500,000 packs per year to 620,000 packs per year).

6.170 The CMA has considered GSK's submission that the above analysis would imply that any supply agreement would involve a value transfer.¹⁰³⁴ The CMA considers that a key distinction between the Alparma-GSK Agreement and a potentially pro-competitive supply agreement is the volume restriction (confining supply to a limited amount of product) within the economic context of the present case, specifically where (a) GSK was already in a position to distribute the product throughout the UK, (b) there were no legitimate economic advantages to GSK from the arrangement, and (c) there were no incentives on Alparma to compete on price or otherwise to do more than substitute, to the extent permitted, for sales by GSK. For the reasons outlined above, the volume restriction ensured that in this context the transfer of GSK's product was essentially the same as a cash payment from GSK to Alparma, in that it provided a means by which GSK could transfer value to Alparma, but without providing for meaningful increases in the actual competitive constraints that GSK faced in the relevant market.

6.171 In contrast, had the Alparma-GSK Agreement not included the volume restriction, Alparma would have had some scope to choose how much paroxetine to purchase and sell in order to maximise its profits and would have had an increased incentive to compete on price to do so. Under such a scenario, it would have been open to Alparma to offer price decreases as a means of increasing its sales to maximise its profits, and the returns it would earn would be a function of how effectively it competed with GSK. In such a scenario, the losses suffered by GSK could have been far greater than the losses it made by transferring a restricted volume of product to Alparma as: (i) additional supplies to Alparma would have resulted in further margin losses on those sales; and (ii) the resulting competition would have been

¹⁰³⁴ GSK SO Written Response (document 2755), paragraph 7.124.

expected to result in materially lower prices (and profit margins) on those sales that GSK did retain. Under such a scenario, the margin would not simply be transferred from GSK to Alparma. Rather, GSK would have been expected to suffer sales losses and margin decreases that would have been associated with more effective competition and lower prices, and purchasing wholesalers and pharmacies would have benefited from more effective competition and the material price decreases that would have been expected to follow. The associated returns generated by Alparma would have been derived from its efforts to compete meaningfully on the market (albeit with GSK product) without the constraint of restricted volumes.

c) Contributions to legal, production and preparation costs

6.172 Under clause 3 of the Alparma-GSK Settlement Agreement, GSK agreed to pay ‘£3,000,000 (three million pounds) in respect of the production and preparation costs for launch in the UK market by Alparma of paroxetine hydrochloride anhydrate’ and under clause 4, GSK agreed to ‘contribute £500,000 (five hundred thousand pounds) towards Alparma’s legal costs incurred in the above litigation’.¹⁰³⁵

6.173 From GSK’s perspective, it is apparent that there were no legitimate benefits to GSK of paying for the legal, production and preparation costs that Alparma had incurred:

- Given that the payments represented compensation for costs that had already been incurred by Alparma, it is implausible that it could otherwise generate value to GSK, either by generating higher revenues or providing for lower costs.
- Given that such payments were otherwise incapable of generating value to GSK, the only plausible rationale for the transfer of such significant sums is that they were made in return for Alparma’s acceptance of the restrictions described above.
- For the reasons outlined at paragraphs 6.191 to 6.196, the CMA does not accept that these payments can be explained by GSK’s desire to avoid the exposure to damages that it faced as a consequence of the cross-undertaking in damages.

¹⁰³⁵ Alparma-GSK Settlement Agreement (document 0356), clauses 3 and 4.

6.174 From Alharma's perspective, the payments were an element of the compensation that Alharma received in return for its acceptance of the entry restrictions.

v) ***The overall level of the value transfers cannot be explained on any other commercial basis that was not anti-competitive, and the value transfers were commercially rational for GSK only on the basis that they would induce Alharma's acceptance of entry restrictions and delay its potential independent market entry***

6.175 There are no other bases (which the Parties have suggested in response to the Investigation, or otherwise that the CMA can discern) on which the Alharma-GSK Agreement could legitimately have involved value transfers totalling £11.8 million from a market incumbent to a potential competitor.

6.176 As set out below, the CMA finds that the avoidance of costs associated with the litigation (including both the costs of the litigation itself and those relating to the settlement of the cross-undertaking in damages that existed in relation to the injunction that was in place pending the litigations outcome) cannot plausibly explain the level of value transfers made by GSK under the terms of the Alharma-GSK Agreement.

6.177 From GSK's perspective, its decision to make value transfers totalling £11.8 million can only be explained by its desire to induce Alharma's acceptance of the entry restrictions and to delay its potential independent generic entry. In carrying out this assessment, it is important to recall, in particular, that:

- because the Alharma-GSK Agreement deferred rather than resolved the underlying questions of patent validity and infringement, the value transfers that GSK made during the term of the Alharma-GSK Agreement did not enable GSK to avoid the costs associated with their litigation, but only to defer them. Although the conduct and outcomes of future litigation could not be forecast with certainty, the two year Alharma-GSK Agreement left the contested issues unresolved and this meant that the costs and damages exposure associated with their litigation would either be deferred to subsequent litigation during the term of those Agreements or, failing that, would be deferred to subsequent litigation with Alharma. In order to avoid those costs, GSK and Alharma would have needed to enter into a subsequent agreement, for a duration as long as the patents under dispute, but their avoidance would not be achieved by the Alharma-GSK Agreement and the value transfers it included.
- GSK has not submitted that its decision to commit to the value transfers can, objectively, be explained solely by a desire to avoid the costs and

exposure relevant to the Alparma Litigation. For example, in its representations, GSK stated that its *'rationale for settlement of the Patent Disputes was in each instance essentially the defence of its valid patent rights and their commercial value (the status quo), and for this it was prepared to compromise based on its assessment of an uncertain litigation outcome. Each Generic Company sought early entry to the UK market for a paroxetine product and each had its own particular conditions for compromise which had to be accommodated to resolve the Patent Disputes.'*¹⁰³⁶

6.178 From Alparma's perspective, its actions demonstrate that it had determined the value transfers would provide it with sufficient compensation for its acceptance of the entry restrictions. It can be inferred that Alparma considered that the Alparma-GSK Agreement provided it with expected returns¹⁰³⁷ that were higher than those associated with continuing with its efforts to enter the market independently of GSK. As outlined above, each of the value transfers was not for its stated purpose. As outlined below, the CMA does not consider that Alparma's acceptance of the value transfers can be explained by the cross-undertaking in damages.

a) *The value transfers cannot be explained by the avoidance of the costs and disruption of litigation*

6.179 GSK submitted that its expected litigation put *'the sums paid under the settlements into proportion'*.¹⁰³⁸ In the context of the Alparma-GSK Agreement, GSK has estimated that it would have incurred further litigation costs of £1.7 million had it pursued litigation in response to Alparma's potential independent market entry.¹⁰³⁹

6.180 The CMA notes that, even on the basis of GSK's own estimate, the £11.8 million that GSK committed to transfer to Alparma was significantly more than the estimated further legal costs of £1.7 million, such that avoiding those costs cannot explain the value transfers that GSK made to Alparma. Moreover, at the time the Alparma-GSK Agreement was entered into, GSK had already committed to make value transfers to IVAX and GUK totalling at

¹⁰³⁶ GSK SO Written Response (document 2755), paragraph 4.26.

¹⁰³⁷ Alparma's 'expected returns' would represent the average of the profits associated with the potential outcomes of its entry strategy (for example, the revenue and costs associated with each outcome relevant to its strategy (such as winning or losing any litigation, and the possible timing of its entry), and the probability of each outcome.

¹⁰³⁸ GSK Second Response, Part Two (document 0734), paragraph 5.3(b).

¹⁰³⁹ GSK Second Response, Part Two (document 0734), paragraphs 5.1–5.16.

least £39.2 million,¹⁰⁴⁰ which meant that on entering into the Alphanma-GSK Agreement, GSK had agreed to make value transfers to IVAX, GUK and Alphanma totalling at least £50.9 million,¹⁰⁴¹ compared to the £5.75 million of litigation costs that GSK submitted were avoided by entering into those Agreements.¹⁰⁴²

6.181 Further, the litigation costs estimated by GSK are a significant overstatement of the litigation costs that GSK avoided by entering into the Alphanma-GSK Agreement.

6.182 First, the CMA emphasises that the Alphanma-GSK Agreement did not relieve GSK of the burden of litigating the patent issues, because the Alphanma-GSK Agreement could not and did not prevent other generic suppliers from litigating against them in the future; nor did GSK even resolve its dispute with Alphanma by, for example, committing not to contest Alphanma's independent generic entry at a specified future date. The estimated litigation costs were not avoided as a consequence of the Alphanma-GSK Agreement, but merely deferred (see also paragraph 6.177).

6.183 Second, although GSK was committed to making value transfers totalling at least £50.9 million on entering into the Alphanma-GSK Agreement (and having already entered into the IVAX-GSK and GUK-GSK Agreements), the litigation costs that it deferred were unlikely to include all of the costs that GSK has estimated that it would have incurred in relation to the Alphanma, GUK and IVAX disputes. This is because, as was ultimately the case following GSK's dispute with Apotex, one concluded case was likely to have provided clarity as to whether and on what terms generic entry was possible without infringing valid patent claims, and had the potential to prompt the widespread generic entry that would have disincentivised GSK from pursuing further litigation.¹⁰⁴³

¹⁰⁴⁰ See paragraph 6.116 for the relevant calculation.

¹⁰⁴¹ See paragraph B.47 for a breakdown of value transfers between the Generic Companies, and for calculations.

¹⁰⁴² GSK Second Response, Part Two (document 0734), paragraphs 5.1–5.16.

¹⁰⁴³ Although a judgment may have related only to whether Alphanma's product infringed valid patent claims, a judgment in Alphanma's favour was likely to prompt further entry and to substantially limit GSK's incentive to pursue further litigation. For example, Alphanma sub-licensed the Alphanma Product from Medis, so were this product found to be non-infringing, at least Alphanma and [§<] would be able to enter the market. Their independent generic entry would have been expected to result in the substantial price declines that GSK was seeking to avoid by pursuing litigation, limiting GSK's incentive to pursue further litigation in response to further entry. Other generic suppliers would also have been more likely to enter 'at risk', particularly if the decision was taken that the risks and exposure to damages had been reduced by the favourable judgment and subsequent entry (indeed Actavis stated it was the level of risk and exposure to damages which was the key consideration for Alphanma in determining whether to launch (Actavis SO Written Response (document 2754), paragraphs 10.20–10.23)). Conversely, had GSK prevailed in litigation, this had the potential to disincentivise other generic companies from pursuing independent entry. This is consistent with the views of [GSK's Finance Director A], who explained that: *'[t]he market could continue as it was if GSK won litigation but if it lost the patent then everything*

- 6.184 Had GSK been confident in its patent position, as it submitted to the CMA during the Investigation, it would have expected to prevail before the Courts and recover at least a significant proportion of its litigation costs. Although it would also have had to take into account the (*ex hypothesi* lower) risk of being unsuccessful and paying a proportion of Alpharma's litigation costs, the net effect of the English rule¹⁰⁴⁴ on costs should have been to reduce GSK's expected litigation costs if it had been confident in its case.
- 6.185 GSK also submitted, in general terms, that *'[l]itigation is a burden to the business in terms of costs and a distraction of management and scientists' time from the daily running of the business'*.¹⁰⁴⁵ GSK stated that as well as direct costs, litigation also diverts scientist, patent attorney and management time which can be disruptive to the business, and that GSK *'needs to focus its resources on its business operations'* in determining its approach.¹⁰⁴⁶ GSK has explained that *'[i]t is impossible to quantify in verifiable figures the huge diversion in management time and the general disruptiveness of litigation to the company as a whole'*.¹⁰⁴⁷
- 6.186 There is no indication from the contemporaneous evidence that this general assertion was a relevant factor in GSK's decision-making at the time of entering into the Agreements, or that it could plausibly explain the value transfers.
- 6.187 To the contrary, in those documents that explain GSK's rationale, the focus is on preventing true generic competition (see, for example, paragraphs 6.197 to 6.198). In his explanations of the rationale for the Agreements, [GSK's Finance Director A] did not mention that an assessment of these factors was made, nor that GSK considered that, having quantified them, such factors justified a commitment to make value transfers totalling at least £50.9 million.
- 6.188 Further, at the time when GSK entered into the Alpharma-GSK Agreement, the litigation had already progressed such that the necessary submissions, experiments and testing would have been largely complete (see paragraphs

would go. There would be intense competition from the generics in the near future. GSK therefore decided, to provide for some period of certainty, to enter into supply agreements.' (Note of meeting between the OFT and GSK dated 19 December 2011 (document 0688), paragraphs 18 and 20). Similarly, a note in which IVAX considered its options for the launch of paroxetine, dated 14 March 2001, states that one benefit of entering into an agreement along the lines of the IVAX-GSK Agreement is that *'every one [sic] else has to start again'*. In contrast if it did choose to test the patent *'[p]rinciples will be established for all'*. ('Seroxat (paroxetine): 14th March 2001' dated 14 March 2001 (document 1699)).

¹⁰⁴⁴ Under the English rule, the law which governs the allocation of court costs and attorney fees, the losing party in litigation bears the costs of both parties.

¹⁰⁴⁵ GSK Second Response, Part Two (document 0734), paragraph 8.1(d).

¹⁰⁴⁶ GSK Second Response, Part Two (document 0734), paragraph 8.10.

¹⁰⁴⁷ GSK Second Response, Part Two (document 0734), paragraph 5.4.

3.326 to 3.354 and 3.363). Those were to that extent sunk costs which could not be avoided by the Alharma-GSK Agreement.

6.189 In any case, as with the litigation costs themselves, any 'disruption' was not avoided by the Alharma-GSK Agreement, but simply deferred until the fundamental issues concerning GSK's patent position became the subject of subsequent litigation.

6.190 The cost and disruption of prospective litigation cannot therefore explain GSK's decision to commit to making value transfers to Alharma of £11.8 million, or more generally its decision to make value transfers totalling at least £50.9 million to the Generic Companies.

b) *The value transfers cannot be explained by the cross-undertaking in damages*

6.191 Actavis submitted that at the time of the negotiations, both Alharma and GSK understood the value to Alharma of the cross-undertaking in damages, and the associated exposure faced by GSK.¹⁰⁴⁸ Actavis submitted that the amounts paid to Alharma reflected Alharma's costs, and did not reflect the lost profits Alharma suffered or indeed the lost profits that GSK would have suffered if Alharma had been in a position to launch.¹⁰⁴⁹ Actavis submitted that Alharma would have been entitled to recover damages pursuant to the cross-undertaking given by GSK,¹⁰⁵⁰ including lost profits on sales it would have made during the period of the cross-undertaking, the costs associated with the product Alharma had purchased from Delta but could no longer sell and its litigation costs.¹⁰⁵¹ Actavis submitted that this analysis is consistent with the document cited at paragraph 3.359, which includes [Alharma ApS's Sales and Marketing Director]'s statement that *GSK 'will offer a lump sum and/or monthly payment which can be turned into either a cross undertaking as part of the settlement or a promotional fee'*.¹⁰⁵² Actavis submitted that had Alharma won at first instance, there is good reason to believe that GSK would have appealed and that the cross-undertaking (and the associated period relevant to a damages claim) would have continued.¹⁰⁵³

¹⁰⁴⁸ Actavis SO Written Response (document 2754), paragraphs 4.4 and 8.13–8.17. See also Actavis written response dated 25 November 2014 to the SSO (document 3653), paragraphs 3.8 and 3.10.

¹⁰⁴⁹ Actavis SO Written Response (document 2754), paragraphs 4.5–4.12.

¹⁰⁵⁰ Actavis SO Written Response (document 2754), paragraph 4.21. See also Actavis written response dated 25 November 2014 to the SSO (document 3653), paragraph 3.9.

¹⁰⁵¹ Actavis written response dated 25 November 2014 to the SSO (document 3653), paragraph 3.9.

¹⁰⁵² Actavis SO Written Response (document 2754), paragraph 4.22.

¹⁰⁵³ Actavis SO Written Response (document 2754), paragraph 8.16.

6.192 In addition Xellia-Zoetis¹⁰⁵⁴ and Actavis submitted that the payments were guaranteed compensation for damages that Alpharma had already suffered. Xellia-Zoetis submitted that the payments were in return for Alpharma giving up its right to pursue GSK's cross-undertaking in damages for the period 1 August 2002 to the date of the Settlement,¹⁰⁵⁵ and that the ongoing payments included within the Alpharma-GSK Agreement were simply structured in a manner that was efficient for Alpharma's finances.¹⁰⁵⁶ Xellia-Zoetis and Actavis refer to the £500k legal costs transfers as reimbursement of the litigation costs that had been billed by Alpharma's advisors by the date of the Agreement (which were £498k),¹⁰⁵⁷ and that the payment of £3 million in relation to production and preparation costs reflected the orders of £3.5 million that Alpharma had placed with Delta.¹⁰⁵⁸

6.193 The CMA does not accept that these payments, or the overall value transfers more generally, can be explained by GSK's desire to avoid a potential exposure to damages under the cross-undertaking.

6.194 First, the proposition that the value transfers were attributable to the extinguishment of GSK's liability under the cross-undertaking is not supported by the terms of the Alpharma-GSK Agreement, by the contemporaneous documents, nor GSK's submissions in the Investigation:

- The Alpharma-GSK Agreement included value transfers (in particular the marketing allowance) that were conditional on Alpharma's ongoing commitment to refrain from entering the market with generic paroxetine over a period of two years (and potentially longer had the Alpharma-GSK Agreement been extended again), as set out in paragraph 6.157.
- At the time of the extension of the Alpharma-GSK Agreement, the cross-undertaking was no longer a relevant consideration, yet the extended Alpharma-GSK Agreement nevertheless incorporated the continued payment of the marketing allowance, and the value transfer through a restricted volume of paroxetine, in return for Alpharma's agreement not to seek to enter the market. Self-evidently, the cross-undertaking cannot therefore explain these value transfers.

¹⁰⁵⁴ Xellia-Zoetis SO Written Response (document 2767), paragraphs 83 and 87.

¹⁰⁵⁵ Slides for Xellia-Zoetis SO Oral Hearing (Session 1) dated 22 October 2013 (document 2994A), slide 21.

¹⁰⁵⁶ Xellia-Zoetis SO Written Response (document 2767), paragraphs 85 and 90. Xellia-Zoetis written response dated 18 November 2014 to the SSO (document 3604), paragraph 10.

¹⁰⁵⁷ Actavis SO Written Response (document 2754), paragraph 8.4, Xellia-Zoetis Written SSO Response (document 3604) paragraphs 84 and 9.

¹⁰⁵⁸ Actavis SO Written Response (document 2754), paragraph 8.2, Xellia-Zoetis SO Written Response (document 2767), paragraph 82.

- Given the shelf-life of Seroxat and generic paroxetine, there would have been no reason for Alharma to seek, or GSK to pay, damages in relation to Alharma's stock costs. At the time of the negotiations, Alharma had determined that its product had a shelf-life of two years, such that it could still have been used following the anticipated period of the cross-undertaking, and for a considerable period thereafter.¹⁰⁵⁹
- Consistent with this, it is apparent that the £3.5 million assigned to legal, production and preparation costs was a sum that was not in practice determined by reference to the cross-undertaking in damages or any costs that Alharma could have sought to recover on the basis of it. In an email from [Alharma ApS's Sales and Marketing Director] to [Alharma Ltd's Director of Sales and Marketing] and others dated 24 October 2002, which discusses the proposed terms of the Alharma-GSK Agreement, the payment of £3.5 million from GSK to Alharma is referred to as being for '*other*' and it is stated that '*[f]or this amount we need input from Finance on ideal timing, so we can try to phrase the contract accordingly*'.¹⁰⁶⁰
- The fact that the ongoing payment of value transfers was conditional on Alharma's future conduct also demonstrates that the payments were not, as Xellia-Zoetis submitted, simply paid over time because it was '*efficient*' for Alharma's finances to structure payments in this way.
- In relation to the document cited by Actavis in paragraph 6.191, the CMA observes that the document refers to various possibilities concerning the treatment of the '*lump sum and/or monthly payment*' that GSK would offer, including that it could either be '*turned into either a cross undertaking as part of the settlement or a promotional fee*'.¹⁰⁶¹ The CMA considers that the fact that Alharma considered that the payment could be described in multiple ways indicates that the sum was in practice for none of the possible purposes referred to, and was in practice a means of transferring value to Alharma to induce it to accept the entry restrictions included in the Alharma-GSK Agreement. In any case, as outlined above, the value

¹⁰⁵⁹ The email from [Alharma Ltd's Marketing Manager] to [an Alharma employee] (and others) dated 24 April 2002 (document 1308) and Alharma spreadsheet entitled 'Opening order quantities of Paroxetine' (document 1348), tab 1 both confirm that the shelf life of Alharma's generic paroxetine product was 24 months. Consistent with this, an email from [Alharma's Finance Director] to [Alharma's Financial Controller] dated 5 February 2004 (document A 0054) observes that the generic paroxetine stock that Alharma had purchased in 2002 could be used for supply in 2004.

¹⁰⁶⁰ Email from [Alharma ApS's Sales and Marketing Director] to [Alharma Ltd's Director of Sales and Marketing] and others dated 24 October 2002, (document 1364).

¹⁰⁶¹ Email chain between [Alharma Ltd's Director of Sales and Marketing], [Alharma ApS's Sales and Marketing Director], [Alharma Inc's Vice President of Intellectual Property], [Alharma Inc's President (Human Generics)], [Alharma ApS's patent attorney], [VP New Products – FP at Alharma ApS], [Alharma Inc's Chief Financial Officer] and [Alharma Inc's Chief Legal Officer] dated 11–14 October 2002 (document 1361).

transfers in the Alpharma-GSK Agreement were not made by reference to the cross-undertaking, and the Alpharma-GSK Agreement instead made reference to '*marketing allowances*' that were contingent on Alpharma deferring its efforts to enter the market independently of GSK.

- GSK has not suggested that the cross-undertaking can explain the level of value transfers it made to Alpharma or to the Generic Companies more generally. GSK submitted that the promotional allowances were part of its ongoing supply arrangements with Alpharma, and that it was open to Alpharma (and IVAX and GUK) to use such payments to fund discounts below the supply price of £8.45 (see paragraph 6.161). Moreover, GSK submitted that its '*confidence in the validity of its patents at the time was strong*',¹⁰⁶² on which basis it would have considered there was a small chance of it being ordered to pay damages to Alpharma and no reason to pay to Alpharma a substantial proportion of Alpharma's possible claim.

6.195 Second, the CMA does not consider that GSK's exposure to a damages claim is in any case capable of explaining the value transfers it committed to make to Alpharma:

- Although the Alpharma-GSK Agreement did extinguish GSK's liability in relation to the litigation that existed at the time, the Alpharma-GSK Agreement only deferred litigation of the contested issues, and the associated costs (see paragraph 6.177).¹⁰⁶³ By way of illustration, had Alpharma sought to enter the market after the initial 12 month term of the Alpharma-GSK Agreement, GSK was highly likely to commence litigation again and to have faced again the damages associated with a cross-undertaking or injunction.¹⁰⁶⁴ Because a cross-undertaking related to potential damages suffered by Alpharma during the period between the date of an undertaking and the date of the associated judgment, the damages exposure associated with a cross-undertaking relates to the period in which the generic supplier is kept out of the market from the date of the undertaking to the date of entry, this deferred damages exposure would be likely to be approximately the same as the damages exposure

¹⁰⁶² GSK Second Response, Part Two (document 0734), paragraph 4.22.

¹⁰⁶³ As outlined at paragraph 6.154, there was no commitment from GSK that it would refrain from patent infringement proceedings if Alpharma entered the UK paroxetine market after the expiry of the Alpharma-GSK Agreement.

¹⁰⁶⁴ The exposure would be comparable if Alpharma had been permitted to enter the market 'at risk'. In that case, GSK would have been expected to suffer losses during the period of the litigation, but could have sought damages had it prevailed in the litigation.

that GSK would have faced if Alharma had continued with the litigation instead of entering into the Alharma-GSK Agreement.

- For that reason, under the terms of the Alharma-GSK Agreement, the value transfers did not in practice materially decrease the total damages exposure that GSK faced in relation to the litigation of the contested issues and, as a consequence, the avoidance of an exposure to damages cannot explain GSK's decision to make value transfers.¹⁰⁶⁵ Similarly, Alharma's acceptance of value transfers related to its commitment to defer its proposed entry (and the resulting litigation process), and not to the settlement of claim that was likely to have been restored had Alharma sought to enter the market at the end of the Alharma-GSK Agreement.

6.196 Moreover, the submissions of Actavis and Xellia-Zoetis concerning the cross-undertaking cannot be reconciled with the restrictive entry terms included in the Alharma-GSK Agreement. For example, if it is accepted that the value transfers reflected GSK's assessment that its case was so weak that it was prudent to pay almost all of Alharma's costs rather than face an order to do so at a later date (see paragraph 6.192), then it must also have accepted that Alharma should be free to enter from the anticipated date of the Court's judgment. This is because, the payment of such compensation by GSK would directly imply that it had no expectation of prevailing in litigation with Alharma, such that it accepted that Alharma should be fully compensated for the costs that it had incurred. Instead, (i) Alharma entered the market on terms that could not be expected to have any meaningful impact on market prices; (ii) Alharma's proposed entry was deferred for a period of two years, after which point GSK remained free to challenge any attempts by Alharma to enter the market on the expiry of the Alharma-GSK Agreement; and (iii) GSK made significant payments on the condition that Alharma refrained from entering the market.

vi) *The evidence of the Parties' subjective intentions supports the objective evidence that the objective aim of the Alharma-GSK Agreement was to restrict competition*

6.197 As set out in paragraphs 6.134 to 6.135, GSK's internal documents demonstrate that in its negotiations with Alharma (and GUK), its intention

¹⁰⁶⁵ Had another generic supplier sought to enter the market during the term of the Alharma-GSK Agreement, it would also be the case that GSK would not have made value transfers that had enabled it to defer the costs exposure associated with the period of litigation. For example, the litigation concerning the central question of whether generic entry was permissible would have simply been deferred as a consequence of the Alharma-GSK Agreement, as would the associated litigation costs and the damages exposure relevant to the period of the litigation. On this basis also, therefore, the expected costs of a damages claim would not have been avoided as a consequence of the Alharma-GSK Agreement, and were likely only to have been deferred.

was to use the value transfers to induce Alpharma (and GUK) to accept the restrictions described above.

6.198 The strategy behind GSK's approach to negotiations with Alpharma is also demonstrated by reports by Alpharma employees during their negotiations with GSK. An internal email from [Alpharma ApS's Sales and Marketing Director] on 1 October 2002 reported on a meeting with [GSK's Finance Director A] and demonstrates that GSK recognised the need to ensure that the terms of the Alpharma-GSK Agreement took account of the returns that Alpharma could have earned had it entered independently of GSK:¹⁰⁶⁶

'GSK prefer a settlement for 12 - 18 months consisting of a lumpsum [sic] and certain ongoing (monthly) payments. We would refrain from launching in this period and acknowledge the IP of GSK and all legal activities between the two companies would be stopped. I promised to come back with a calculation of what these figures can be.'

'He understood the value of an early entry by us compared to any other competitor (except IVAX who are on the market with GSK product). Consequently this must be factored into a contract. GSK wants to supply product to us if we enter. They want to attack all non-GSK product entering the market [...].'

6.199 As set out below, evidence concerning the negotiation of the Alpharma-GSK Agreement confirms that Alpharma determined whether the value transfers offered by GSK would provide it with sufficient profits by comparing them to the expected returns of pursuing its efforts to enter the market independently of GSK.

6.200 Although Alpharma had initially sought a settlement agreement that would provide for its independent generic entry (subject to a royalty payment) from April 2003 (see paragraph 3.355), following GSK's rejection of that offer Alpharma's intention was to ensure that any settlement provided sufficient compensation for its commitment to delay its efforts to enter the market.¹⁰⁶⁷

¹⁰⁶⁶ Email from [Alpharma ApS's Sales and Marketing Director] to [Alpharma Inc's Vice President of Intellectual Property] and others entitled 'Today's meeting with [GSK's Finance Director A], GSK, re. settlement possibilities for Paroxetine' dated 1 October 2002 (document 1356).

¹⁰⁶⁷ Actavis submits that this evidence indicates that Alpharma sought to negotiate as competitive terms as was possible in the circumstances (Actavis SO Written Response (document 2754), paragraph 8.11). The CMA notes that while Alpharma may have initially sought a settlement that provided for its independent entry by April 2003, the evidence demonstrates that it was ultimately willing to accept value transfers from GSK in return for Alpharma's commitment not to enter the market independently of GSK (see paragraphs 3.355–3.362). Just as GSK was apparently unwilling to accept the terms proposed by Alpharma, it was open to Alpharma to refuse the entry restrictions and the value transfers which were made in return for its acceptance of them. The CMA considers that this evidence supports, rather than contradicts, its assessment that Alpharma, as a potential

Alpharma's internal documents reveal a focus on ensuring that the 'lump sum' value transfers it received would provide it with adequate compensation for its agreement to accept the restrictions described above (see paragraph 6.198 in relation to [Alpharma ApS's Sales and Marketing Director]'s report following negotiations with GSK).¹⁰⁶⁸

6.201 Similarly, when reporting to colleagues on a meeting with [GSK's Finance Director A] and [GSK's Associate General Counsel for Europe], [Alpharma ApS's Sales and Marketing Director] stated:¹⁰⁶⁹

'GSK will offer a lump sum and/or monthly payment which can be turned into either a cross undertaking as part of the settlement or a promotional fee. We clearly have to negotiate this further, and decide the minimum we can accept.'

6.202 In his witness statement, [Alpharma ApS's Sales and Marketing Director] has confirmed that Alpharma's intention was to accept the payments and value transfers from GSK rather than continue with its uncertain strategy of maintaining its efforts to enter the market independently of GSK. [Alpharma ApS's Sales and Marketing Director] stated that:

*'Ultimately, in my view, the reason for entering into the settlement arrangement with GSK was not a commercial one, but more financial. Put simply, it was to remove the uncertainty of potentially winning at a later date with the certainty of getting some money now.'*¹⁰⁷⁰

'Considering points 1 to 5 of the email at page 17 of Exhibit [X]1, 1071 it would be fair to characterise the agreement as GSK paying Alpharma

competitor, regarded the value transfers as compensation that it required in return for its acceptance of the restrictions on its independent market entry.

¹⁰⁶⁸ Email from [Alpharma ApS's Sales and Marketing Director] to [Alpharma Inc's Vice President of Intellectual Property] and others dated 1 October 2002 (document 1356). Similarly, in an email dated 11 October 2002, [Alpharma ApS's Sales and Marketing Director] explained how Alpharma would receive value transfers in return for its commitment to adhere to the restriction described above – the key issue being how much Alpharma was willing to accept (see email chain between [Alpharma Ltd's Director of Sales and Marketing], [Alpharma ApS's Sales and Marketing Director], [Alpharma Inc's Vice President of Intellectual Property], [Alpharma Inc's President (Human Generics)], [Alpharma ApS's patent attorney], [VP New Products – FP at Alpharma ApS], [Alpharma Inc's Chief Financial Officer], [Alpharma Inc's Chief Legal Officer], entitled 'UK settlement negotiations for Paroxetine – meeting October 11, 2002' dated 14 October 2002 (document 1361).

¹⁰⁶⁹ Email chain between [Alpharma Ltd's Director of Sales and Marketing], [Alpharma ApS's Sales and Marketing Director], [Alpharma Inc's Vice President of Intellectual Property], [Alpharma Inc's President (Human Generics)], [Alpharma ApS's patent attorney], [VP New Products – FP at Alpharma ApS], [Alpharma Inc's Chief Financial Officer], [Alpharma Inc's Chief Legal Officer], and [Alpharma Inc's Vice President of Intellectual Property] entitled 'UK settlement negotiations for Paroxetine – meeting October 11, 2002' dated 14 October 2002 (document 1361).

¹⁰⁷⁰ [X]WS (document 3172), paragraph 8.4.

¹⁰⁷¹ 'Exhibit [X]1' refers to the index of documents for [Alpharma ApS's Sales and Marketing Director] interview on 26 March 2014 (document 3172A).

*a certain sum of money to compensate Alpharma for abandoning its own efforts at that time to enter the market independently of GSK. Entering the market independently would always entail risk, in particular uncertainty as regards the outcome of the legal action, and the agreement with GSK provided certainty – this was key for Alpharma.*¹⁰⁷²

6.203 Taken together, the evidence regarding intentions confirms the CMA's analysis of the objective aim of the Alpharma-GSK Agreement set out above. It confirms that GSK's intention was to use the value transfers as a means of securing entry restrictions and deferring the threat of generic entry. It also confirms that Alpharma's intention was to accept the value transfers on the basis that they provided sufficient compensation for its acceptance of the entry restrictions.

vii) Conclusion on restriction of competition by object

6.204 Under the Alpharma-GSK Agreement, GSK made cash payments and other value transfers in return for Alpharma's acceptance of entry restrictions. The CMA finds that the objective aim of the Alpharma-GSK Agreement was to restrict competition. The value transfers were conditional on Alpharma not entering the UK paroxetine market independently of GSK during the term of the Alpharma-GSK Agreement. Further, the value transfers cannot be explained by legitimate commercial objectives, as submitted by the Parties, or which the CMA can discern; they only made commercial sense on the basis that GSK would benefit from delays to Alpharma's potential independent entry and they were accepted by Alpharma as compensation for its acceptance of the entry restrictions.

6.205 The CMA finds that the Alpharma-GSK Agreement - viewed in its economic and legal context - was, by its very nature, restrictive of competition. It reveals, in and of itself, a sufficient degree of harm to competition and therefore had the object of restricting competition.

6.206 In view of all of the foregoing (and the other aspects of the legal assessment set out at Part 10), the CMA finds that GSK and Alpharma infringed the Chapter I prohibition by participating in an agreement (the Alpharma-GSK Agreement) that had as its object the prevention, restriction or distortion of competition.

¹⁰⁷² [REDACTED] WS (document 3172), paragraph 8.4.

7. EFFECTS ASSESSMENT

A. Overview

- 7.1 In this Part, the CMA sets out its assessment of the likely effects of the GUK-GSK Agreement and the Alpharma-GSK Agreement.
- 7.2 In summary, the CMA finds that in addition to having the object of restricting competition (as set out in Part 6), the GUK-GSK and Alpharma-GSK Agreements also had the likely effect of restricting competition to an appreciable extent. In return for the value transfers from GSK, both GUK and Alpharma agreed to delay their efforts to enter the UK paroxetine market independently of GSK. Instead of continuing with those efforts, they entered the market under arrangements with the incumbent, GSK, which avoided any meaningful increase in the actual competitive constraints faced by GSK. Neither the controlled entry by GUK, nor the controlled entry by Alpharma, had a discernible impact on market prices for paroxetine in the UK paroxetine market during the term of their respective Agreements with GSK. The market position did not change until another generic supplier (Apotex) prevailed in litigation with GSK, when true generic competition emerged and substantial price declines followed.
- 7.3 In the absence of the Infringing Agreements, it is likely that the relevant litigation would have continued and the validity and infringement of GSK's patent rights would have been tested by GUK and/or Alpharma in court, or else the Parties would have entered into settlements on terms that reflected the real uncertainty that GSK faced about the strength of its patent claims. Had GUK and/or Alpharma pursued their strategy of independent entry by progressing the litigation, there would have been the real possibility of a victory for GUK and Alpharma, leading to independent, effective, generic competition. Alternatively, if the Parties had settled their differences, the agreed terms would not have involved the transfer of value by the incumbent to delay independent entry by the challengers.
- 7.4 The following paragraphs of this Part are structured as follows:
- Section B summarises the legal test for finding that an agreement has the effect of restricting competition;
 - Section C assesses whether the GUK-GSK Agreement restricts competition by effect;

- Section D assesses whether the Alpharma-GSK Agreement restricts competition by effect; and
- Annex I sets out, and responds to, the SO Addressees' representations in relation to the CMA's effects assessment.

B. The legal test for an agreement which has the effect of restricting competition

- 7.5 In assessing the restrictive effects of an agreement, account should be taken of the actual conditions in which it produces its effects, in particular the economic and legal context in which the undertakings concerned operate, the nature of the product concerned, the real operating conditions and the structure of the market concerned.¹⁰⁷³
- 7.6 Article 101 TFEU and the Chapter I prohibition apply both to actual and potential anti-competitive effects.¹⁰⁷⁴ The agreement must have, or be likely to have, an appreciable anti-competitive effect on the market.¹⁰⁷⁵
- 7.7 The restrictive effects of an agreement must be made in comparison to the actual legal and economic context in which competition would occur in the absence of the agreement.¹⁰⁷⁶ The exercise entails an assessment of the competitive landscape that would exist in the absence of the agreement.¹⁰⁷⁷ An analysis of the effects of an agreement must be based not only on existing competition between undertakings already present on the relevant market but also on potential competition.¹⁰⁷⁸
- 7.8 The anti-competitive nature of the investigated party's acts must be evaluated at the time those acts were committed.¹⁰⁷⁹
- 7.9 Market power may be considered in determining the likely restrictive effects of an agreement.¹⁰⁸⁰ The Commission has stated that *[n]egative effects on competition within the relevant market are likely to occur when the parties individually or jointly have or obtain some degree of market power and the*

¹⁰⁷³ Judgment of 14 April 2011, *Visa Europe v Commission*, T-461/07, ECR, EU: T:2011:181, paragraph 67.

¹⁰⁷⁴ Judgment in *Asnef-Equifax and Other v Ausbanc*, C-238/05, EU:C:2006:734, paragraph 50.

¹⁰⁷⁵ Horizontal Guidelines, paragraph 26.

¹⁰⁷⁶ Horizontal Guidelines, paragraph 29.

¹⁰⁷⁷ *Racecourse Association v OFT* [2005] CAT 29 at [153]. See also Judgment in *MasterCard and Others v Commission*, C-382/12 P, EU:C:2014:2201, paragraph 108.

¹⁰⁷⁸ See Judgment of 14 April 2011, *Visa Europe v Commission*, T-461/07, ECR, EU: T:2011:181, paragraph 68,

Judgment of 12 June 1997, *Tiercé Ladbroke v Commission*, T-504/93, ECR, EU:T:1997:84, paragraph 158.

¹⁰⁷⁹ Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 110.

¹⁰⁸⁰ Horizontal Guidelines, paragraph 28.

agreement contributes to the creation, maintenance or strengthening of that market power or allows the parties to exploit such market power.¹⁰⁸¹

7.10 The CMA's analysis, as set out in the following sections, has considered the likely effects of the GUK-GSK and Alpharma-GSK Agreements at the time each of those Agreements was entered into, taking into account the relevant context in which each Agreement operated.

C. Assessment of whether the GUK-GSK Agreement restricts competition by effect

7.11 In this Section, the CMA sets out its detailed assessment of the likely effect of the GUK-GSK Agreement¹⁰⁸² on competition.

7.12 In summary, the CMA finds that the likely effect of the GUK-GSK Agreement was to restrict competition between 13 March 2002 and at least 30 November 2003. In particular, the CMA finds that:

- The context at the time of the GUK-GSK Agreement was as follows:
 - As set out at paragraphs 6.47 to 6.64, at the time the GUK-GSK Agreement was entered into GUK was a potential competitor to GSK in the UK paroxetine market for both paroxetine 20mg and paroxetine 30mg. GUK was pursuing entry strategies aimed at entering the market with generic paroxetine sourced independently of GSK.
 - As set out at paragraphs 6.34 to 6.39, had true generic competition emerged, such competition was expected to result in significant decreases in paroxetine prices in the UK and a decline in GSK's market share; and
 - At the time the GUK-GSK Agreement was entered into, GSK had market power in the UK paroxetine market.
- The value transfers in the GUK-GSK Agreement had the likely effect of inducing GUK to accept entry restrictions, thereby delaying its potential

¹⁰⁸¹ Commission Notice: Guidelines on the application of Article 81(3) of the Treaty (now Article 101(3) of the TFEU, OJ C 101/97, 27.4.2004 (the 'Article 101(3) Guidelines'), paragraph 25.

¹⁰⁸² As set out at paragraph 5.9, the CMA finds that the value transfers were made directly from GSK to GUK pursuant to the GUK-GSK Settlement Agreement, with the following exception. The transfer of a restricted volume of paroxetine and the associated profit guarantee were made by GSK to GUK, indirectly via IVAX, pursuant to the IVAX-GSK Agreement and the GUK-IVAX Agreement.

independent entry¹⁰⁸³ and the associated price decreases. As regards the structure of the market, the GUK-GSK Agreement also had the likely effect of assisting GSK in preserving the patent entry barriers faced by GUK and other potential entrants and thereby enabling GSK to maintain its market power.¹⁰⁸⁴

- GUK's entry as a distributor of GSK product was not likely to materially increase the actual competitive constraints faced by GSK. As a consequence of the volume restriction GUK's entry was likely to have no meaningful impact on actual competition in the UK paroxetine market.¹⁰⁸⁵
- Developments observed in the UK paroxetine market during the term of the GUK-GSK Agreement are consistent with this analysis: (i) GUK deferred its efforts to enter the market independently of GSK and (ii) GUK's restricted entry as a GSK distributor had no material impact on market prices.
- Absent the restrictions in the GUK-GSK Agreement, GUK would have remained a potential competitor that was pursuing its efforts to enter the market independently of GSK. GUK's competitive behaviour would not have been distorted by value transfers made in return for entry restrictions. The realistic and likely outcomes are that GUK would have continued with its efforts to enter the UK paroxetine market independently of GSK, or else it would have settled the litigation on less restrictive terms.
- The absence of other relevant sources of competition to GSK meant that the GUK-GSK Agreement assisted GSK in preserving its market power, given:
 - that at the time the GUK-GSK Agreement was entered into, GSK did not face true generic competition;

¹⁰⁸³ Moreover, GUK was unable to facilitate generic market entry by transferring or assigning its MA to another company.

¹⁰⁸⁴ Consistent with this, paragraph 25 of the Commission's Article 101(3) Guidelines notes that: '*Negative effects on competition within the relevant market are likely to occur when the parties individually or jointly have or obtain some degree of market power and the agreement contributes to the creation, maintenance or strengthening of that market power or allows the parties to exploit such market power.*'

¹⁰⁸⁵ Even if it had been the case that such entry materially constrained GSK, the CMA considers it likely that in the counterfactual the terms of entry would have been less restrictive. That is because in the absence of a value transfer in return for entry restrictions it is reasonable to expect that GUK's acceptance of any settlement agreement would have required more competitive terms because GSK would have been required to offer more competitive terms to GUK to provide GUK with alternative sources of remuneration and a sufficient incentive to settle (see paragraph 7.55).

- that no other generic suppliers were as advanced in launching generic paroxetine and/or challenging GSK's patent claims (though GSK had commenced proceedings against the bulk supplier BASF); and
- the limited number of further potential entrants.

7.13 This Section sets out, in relation to the GUK-GSK Agreement:

- GSK's competitive position;
- the restrictive effects of the Agreement;
- the counterfactual; and
- other relevant sources of competition to GSK.

7.14 A number of the representations in relation to the effect of the GUK-GSK Agreement are discussed in this Section. Representations of relevance to all of the Agreements are presented in Annex I.

j) GSK's competitive position

7.15 As set out at Part 4, the relevant market is the supply of paroxetine in the UK.

7.16 The CMA finds that, at least between January 1998 and November 2003 (the month before independent generic entry began, see paragraph 3.21), GSK had market power in the UK paroxetine market.¹⁰⁸⁶ In particular:

- GSK's market share for the supply of finished product to pharmacies/wholesalers (by volume) was in excess of 60% and it remained the sole manufacturer of paroxetine sold in the UK between January 1998 and November 2003 (with a market share by value or volume of 100% at the production level). Rival suppliers' shares were significantly smaller and not capable of undermining GSK's leading position in the relevant market (see paragraphs 4.105 to 4.110).
- Prior to independent generic entry, GSK was able to sustain prices and profits that were significantly higher than those observed following

¹⁰⁸⁶ The CMA considers that, irrespective of the conclusion reached in relation to the relevant market, it is in any case clear that GSK had market power at the time it entered into the GUK-GSK Agreement. Having sustained comparably higher prices and profits over a number of years prior to independent generic entry, GSK's internal documents indicate that GSK was concerned that generic competition would lead to significant price, profit and market share erosion. Indeed, following the eventual emergence of true generic competition in December 2003, GSK experienced a significant decline in its paroxetine prices, profits and market share. On the basis of these trends, the CMA has concluded that GSK retained market power at least between January 1998 and at least November 2001 and, as a consequence of the Agreements, until at least November 2003.

independent generic entry. Prices were some 90% higher and profits were around 8.5 times higher than those observed following independent generic entry (see paragraph 4.111).

- Barriers to expansion were significant in this market. Parallel importers were limited in their ability to expand and exercise a greater competitive constraint on GSK. The volume restriction imposed by GSK on IVAX (which had entered the market as a distributor for GSK pursuant to the IVAX-GSK Agreement) limited the competitive constraint from IVAX (see paragraphs 4.112 to 4.115).
- GSK's patents in relation to paroxetine represented a barrier to entry, and, for as long as they remained unchallenged, enabled GSK to litigate, and seek injunctions, in response to the proposed market entry of potential competitors (see paragraphs 4.116 to 4.123).
- Over the relevant period, the NHS did not exert countervailing buyer power vis-à-vis GSK for the supply of Seroxat (see paragraphs 4.124 to 4.126).

7.17 In the context of the GUK-GSK Agreement, GSK had an interest in protecting its position of market power, as there had been no launch of independent generic paroxetine and therefore GSK was able to sustain far higher profits than was likely to be the case following independent generic entry (see paragraphs 3.161 to 3.164).¹⁰⁸⁷

ii) *The GUK-GSK Agreement's restrictive effects*

a) *The likely effect of the value transfers was to induce delays to the potential emergence of true generic competition and to assist GSK in preserving its market power*

7.18 As set out at paragraphs 6.88 to 6.90, the GUK-GSK Agreement included entry restrictions that prevented GUK, for the term of that Agreement, from (i) supplying generic paroxetine sourced independently of GSK, and/or (ii) facilitating generic market entry by transferring or assigning its MA to another company. As set out at paragraphs 6.91 to 6.139 the CMA has considered the purpose of the value transfers from GSK to GUK, and concluded that they were made in return for GUK's agreement not to enter the UK paroxetine market independently of GSK.

¹⁰⁸⁷ This is consistent with GSK's strategy regarding defence strategies to protect Seroxat from generic entry (see paragraphs 3.144–3.154).

- 7.19 In the absence of the value transfers described above (and in the absence of a more competitive settlement), GUK would not have been incentivised to accept the entry restrictions in the GUK-GSK Agreement. GUK was a potential competitor that was otherwise seeking to enter the UK paroxetine market independently of GSK (see paragraphs 6.47 to 6.64), and was unlikely to have accepted the same entry restrictions without sufficient compensation. This analysis is supported by GUK's internal documents (see paragraphs 6.136 to 6.138) which indicate that absent sufficiently high value transfers from GSK, GUK was minded to maintain its efforts to enter the market independently of GSK and to continue to contest the GUK Litigation.
- 7.20 As set out at paragraph 6.90, the CMA observes that the GUK-GSK Agreement did not resolve the litigation as there was no counterpart to the entry restrictions in the form of any commitment from GSK that it would refrain from patent litigation proceedings if, after the expiry of the GUK-GSK Agreement, GUK sought to supply its own generic paroxetine product. As such, while the threat of GUK's potential independent entry was delayed by the GUK-GSK Agreement, the Agreement's terms were such that GUK would continue to face the prospect of litigation (see paragraphs 4.116 to 4.123) in the event that it sought to enter the UK paroxetine market with a generic paroxetine product sourced independently of GSK, even after the expiry of the GUK-GSK Agreement.
- 7.21 The potential for further litigation was clear from the GUK-GSK Settlement Agreement which, at clause 11, stated:¹⁰⁸⁸
- 'On termination of the [GUK-IVAX Agreement], whether by effluxion of time or otherwise [GSK] and/or GUK shall be at liberty to restore the Litigation.'*
- 7.22 The likely effect of the GUK-GSK Agreement, including the value transfers that were used to induce the entry restrictions, was therefore to delay GUK's potential independent generic entry. By delaying GUK's potential independent generic entry and associated challenge to GSK's patent position, the likely effect of the GUK-GSK Agreement was also to assist GSK in preserving the patent entry barriers faced by other potential entrants, which would continue to face the prospect of litigation in the event that they sought to enter the UK paroxetine market with a generic paroxetine product sourced independently of GSK (see also paragraphs 7.63 to 7.64).¹⁰⁸⁹ The GUK-GSK Agreement

¹⁰⁸⁸ GUK-GSK Settlement Agreement dated 13 March 2002 (document 0995).

¹⁰⁸⁹ Although the BASF Litigation had commenced in July 2001, the CMA notes that in the absence of a judgment that a generic paroxetine product had been found not to be infringing, even a successful outcome for BASF in the

therefore made the independent entry of competitors onto the market more difficult, thereby interfering with the structure of competition on the market.

Parties' representations

7.23 GUK submitted that the CMA is incorrect to suggest that by discontinuing its litigation, GUK delayed others from coming onto the market.¹⁰⁹⁰ GUK's submission is premised on the following:

- The CMA has not established that the GUK-GSK Agreement deterred others from challenging GSK's patents. Indeed, BASF's challenge of GSK's patent continued, even after the GUK-GSK Agreement had been entered into.¹⁰⁹¹
- The CMA has not established that GUK was uniquely positioned to challenge GSK's patents.
- It is misplaced to subject GUK to a duty to litigate in order to attempt to remove barriers to entry for other generic competitors.¹⁰⁹² Such an approach would discourage generic suppliers from challenging patents.

7.24 The CMA considers that the GUK-GSK Agreement assisted GSK in preserving the patent entry barriers faced by GUK and other potential entrants. In relation to GUK's individual points:

- The CMA has not stated that other generic suppliers' incentives to challenge were altered or that BASF's challenge was affected as a result of the GUK-GSK Agreement.
- The CMA has assessed the likely effect of the GUK-GSK Agreement on GUK's entry strategy, and how this in turn was likely to affect the timing and likelihood of generic entry more generally. These issues are considered further at paragraphs 7.48 to 7.53. The CMA does not consider

BASF Litigation may not have facilitated immediate generic entry. By way of example, although the judgment in the BASF Litigation was that of the various claims in the Anhydrate Patent, only claim 10(i) and claim 11 were valid, GSK continued to challenge generic entry after this judgment (in July 2002). In particular, GSK varied the case against Alpharma to allege that claim 11 was infringed and issued proceedings against the Apotex Parties. It was not until the Apotex Litigation in December 2003 when a finding was made on a product not infringing that independent generic entry occurred.

¹⁰⁹⁰ GUK SO Written Response (document 2752), paragraph 6.11.

¹⁰⁹¹ Annex 1 to GUK SO Written Response (document 2753), page 9.

¹⁰⁹² GUK SO Written Response (document 2752), paragraph 6.12, Annex 1 to GUK SO Written Response (document 2753), pages 2, 5, 8–10.

it necessary to establish, as GUK suggests, that GUK was uniquely positioned to challenge GSK's patents.

- The CMA's finding of infringement in relation to the GUK-GSK Agreement concerns value transfers made in return for entry restrictions rather than settlement agreements¹⁰⁹³ more generally.

b) *The likely effect of GUK's entry as a GSK distributor was no material increase to the actual competitive constraints faced by GSK*

7.25 The transfer of a restricted volume of product from GSK to GUK was not likely to materially increase the actual competitive constraints faced by GSK in the supply of paroxetine in the UK.

7.26 As set out at paragraphs 6.103 to 6.104, under the terms of the GUK-GSK Agreement, GSK transferred value to GUK by supplying it with a restricted volume of paroxetine and GUK was able to purchase no more than 750,000 packs of GSK product each year. For the reasons set out at paragraph 6.104, the transfer of a restricted volume of product itself represented a value transfer that involved GSK transferring to GUK the margin it would otherwise have earned on such volumes.¹⁰⁹⁴ In the same way as a payment, GSK was able to use this mechanism to make a value transfer to GUK through a means that would not meaningfully increase the price competition it was facing on the market. Consistent with this, the likely effect of the transfer of a restricted volume of paroxetine¹⁰⁹⁵ was no material increase in the actual competitive constraints faced by GSK and no meaningful impact on the degree of actual competition in the UK paroxetine market:

- In the event that GUK reduced its prices to a level that was materially below the level of its competitors in the UK paroxetine market (namely GSK, IVAX and parallel importers of Seroxat), the associated increase in its orders would have resulted in GUK quickly reaching the volume

¹⁰⁹³ For the reasons set out at paragraph 7.20 the GUK-GSK Agreement did not settle the GUK Litigation.

¹⁰⁹⁴ GSK submitted that the volume restriction was not restrictive in the way the CMA contends, and that there was no evidence that the Generic Companies sought additional supplies (GSK SO Written Response (document 2755), paragraphs 1.142 and 8.46). See paragraph 7.37 for the CMA's responses to these points.

¹⁰⁹⁵ The CMA notes that as IVAX supplied GUK with paroxetine, IVAX was therefore aware of the supply terms that GUK faced, in particular the supply price, profit guarantee and volume restriction clauses. As such, IVAX would have known that GUK faced no incentive to meaningfully compete with GSK, for the reasons established in paragraphs 7.26–7.27. Therefore, IVAX's awareness of the terms of the GUK-GSK Agreement and its knowledge that GUK did not pose a competitive threat ensured that there was no incentive for IVAX to reduce its price or end its Agreement with GSK and seek to enter independently.

restriction of 750,000 packs of paroxetine 20mg, thereby harming its reputation with customers by not being able to meet customers' orders.

- Were GUK to lower its prices this would either have no impact on, or reduce, the profits it was able to make. As a result of the volume restriction, GUK's incentive to reduce prices materially below the prevailing price at the time would have been minimal:
 - the profit guarantee clause in which GUK was guaranteed to receive minimum profits of £2.85 million per year¹⁰⁹⁶ ensured that a price reduction to any price between £12.25 and £8.45 would not have resulted in any greater profits for GUK.¹⁰⁹⁷
 - were GUK to reduce its price to below £8.45 per pack, its profits would be lower than would have otherwise been the case, because GUK would be making a lower mark-up on each pack sold without being able to sell additional packs.
 - As GUK could not sell more than 750,000 packs,¹⁰⁹⁸ it could not expand its market share by volume beyond 12% of the UK paroxetine market, and IVAX and GUK between them could supply no more than 24% of the UK paroxetine market.¹⁰⁹⁹ Therefore, having secured customers to whom it would make its allocation of paroxetine sales,¹¹⁰⁰ GUK would have had no incentive to compete for other customers to whom GSK was supplying Seroxat. As a result, the impact that sales by GUK could have on GSK's market share of UK-supplied product was capped, helping to protect GSK's share of the UK paroxetine market.

¹⁰⁹⁶ This figure equates to the margin that GUK would make if it sold its total allocation of 750,000 paroxetine packs at a price of £12.25 with a supply price of £8.45.

¹⁰⁹⁷ GUK suggested that *'the profit guarantee clause actually provided "perverse" incentives (from GSK's perspective) because it meant that the generics could reduce the price to £8.45 and then claim the lost profit from GSK. There was thus an in-built incentive in the agreement to bring down the price.'* (See Note of meeting between the CMA and GUK dated 7 February 2012 (document 1210), paragraph 27). However, although GUK is correct that lowering its prices would not necessarily have resulted in a profitability decline, such a strategy would mean that GUK was quickly bound by the volume restriction and would then be unable to satisfy orders for the remainder of the relevant period. Such a strategy would be expected to be to the detriment of its relationship with its customers, who, for long periods, would have been unable to order the product from GUK and GUK's portfolio 'offer' would have been less attractive. It is for this reason that GUK presumably chose: (i) to not offer material discounts as compared to IVAX and parallel importers (see paragraph 7.39); and (ii) to order a consistent monthly volume of paroxetine from IVAX. For example, between May 2002 and November 2003 GUK ordered between 59,670 and 66,655 packs each month from IVAX (part two of the response dated 4 May 2012 to the Teva Second Section 26 Notice and Annexes 1–3 (documents 2049 and 2050)).

¹⁰⁹⁸ As described in paragraph 3.224, to allow for GUK's supply, GSK increased the overall quantities that IVAX could supply to 1,520,000 packs in the Second Addendum (document 0318), (increasing IVAX's original volume restriction of 770,000 packs by GUK's 750,000 packs).

¹⁰⁹⁹ Calculated based on the UK paroxetine market size in the 12 months to March 2002, using data submitted by relevant parties.

¹¹⁰⁰ See paragraph 7.33 for an explanation of why it was expected that GUK's sales as a GSK distributor would replace sales by parallel importers.

- As the restricted product volumes that were supplied to GUK were limited to paroxetine 20mg packs, under the terms of the GUK-GSK Agreement, GUK was unable to supply any paroxetine 30mg packs. Prior to entering into the GUK-GSK Agreement, GUK was a potential competitor with respect to both 20mg and 30mg tablets (see paragraph 7.12). Therefore, GSK, in providing for GUK to sell only 20mg tablets, removed the threat of independent generic entry by a potential competitor in relation to its sales of 30mg packs.
- Because of the volume restriction, GUK's potential market shares were capped.

7.27 As a further consequence of the volume restriction, GSK would have had little incentive to respond to GUK's entry (or, for the same reasons, the entries of IVAX and AlphaPharma) by competing on price:

- The majority of GSK's existing customers were unlikely to be the subject of an approach from GUK (or IVAX) given the volume restrictions that IVAX and GUK were subject to and the expectation that IVAX's and GUK's sales would in part replace those of parallel importers (see paragraph B.149 and 7.32).

- GSK's own pricing policy was not to pre-emptively decrease its price to gain market share: *'Experience shows that GSK should not drop prices pre-emptively. This only forces a price war. Optimal strategy for branded products generally to follow price reduction rather than lead.'*¹¹⁰¹
Consistent with this, it was likely that GSK would not drop its prices below those charged by GUK, as it would have been aware that, had it done so, GUK and IVAX would continue to match GSK's prices until prices were competed down close to approximately £8.45 per pack (that is, the cost per pack for the Generic Companies) such that GSK would make substantially lower profits overall. Moreover, had GUK's price fallen below £12.25 per pack, GSK would have lost further profits through its contractual requirement to make payments (of up to £2.85 million) to GUK as required by the profit guarantee clause in the GUK-GSK Agreement. GSK's most profitable response to the restricted entry of the Generic

¹¹⁰¹ Seroxat Brand Planning Europe December 2002 (document D 124), page 34. [GSK's Finance Director A's] witness statements during the AlphaPharma Litigation also imply that GSK would react to price falls rather than leading them: *'A further result of the price of Generic Paroxetine falling substantially would be that GSK would be obliged to respond by increasing its brand equalisation discounts for as many of its customers as possible.'* ([REDACTED]WS1 (AlphaPharma) (document 0241), paragraph 9.8), and *'GSK's brand equalisation discounts are only offered in reaction to market pressures, principally the prices charged by parallel importers. [...] It is bizarre to suggest that GSK would offer such discounts without having to do so.'* (emphasis in original) ([REDACTED]WS2 (AlphaPharma) (document 0289), paragraph 2.2).

Companies was therefore to preserve its prices at prevailing levels. Consistent with this, prices remained broadly constant during the term of the GUK-GSK Agreement (see paragraph 7.44).

- Had GSK instigated price cuts that limited the margins available to GUK, GUK would (other things being equal) have a decreased incentive to extend its Agreement beyond the relevant expiry date.
- Were GSK to reduce its prices to a level below £8.45, IVAX and GUK would have been entitled to terminate their Agreements with GSK and continue their efforts to enter the UK paroxetine market independently of GSK.¹¹⁰²

7.28 Consistent with this, contemporaneous evidence demonstrates that both GUK and GSK considered that the expected impact of a supply agreement¹¹⁰³ containing volume restrictions would be continued price stabilisation:¹¹⁰⁴

- GSK anticipated that the appointment of sub-distributors by IVAX would not result in greater competition in the UK paroxetine market or in GUK competing meaningfully on price, as noted by [GSK's Finance Director A]:

¹¹⁰² As set out at paragraphs B.108–B.131, IVAX was incentivised by the IVAX-GSK Agreement to delay its efforts to enter the market independently of GSK.

¹¹⁰³ This is also consistent with evidence that GSK's expectation was that the supply agreements would lead to price stabilisation. For example, in 2001, a GSK internal presentation considering the 'Seroxat Patent Challenge' concluded that entering into a supply agreement would lead to a '*Generic price 75% MSP to compete with PI [Parallel Imports]*' (GSK presentation entitled 'Seroxat Patent Challenge' dated 5 February 2001 (document 0123), page 4) and [GSK's Finance Director A] confirmed in a post-SSO witness interview that in planning it was assumed that the generic selling price would be 75% of the MSP ([§]1 (document 4008R), page 32). In GSK Third Response (document 0750) GSK indicated that 'MSP' referred to the list price at the time of £17.76. Consistent with this a Seroxat Brand Planning document dated December 2002 noted for the UK that: '*GSK-Norton co-marketed version of Seroxat available with a price of approx. 70% of branded version. [...] Early indications are that total Seroxat revenues are holding up well.*' (Seroxat Brand Planning Europe December 2002 (document D 124), page 25). [GSK's Finance Director A] further stated that the intention of the Agreements was to allow GSK to meet its budget agreed over a three-year planning horizon. [GSK's Finance Director A] stated that GSK was not anticipating multiple generics entering the market and competing on price for several years, and it sought to maintain that position of '*some level of certainty*' ([§]1 (document 4008R), pages 15-16). Consistent with this, an internal GSK document dated January 2004 indicated that unrestricted competition independently of GSK would result in substantial price declines: '*The Apotex court ruling means the UK competitive environment is significantly altered. We now expect the [sic] to face a generic not supplied by GSK, leading to aggressive price competition*' (Synthon STP dated 16 January 2004 (document 0456)).

¹¹⁰⁴ GSK submitted that witness statements in patent litigation suggesting that the impact of the IVAX-GSK or GUK-GSK Agreements was not, or was not likely to be, substantial are of no evidential value. GSK stated that the relevant comments were made by comparison to true generic competition and the associated irreversible price decline, whereas the relevant counterfactual is the maintenance of a presumptively valid patent (GSK SO Written Response (document 2755), paragraphs 8.28–8.29, 8.45). The CMA does not agree that these points undermine the statements' evidential value because: (i) the statements in question directly relate to the impact of the Agreements, and as such are therefore relevant, and (ii) the CMA does not consider that the context undermines the statements as they merely articulate that the impact of the Agreements was expected to be minimal compared to the situation at the time (that is, prior to any independent generic entry having taken place).

*'Whom Ivax appoints and on what commercial terms is entirely up to Ivax. However, GSK concluded, since Ivax's selling price to its sub-distributors is likely to be above the price which Ivax pays to GSK, any sub-distributors' prices to their customers are unlikely greatly to undercut Ivax's own and, therefore, the financial impact on GSK would, again, be minimised.'*¹¹⁰⁵

*'it is clear [...] that [IVAX] is willing for GUK to be a sub-distributor. **This would enable GUK to mitigate its loss by selling paroxetine at the parallel import price. It would not enable it to severely undercut this price and de-stabilize the market.***¹¹⁰⁶ (emphasis added)

- Internal GUK documents indicate that GUK had considered that a supply agreement with GSK would include limitations on GUK's ability to effectively compete. For example, in an internal email dated 24 October 2001, [✂], GUK's Managing Director, referred to GUK as having a more competitive offer, in contrast with his expectation that the IVAX-GSK Agreement would contain volume limitations and involve no material impact on market prices:¹¹⁰⁷

'We are not fully informed as to the nature of this agreement but it is very likely that Norton will be heavily controlled by GSK in the amount of product they can sell and the price they sell it at - probably a penny or two under the PI [parallel import price]. [...] Assuming Norton launch limited quantities into the market in December [the earliest date we have heard] we will only have to wait a further three months to launch our own product which we know will be much more competitive than Norton.

Additionally, it will be patently clear to our customers that Norton again are the generic spoilers in this regard in aiding and abetting a multinational company by preventing true generic competition' (emphasis added).

- Following the GUK Interim Injunction, GUK contacted a number of its customers to provide some reassurance in relation to the supply of its

¹¹⁰⁵ [✂]WS1 (Apotex) (document 0333), paragraph 6.6.

¹¹⁰⁶ Skeleton argument of claimant (GSK) in support of the GUK Interim Injunction dated 23 October 2001 (document 0910), paragraph 54.

¹¹⁰⁷ Email from [GUK's Managing Director] to [GUK's Sales and Marketing Director] and others dated 24 October 2001 (document 0913).

paroxetine product. In a letter sent to all of GUK's wholesalers on 29 October 2001, GUK said that:¹¹⁰⁸

'It is my greatest wish to be able to supply you [with Paroxetine] and break GSK's dominance and manipulation of the product via other 3rd parties.'

- A strategy document dated December 2002 indicates that GSK considered that the expected impact of the Agreements would be price stabilisation at prevailing price levels:¹¹⁰⁹

'Price Defence Strategy: Defences undertaken to date are crucial to protect Seroxat prices:

*...Co-marketing strategies avoid generic reference pricing (e.g. UK, Ger, Den, Netherlands, and Spain) and **allow participation in generic market without undermining Seroxat price.**'* (emphasis added)

7.29 The evidence indicates that GUK ordered from IVAX (as GSK's sub-distributor) the maximum number of packs that it was entitled to under the volume restriction for the duration of the GUK-GSK Agreement and prior to independent generic entry.¹¹¹⁰ Data on the volume of product supplied to GUK by IVAX shows that, during the GUK-GSK Agreement, GUK received 625,285 packs in the first contract year and 754,935 packs in the second contract

¹¹⁰⁸ Email from [a GUK Marketing Assistant] to [GUK's General Manager] and others at GUK dated 29 October 2001 (document 0922) attaching letter to wholesalers dated 29 October 2001 (document 0921).

¹¹⁰⁹ Seroxat Brand Planning Europe December 2002 (document D 124), page 34. As set out at paragraph 3.147, GSK also referred to 'supply agreements' as 'co-marketing agreements'.

¹¹¹⁰ The CMA notes that GSK stated that in respect of the total restricted volume available to the Generic Companies: 'It is important to appreciate that Ivax only ever asked for a fraction of this entitlement. In other words, far from being restricted, Ivax had available to it far greater volumes than it actually called for. The volume quota in the agreement therefore did not have the effect of a "restriction" on quantities available.' (GSK Second Response, Part Two (document 0734), paragraph 11.3). GSK subsequently provided data which showed that this was not the case, such that the Generic Companies did order the full allocation of volumes available to them in 2002 and 2003 (source: CMA calculations based on PDF 'Apotex damages disclosure document 171' undated (document 2525), attached to the response dated 30 January 2013 to the Section 26 Notice dated 18 December 2012 sent to GSK (document 2515)).

year.¹¹¹¹ These volumes equate to 100%¹¹¹² and 101% of the restricted volume available to GUK in each year respectively.¹¹¹³

7.30 Consistent with this, when planning its own independent entry,¹¹¹⁴ GUK had been planning to supply a greater volume of paroxetine than it could supply pursuant to the GUK-GSK Agreement:¹¹¹⁵

- When considering its volume requirements in order to launch its paroxetine product in the UK, GUK was aiming to supply '*50-55% of the generic market*' and aiming to '*sell 160k/month all labels with a 700k launch volume*'.¹¹¹⁶

¹¹¹¹ Part two of the response dated 4 May 2012 to the Teva Second Section 26 Notice, with Annexes 1–3 (documents 2049 and 2050).

¹¹¹² The first year of the GUK-GSK Agreement was from March 2002 to February 2003. However, GUK did not receive any product from IVAX in the first two months until May 2002 and therefore did not make any sales during this time. The CMA notes that under clause 3.1 of the GUK-IVAX Agreement (document 1003), GUK could receive £237,500 in each of the first two months, as an alternative to receiving product, if there was a delay in supply. The evidence indicates this clause was invoked as GUK claimed a 'margin' of £237,500 in both March and April 2002 (See email from [a GUK Sales and Marketing employee] to [IVAX's Sales and Marketing Manager] dated 6 March 2003 (document 1112) entitled 'Paroxetine yr 1 reconciliation [sic]' attaching spreadsheet entitled 'Norton/GUK Paroxetine Deal 2002/3' (document 1108)). The CMA has therefore pro-rated the volume restriction for the remaining ten months of the first contract year accordingly.

¹¹¹³ These figures are virtually identical to GUK's own sales data. GUK sold 625,267 packs in the first contract year and 713,021 packs in the second contract year (see GUK spreadsheet entitled 'Annex 2 - customer sales volume and value data for paroxetine 20mg and 30mg from 2002 onwards' dated 13 July 2012 (document 1267)). These volumes equate to 100% and 95% of the appropriately pro-rated restricted volume in each year respectively. GSK submitted that as GUK ordered only 95% of its volume allowance in the second year, this is inconsistent with the allowance operating as a restriction in practice (GSK SO Written Response (document 2755), paragraph 8.46). In making this statement GSK has mistakenly referred to the figures being order data, when in fact they are sales data. The CMA considers that it is order data rather than sales data which is informative when considering whether the volume restriction was binding because GUK was limited in the quantity it could order from GSK under the GUK-GSK Agreement, and there will inevitably be a time lag between orders being placed and sales being made. The CMA notes that GUK ordered the full volume available to it (as stated in paragraph 7.29) whereas it sold 95% of this volume during the second year of the Agreement.

¹¹¹⁴ The CMA notes that [GUK's General Manager] stated that, in the context of GUK's independent entry, GUK would not seek to take more of the market share than was already held by parallel importers as doing so was probably beyond the marketing resources at GUK's disposal ([redacted]WS (document 0901), paragraph 33). The CMA considers this statement to be inconsistent with the contemporaneous internal emails cited in this paragraph which indicate that GUK was anticipating to sell a share greater than that held by parallel importers (which was 22% by volume in 2001, see Table 3.5). Finally, it is reasonable to expect that were GUK the first independent entrant its incentives would be to seek to maximise its market share in order to benefit fully from its first-mover advantage (see paragraph 3.59).

¹¹¹⁵ The CMA also notes that during the negotiation of the GUK-GSK Agreement, GUK requested a higher allocation of packs allocation than the 750,000 packs eventually included in the Agreement, but this was rejected by GSK. See letter from [GUK's General Manager] to [IVAX's Commercial Director] dated 24 January 2002 (document 0965), in which [GUK's General Manager] wrote: '*As you know, one of the principal sticking points has been that Glaxo SmithKline, through yourselves, has been unwilling to meet our required demand of 1 million packs per year*'.

¹¹¹⁶ Email chain between [a GUK Sales and Marketing employee], [GUK's General Manager], [GUK's Sales and Marketing Director] [and other GUK employees] dated 25 to 30 October 2001 (document 0923).

- By 21 September 2001 GUK had received customer orders for 492,800 packs of its own paroxetine product and anticipated significant further orders over the next six months.¹¹¹⁷

7.31 The evidence also confirms that price stability was in fact observed:

- As explained in paragraph 7.44, the GUK-GSK Agreement did not have a material impact on prices in the market: there was no material fall in prices either following the introduction of the Agreement or during its term. For example, paroxetine 20mg prices and Seroxat 20mg prices in the three months after GUK's entry pursuant to the GUK-GSK Agreement were 1% lower and 0.5% lower respectively compared to the three months before GUK's entry.
- [GSK's Finance Director A] indicated in a witness statement dated 22 October 2002 that prices had not fallen after IVAX, GUK and Tillomed had entered the market as GSK sub-distributors:¹¹¹⁸ *'Ivax would be unlikely to want to undercut the existing price paid by customers for parallel imported paroxetine. This is the price to which GSK was already discounting a number of brand equalisation deals [...] I believe the current situation, therefore, is that the price at which both Ivax and its sub-distributors sell Distributed Paroxetine has remained stable since the coming into effect of the Ivax Agreement.'*¹¹¹⁹

7.32 As set out in paragraph 7.26, another likely effect of the volume restriction was that GUK's entry as a GSK distributor would have only a limited impact on GSK's market share of UK-supplied paroxetine. In part, this would be

¹¹¹⁷ GUK had received customer indications of their estimated monthly requirements for the next six months, totalling approximately £35 million in potential sales; see [REDACTED]WS (document 0901), paragraph 17, and Exhibit [REDACTED]1 Tab 3 entitled 'Order notes for purchase of paroxetine' dated 15 October 2001 (document 0174).

¹¹¹⁸ [REDACTED]WS1 (Apotex) (document 0333), paragraphs 6.5 and 6.7. GSK submitted that what was meant by this statement was that the price had not decreased further since the original low prices at which IVAX and GUK respectively had sold authorised generic paroxetine into the market, and the focus of this witness statement, given that it was made in litigation during October 2002, was on the lack of further price decreases rather than the original price decrease. (GSK SO Written Response (document 2755), paragraph 8.38). The CMA considers that the interpretation it has given to this statement remains accurate given both: (i) the context in which this statement was made that GSK considered that IVAX would be unlikely to undercut prices as compared to existing levels; and (ii) the evidence presented at paragraph B.166 that paroxetine prices did not fall materially following IVAX's entry as a GSK distributor.

¹¹¹⁹ The CMA notes that IVAX and GUK did not need to undercut parallel import prices in order to make sales given an apparent preference for UK packaging. For example, [GSK's Finance Director A] stated during the Apotex Litigation that: *'The Distributed Paroxetine sold by Ivax and its sub-distributors does not displace parallel imported SEROXAT on price, but because there is a demand for UK packaging.'* [REDACTED]WS2 (Apotex) (document 0352), paragraph 3.2.

because sales by GSK's distributors would replace sales by parallel importers.¹¹²⁰ This was anticipated by both GSK and GUK. For example:

- An internal GSK presentation (undated) in relation to co-marketing agreements in Germany stated: *'Our assumption was that a co-marketing deal or a supply agreement will reduce PIs [Parallel Imports]'*.¹¹²¹
- [GUK's General Manager] stated in a witness statement dated 15 October 2001 in the GUK Litigation in relation to IVAX's entry as a GSK distributor: *'SB is therefore targeting the PI [Parallel Imports] sector of the market, through Norton [IVAX], which is the typical strategy of any generic company coming to market in the UK.'*¹¹²²
- In 2001, a GSK internal presentation considering the *'Seroxat Patent Challenge'* concluded that entering into a supply agreement would lead to a *'Generic price 75% MSP to compete with PI [Parallel Imports]'*¹¹²³

7.33 As a GSK distributor, GUK's sales were expected to replace sales by parallel importers because, prior to entering into the Agreements, GSK was protecting its market share by offering discounts similar to brand equalisation deals to larger customers, and could adopt the same approach in response to sales made by its distributors. For example, in the GUK Litigation [GSK's Finance Director A] stated that:¹¹²⁴ *'In order to maintain our market share against these lower priced products [parallel imported paroxetine], we offer our customers discounts similar to brand equalisation deals'* However, it was not practical for GSK to negotiate brand equalisation deals with all customers, as noted by [GSK's Finance Director A]: *'there is a large number of pharmacists - about 40% of the market - in respect of whom it is impracticable to negotiate such discounts [brand equalisation discounts].'*¹¹²⁵ This meant that parallel importers or generic suppliers were more likely to be able to supply those customers that GSK could not retain by offering discounts. For example, [GUK's General Manager] stated that: *'many of our customers will not have*

¹¹²⁰ GSK submitted that the Generic Companies more than displaced parallel imports, and took 20 percentage points of 20mg volume share from GSK (GSK SO Written Response (document 2755), paragraphs 8.18–8.20). The CMA has not stated that sales made by the Generic Companies pursuant to the Agreements would displace only sales by parallel importers. The CMA notes that the data submitted by GSK on this point is consistent with that which the CMA has included in Figures 3.4 and 3.5.

¹¹²¹ GSK presentation entitled 'Generic offence strategy in Germany' by [GSK's Head of Marketing (CNS Gastro & Urology)] undated (document 0094), slide 10. In GSK Third Response (document 0750) GSK indicated that 'MSP' referred to the list price at the time of £17.76.

¹¹²² [redacted]WS (document 0901), paragraph 33.

¹¹²³ GSK presentation entitled 'Seroxat Patent Challenge' dated 5 February 2001 (document 0123), page 4.

¹¹²⁴ [redacted]WS2 (GUK) (document 0182), paragraph 3.2.

¹¹²⁵ [redacted]WS1 (Alpharma) (document 0241), paragraph 5.4.

*built up stocks of Seroxat from parallel importers in recent months in the expectation that GUK will launch its generic product.*¹¹²⁶

7.34 The evidence confirms that GSK was successful in protecting its market share of UK-supplied Seroxat sales by replacing sales by parallel importers with sales by the Generic Companies as its distributors:

- For example, in 2002, [GSK's Finance Director A] stated that:¹¹²⁷ *'Before the coming into effect of the Ivax Agreement, about 40% of paroxetine dispensed against prescriptions in the UK was parallel imported. I believe that Distributed Paroxetine sold by Ivax and its sub-distributors has now largely displaced that parallel imported product'*.¹¹²⁸
- As explained in paragraph 7.45, sales of parallel imports continued to decline after GUK's entry into the UK paroxetine market as a GSK distributor¹¹²⁹ such that the impact on GSK's market share for the supply of finished product to pharmacies/wholesalers was limited.¹¹³⁰

Parties' representations

7.35 GSK¹¹³¹ and GUK¹¹³² submitted that the GUK-GSK Agreement resulted in GUK's early entry into the market and introduced more price competition into the supply of paroxetine in the UK. GSK and GUK stated that for this reason the effect of the GUK-GSK Agreement cannot have been to restrict competition. This sub-section addresses those submissions.

¹¹²⁶ [§]WS (document 0901), paragraph 47.

¹¹²⁷ [§]WS1 (Apotex) (document 0333), paragraph 6.8. The CMA notes that the figure of 40% as the market share of parallel importers at the time is too high, see footnote 1130.

¹¹²⁸ See also [§]WS2 (Alpharma) (document 0289), paragraph 3.1: *'Ivax, GUK and Tillomed [...] have taken much of the parallel importers' customer base ...'*, and [§]WS2 (document 1325), paragraph 29: *'In any event, the volume of parallel imports appear to have been reduced significantly and I think it is undoubtedly true that their market share has been replaced by that of the generics [IVAX and GUK].'*

¹¹²⁹ Parallel import sales began to decline following IVAX's entry as a GSK distributor (see paragraph B.167).

¹¹³⁰ The CMA notes that during the GUK Litigation, [GSK's Finance Director A] stated that *'a substantial proportion (about 40%) of the SEROXAT (paroxetine) dispensed in the UK is in the form of parallel imports.'* ([§]WS1 (GUK) (document 0885), paragraph 3.3). This implies that GSK's market share (for the supply of finished product to pharmacists/wholesalers) was 60% during 2001. However, as set out in Tables 3.4 and 3.5, GSK's market share, based on data submitted by GSK, was significantly higher than this, 79% by value and 77% by volume in 2001. At this time GSK remained the sole manufacturer of paroxetine sold in the UK (with a market share by value or volume of 100% at the production level).

¹¹³¹ For example, GSK stated *'Far from restricting competition, the GSK Agreements accelerated early entry of generic paroxetine to the UK market'*. See GSK SO Written Response (document 2755) page 142. See also paragraphs 4.6, 4.15, page 158, paragraphs 6.111, 6.119 and 8.58. See also GSK submission to the OFT dated 27 June 2012 (document 0746), section 5.

¹¹³² GUK SO Written Response (document 2752), paragraph 1.3, page 5, paragraphs 5.7, 6.9, 7.2, Annex 1 to GUK SO Written Response (document 2753), page 3, section 2.4 (pages 14–16). See also GUK submission to the OFT dated 22 February 2012 (document 1214), paragraph 5.3.

Volume restrictions

- 7.36 GSK and GUK submitted that the volume restrictions were not restrictive because the volumes supplied to the Generic Companies were substantial,¹¹³³ and were not binding, based on there being no evidence that GUK requested an increase in volumes subsequent to the signing of the GUK-GSK Agreement and GUK ordered only 95% of its volume allowance in the second year.¹¹³⁴
- 7.37 The CMA considers that the volume restriction was binding, in the sense that GUK ordered the maximum number of packs which it was contractually entitled to, for the reasons set out at paragraph 7.29, and that the Generic Companies would have taken more product had it been available to them. The CMA considers that GSK found no evidence that the Generic Companies requested additional volumes because the Generic Companies understood, given that the volume restrictions were terms required by GSK in the Agreements, and GSK had at the time of their negotiation refused GUK's request for a higher volume allowance (see footnote 1115), that they could not expect any request for additional volumes to be granted.

Supply Price

- 7.38 GSK and GUK submitted that the supply price was at a level such that GUK was able to compete effectively with GSK:
- The Parties stated that the supply price allowed for a substantial margin compared to prevailing prices, to enable the Generic Companies to exert downward pressure on prices, which they did.¹¹³⁵ GSK submitted that the Generic Companies had the ability to sell at competitive prices, on the basis of: (i) the supply price allowing for margins of 35 to 45% against prevailing prices, and (ii) marketing allowances being available for discounting against the supply price.¹¹³⁶
 - GUK priced to the market at a broadly similar level under the GUK-GSK Agreement as it was intending to supply its own product (sourced from Sumika).¹¹³⁷

¹¹³³ GSK SO Written Response (document 2755), paragraphs 1.142, 8.19, 8.46.

¹¹³⁴ GSK SO Written Response (document 2755), paragraph 8.46.

¹¹³⁵ GSK SO Written Response (document 2755), summary box page 257.

¹¹³⁶ GSK SO Written Response (document 2755), paragraphs 8.24–8.26.

¹¹³⁷ GSK SO Written Response (document 2755), paragraph 6.171.

- GUK typically supplied the lowest priced generic paroxetine product until independent generic entry in December 2003, and therefore did '*offer material discounts as compared to IVAX and parallel importers.*' GUK estimated that its customers saved £1.6 million compared to the parallel import price over the duration of the agreements.¹¹³⁸
- The GUK-GSK Agreement provided scope for customers to negotiate lower prices with other suppliers using the threat to switch to GUK as a bargaining tool.¹¹³⁹

7.39 Regarding the submissions in relation to the supply price being at a competitive level:

- The CMA does not accept that the margins available could reasonably have been expected to be used for discounting. As explained at paragraph 7.26, the CMA considers that, as a consequence of the volume restriction, GUK was not incentivised to charge a price that was materially below prevailing levels. Instead, as explained at paragraphs 6.103 to 6.104, the transfer of a restricted volume of paroxetine and the associated margins constituted a value transfer. For the reasons set out at paragraph 6.97 the CMA considers that the marketing allowances did not increase GUK's incentive to offer lower prices. Consistent with these analyses, the CMA observes that the GUK-GSK Agreement did not have a material impact on prevailing prices in the relevant market (see paragraph 7.44).
- The forecast price referred to by GUK is the price it expected to charge on first entering the market. This represents an inappropriate approximation of the impact of its independent generic entry and of true generic competition, which would have been expected to result in significant price decreases over time. GUK's initial price was likely to have been sustained for a short period only (see paragraphs 3.59 to 3.63). For example, the CMA observes that, as predicted by GSK's own expert witness, [X], there were rapid price declines (of 52% in the first six months following independent entry) as the independent entry of Apotex (through its distributors) was followed by the entry of other generic suppliers (see paragraph 3.21).

¹¹³⁸ GUK SO Written Response (document 2752), paragraph 6.9, Annex 1 to GUK SO Written Response (document 2753), page 3, Section 2.4.2 (pages 14–15).

¹¹³⁹ GUK SO Written Response (document 2752), paragraphs 6.9 and 7.3; Annex 1 to GUK SO Written Response (document 2753), pages 3 and 14–15.

- The CMA notes that the £1.6 million which GUK reported its customers saved is likely to be an overestimate of any savings due to the way the pricing data was constructed. In particular, to construct a price that represented the price paid by pharmacies the CMA applied a mark-up to prices for sales made to wholesalers.¹¹⁴⁰ That mark-up was cautiously set at 5%.¹¹⁴¹ Since the SO [Alpharma Ltd's Director of Sales and Marketing] has confirmed that a 20% mark-up would have been the industry norm at the time.¹¹⁴² This recollection is based on a contemporaneous email in which [Alpharma Ltd's Director of Sales and Marketing] stated that a retail price of £13.15 would imply an average selling price of £10.50 for Alpharma (of which 85% of sales would be made to wholesalers), suggesting that the wholesale mark-up was expected to be in the region of 25% to 30%.¹¹⁴³ Taken together, the CMA considers that a mark-up of 5% was unduly cautious given the evidence, and that a higher mark-up was likely to have applied in practice. Therefore the CMA has applied a mark-up of 20% to GUK's wholesale prices accordingly. Based on these revised prices, GUK customers had virtually no price advantage when compared to parallel import prices.¹¹⁴⁴ Moreover, as set out at paragraph 7.43, the

¹¹⁴⁰ See footnote 1148.

¹¹⁴¹ The CMA notes that applying a mark-up of 5% was cautious because 5% was the lowest in the range of estimates for the wholesaler mark-up provided by the Generic Companies (Teva suggested a range of 5% to 17.5%: response dated 17 October 2012 to the Section 26 Notice dated 1 October 2012 sent to Teva (document 2160), Actavis suggested a range of 5% to 100% for short-line wholesalers and 15% to 20% for full-line wholesalers, see the response dated 18 October 2012 to the Section 26 Notice dated 1 October 2012 sent to Actavis (document 1510), while GUK did not provide an estimate). Given that applying a greater mark-up increases the Generic Companies' prices to pharmacies by a greater amount, applying the lowest estimate provided was cautious because it resulted in the lowest possible estimate of prices to pharmacies, to the benefit of the Generic Companies.

¹¹⁴² Witness statement of [Alpharma Ltd's Director of Sales and Marketing], signed on 27 August 2014 (document 3232), paragraph 7.9.

¹¹⁴³ Email chain between [Alpharma Ltd's Director of Sales and Marketing], [Alpharma ApS's Sales and Marketing Director], [Alpharma Inc's Vice President of Intellectual Property], [Alpharma Inc's President (Human Generics)], [Alpharma ApS's patent attorney], [VP New Products – FP at Alpharma ApS], [Alpharma Inc's Chief Financial Officer], [Alpharma Inc's Chief Legal Officer], dated 11–14 October 2002 (document 1361). A mark-up of 30% is based on a selling price to wholesalers of £10.03, which is consistent with a weighted average selling price of £10.50 when 85% of sales are made to wholesalers, and the remaining 15% of sales are made at a price of £13.15 to pharmacies. A mark-up of 25% is based on the expected average selling price of £10.50 mentioned in document 1361 being the selling price to wholesalers, rather than a weighted average selling price to all customers.

¹¹⁴⁴ GUK submitted that the CMA has no basis to assume the recollection of a former Alpharma employee bears any resemblance to GUK's position, and that there was no standard industry practice as regards mark-ups made by wholesalers at the time. GUK also submitted that applying a mark-up of 20% resulted in prices for the Generic Companies which would have exceeded those of parallel importers and Seroxat at the relevant time, which, GUK submitted, was an incoherent and flawed result. (GUK response dated 26 September 2014 to the First Letter of Facts (document 3502), paragraphs 3.4 and 4.1). The CMA notes that [Alpharma Ltd's Director of Sales and Marketing]'s recollection was supported by a contemporaneous email and, in the absence of any estimate from GUK regarding the level of any mark-up applied by wholesalers, considers it reasonable to use the estimate provided by [Alpharma Ltd's Director of Sales and Marketing] as a means of testing the cautious figure previously adopted by the CMA. The CMA agrees that it would not expect the Generic Companies' prices to be materially above those of GSK or parallel importers, though notes that the revision to the mark-up used (as well as an adjustment for rebates to customers made by the CMA following receipt of additional data) has resulted in average prices for GUK within 2% of Seroxat 20mg prices and parallel import paroxetine 20mg prices. The CMA

CMA observes that paroxetine 20mg prices remained broadly constant during the term of the Agreements subsequent to GUK's entry and prior to independent generic entry, and that GUK's entry had no discernible impact on the Seroxat prices that GSK was able to sustain. Furthermore, the CMA remains of the view that, as a consequence of the volume restriction, GUK was not incentivised to reduce prices materially below prevailing levels.

- The CMA does not consider that switching to GUK was a credible threat for customers of GSK or IVAX. Both GSK and IVAX were aware that GUK was subject to a volume restriction and would not be able to meet increased demand from customers were it to lower its price, as explained in paragraph 7.26. Therefore, neither GSK nor IVAX would have been willing to reduce their own prices were customers to attempt this negotiation tactic. For example, in 2003 Moss reportedly received an offer of a price from Alparma which undercut IVAX's market price, albeit that Alparma would (as a consequence of its volume restriction) only be able to supply a proportion of the volumes required by Moss. In response, IVAX told Moss it could not offer reduced prices as all the restricted volumes IVAX was getting were being sold immediately at its market price. Moss also noted that it had received a letter from Alparma confirming that volume limitations were in place, and requested that IVAX also send a letter to confirm that this was the case.¹¹⁴⁵

Competitive pressure on GSK

- 7.40 GSK and GUK submitted that the decline in parallel import volumes was evidence of increased competitive pressure due to the Agreements. GSK's share of sales volumes declined during the Agreements, which, GSK submitted, implies that it faced increased competitive pressure over the period.¹¹⁴⁶
- 7.41 The CMA does not consider that GSK's falling share of sales volumes can be attributed to an increase in competitive pressure. The market share losses suffered by GSK were the consequence of its allocation of volumes to the Generic Companies. However, for the reasons set out at paragraph 7.26, the transfer of a restricted volume of product to the Generic Companies could not

also notes that the market share of parallel importers was extremely low during the GUK-GSK Agreement (for example parallel importers had a market share of 5% by value between May 2002 and November 2003).

¹¹⁴⁵ Moss Pharmacy contact report dated 20 March 2003 (document 1827). Although the report indicates that Alparma had offered Moss a lower price, this is not consistent with Alparma's subsequently sending a letter saying it was constrained in the volumes it could offer.

¹¹⁴⁶ GSK SO Written Response (document 2755), paragraphs 8.21–8.23.

reasonably have been expected to expose GSK to a meaningful increase in competition.

c) *The market developments observed during the GUK-GSK Agreement*¹¹⁴⁷

- 7.42 Although not a necessary part of the analysis of the likely effect of the GUK-GSK Agreement, the CMA considers that the developments observed during the term of the Agreement reveal that there was no material increase in the actual competitive constraints faced by GSK, and the threat of true generic competition was deferred. Developments in the UK paroxetine market during the period of the Agreements are set out at paragraphs 3.380 to 3.398.¹¹⁴⁸
- 7.43 In relation to the deferral of potential competition, the evidence set out at paragraphs 3.382 to 3.383, demonstrates that as a consequence of the GUK-GSK Agreement, GUK deferred its efforts to enter the UK paroxetine market. In particular, GUK did not supply generic paroxetine that was sourced independently of GSK in the period 13 March 2002 to 1 July 2004,¹¹⁴⁹ and, having entered into the GUK-GSK Agreement, GUK chose not to progress orders with Alphapharm (with API being supplied by Sumika),¹¹⁵⁰ which it had identified and sourced paroxetine tablets from (see paragraphs 3.255 to 3.260). GUK's independent generic entry did not take place until after Apotex had eventually prevailed in litigation with GSK in December 2003.
- 7.44 The evidence also demonstrates that, as a consequence of the GUK-GSK Agreement, GSK did not face an increase in the actual competitive constraints it faced until independent generic entry took place in December 2003:
- GUK's entry as a GSK distributor had no meaningful impact on paroxetine 20mg price levels. During the term of the GUK-GSK Agreement, GUK priced at, or very close to, prevailing levels and price levels of paroxetine 20mg stayed fairly constant both immediately following GUK's entry and

¹¹⁴⁷ The CMA is not required, and has not sought, to assess or quantify the actual effects on competition. See paragraph 7.6.

¹¹⁴⁸ In considering developments in prices throughout the term of the Agreements, the CMA has used data provided by the relevant parties on the actual prices, net of discounts and rebates where available, at which branded and generic paroxetine was sold. The CMA does not consider that assessing Drug Tariff reimbursement prices would be sufficient for this purpose given that the Drug Tariff is not necessarily an accurate reflection of actual prices, as it does not take into account, for example, discounts and rebates or parallel import prices (see also paragraphs I.2 –I.7). For a fuller description of the data used, see footnote 611.

¹¹⁴⁹ The GUK-GSK Agreement was terminated with effect from 1 July 2004. GUK subsequently entered the UK paroxetine market selling a paroxetine product sourced independently of GSK. GUK began selling paroxetine 20mg in August 2004, and paroxetine 30mg in February 2005.

¹¹⁵⁰ Witness statement of [Merck's Head of Patents and Raw Material Support Group] in the GUK Litigation, dated 15 October 2001 (document 0900), paragraph 16.

throughout the period when GUK was supplying paroxetine pursuant to the Agreement, until December 2003 when independent generic entry began. For example, paroxetine 20mg and Seroxat 20mg prices in the three months after GUK's entry pursuant to the GUK-GSK Agreement were 1% lower and 0.5% lower respectively compared to the three months before GUK's entry.¹¹⁵¹

- GUK's entry as a GSK distributor had no impact on paroxetine 30mg price levels. The price of paroxetine 30mg remained broadly constant throughout the GUK-GSK Agreement and GSK remained the sole supplier of paroxetine 30mg in the UK until after independent generic entry in February 2004.¹¹⁵²
- GSK did not face any actual competition at the manufacturer level. GSK remained the sole manufacturer of paroxetine sold in the UK throughout the term of the Agreements and prior to independent generic entry which began in December 2003 (with a market share by value or volume of 100% at the production level).

7.45 The impact of GUK's entry as a GSK distributor on GSK's market shares was limited as a consequence of the volume restriction included in the GUK-GSK Agreement. Following GUK's entry under the GUK-GSK Agreement, GSK retained an average market share for the supply of finished product to pharmacies/wholesalers of 70% by value (or 65% by volume).¹¹⁵³ During the period between its entry under the GUK-GSK Agreement in May 2002 and November 2003, the last month prior to independent generic entry, GUK achieved an average market share for the supply of finished product to pharmacies/wholesalers of 11% by value (or 14% by volume).¹¹⁵⁴ In the first nine months (between April 2002 and January 2003) that GUK supplied paroxetine as a GSK distributor, the market share for the supply of finished product to pharmacies/wholesalers by volume of the parallel importers fell from around 14% to just 2%.

¹¹⁵¹ This is based on a comparison of weighted average paroxetine 20mg and Seroxat 20mg prices in the period February 2002 to April 2002 with May 2002 to July 2002.

¹¹⁵² As set out at paragraph 3.383, independent generic entry as regards paroxetine 30mg began later than as regards paroxetine 20mg.

¹¹⁵³ Calculated as GSK's average market share between May 2002 and November 2003, based on data provided by relevant parties.

¹¹⁵⁴ There was no market expansion following GUK's entry into the UK paroxetine market as a GSK distributor, and nor could GSK have reasonably expected it to result in expansion (see paragraph 6.103).

iii) The counterfactual

- 7.46 This sub-section examines the competitive landscape that was likely to have existed in the absence of the GUK-GSK Agreement.
- 7.47 Absent the GUK-GSK Agreement, GUK would have continued to be a competitive threat and remained a potential competitor to GSK that was pursuing its efforts to enter the market independently of GSK.¹¹⁵⁵ GUK's competitive behaviour would not have been distorted by value transfers made in return for entry restrictions. The realistic and likely outcomes are that GUK would have pursued its challenge to GSK's patent claims or, alternatively, that GUK would have entered into a settlement on terms that were not 'bought' using the value transfers, and that legitimately reflected the uncertainty regarding GSK's patent claims.

a) GUK seeks to enter the UK paroxetine market independently of GSK

- 7.48 Had GUK not entered into the GUK-GSK Agreement (or an alternative settlement agreement, see paragraphs 7.54 to 7.57), the prospect of GUK's potential independent entry would have been maintained (see paragraph 7.12). In the absence of the GUK-GSK Agreement, it would have been open to GUK to reject other settlement proposals, to continue with its efforts to enter the UK paroxetine market independently of GSK and to continue to defend the GUK Litigation. In that case, the prospect of GUK's independent entry, and of true generic competition, would have been maintained and the processes necessary to determining whether it could have entered the UK paroxetine market would have continued.
- 7.49 Had GUK declined to settle, the hearing with GSK would have commenced almost immediately (see paragraph 3.305) and the process necessary to determining the validity of the relevant patent claims, and whether GUK's product was non-infringing, would have commenced.
- 7.50 The progression of that litigation would have been of relevance to other potential competitors,¹¹⁵⁶ in addition to GUK, as it would have provided

¹¹⁵⁵ As explained at paragraph 7.12, at the time the GUK-GSK Agreement was entered into, the CMA finds that GUK was a potential competitor to GSK.

¹¹⁵⁶ GUK stated that the counterfactual to the GUK-GSK Agreement was that litigation would have prevented GUK from entering the UK paroxetine market for a considerable time: *'Taking all these different considerations into account, it is likely - in the counterfactual - that GUK would not have launched until the middle and possibly the end of 2003.'* (GUK submission to the OFT dated 22 February 2012 (document 1214), paragraph 5.3). The CMA notes however that GUK agreed not to enter the market for the duration of the Agreement (see paragraphs 6.88–6.90) and that, in the event that it then launched its own generic paroxetine product after the

greater clarity as to the validity of the Anhydrate Patent, and the terms on which a generic product was found to be non-infringing.¹¹⁵⁷ Further, it would also have affected GSK's incentive to pursue litigation against other companies that sought to supply generic paroxetine in the UK. For example, IVAX noted that if it was successful in patent litigation with GSK the relevant '*[p]rinciples will be established for all*'¹¹⁵⁸ and similarly GSK acknowledged, with respect to Alparma, that independent entry by a generic supplier would lower entry barriers for other generic suppliers: '*Alparma's presence on the market would be a signal that they need no longer fear an injunction.*'¹¹⁵⁹

7.51 It is therefore likely that, had the litigation progressed and had GUK successfully defended its product launch before the courts, other generic suppliers would have entered soon after.¹¹⁶⁰ For example, GSK expected that entry by one generic supplier would '*result in the introduction of other generic products onto the marketplace shortly thereafter with a further wave following*

expiry of the Agreement, GUK would have continued to face the prospect of litigation from GSK. To that extent, the GUK-GSK Agreement served to delay the processes relevant to resolving the dispute (including the entirety of the litigation process that GUK refers to), whereas in the counterfactual that process had already been commenced. To that extent, the GUK-GSK Agreement delayed the potential emergence of true generic competition.

¹¹⁵⁷ By way of example, after the Apotex Parties successfully demonstrated a product was non-infringing, several generic suppliers entered the UK paroxetine market (see paragraph 3.21).

¹¹⁵⁸ 'Serostat (paroxetine): 14th March 2001' dated 14 March 2001 (document 1699).

¹¹⁵⁹ [redacted] WS2 (Alparma) (document 0289), paragraph 6.2.

¹¹⁶⁰ Although a judgment may have related only to a specific product that did not infringe GSK's paroxetine patents, such as whether GUK's product infringed valid patent claims, a judgment in GUK's favour was likely to prompt further entry and to substantially limit GSK's incentive to pursue further litigation against other parties. For example, GUK's entry was very likely to have led to entry by at least Ratiopharm and Novartis (to whom GUK had agreed to sub-license its product) and GUK was considering sub-licencing its product to other suppliers (see paragraph 3.261). Their independent generic entry would have been expected to result in the substantial price declines that GSK was seeking to avoid by pursuing litigation, limiting GSK's incentive to pursue further litigation in response to further entry. Conversely, had GSK prevailed in litigation because multiple claims of the anhydrate patent were held valid, this had the potential to disincentivise other generic suppliers from pursuing independent entry. This is consistent with the views of [GSK's Finance Director A], who explained that: '*[t]he market could continue as it was if GSK won litigation but if it lost the patent then everything would go. There would be intense competition from the generics in the near future. GSK therefore decided, to provide for some period of certainty, to enter into supply agreements* (Note of meeting between the OFT and GSK dated 19 December 2011 (document 0688), paragraphs 19 and 20). Similarly, a note in which IVAX considered its options for the launch of paroxetine, dated 14 March 2001, states that one benefit of entering into an agreement along the lines of the IVAX-GSK Agreement is that '*every one [sic] else has to start again*'. In contrast if it did choose to test the patent '*[p]rinciples will be established for all*' ('Serostat (paroxetine): 14th March 2001' dated 14 March 2001 (document 1699)). The CMA also notes that entry by one or more generic suppliers would change the risk and damages profile such that other generic suppliers may also have entered, as happened following the Apotex litigation. For example, (i) GSK's incentive to litigate in response to further entry would have been limited following the entry of GUK, Ratiopharm and Novartis, as their independent generic entry would have been expected to result in the substantial price declines that GSK was seeking to avoid; and (ii) other potential entrants would have had less concern that their entry would expose them to a significant damages claim from GSK, as the entry of other firms would have already caused substantial price declines. This is consistent with GSK's statement that independent entry from Alparma would be a signal to other generic companies that they need no longer fear an injunction (GSK SO Written Response (document 2755), paragraph 8.50). For these reasons the CMA does not accept GSK's submission that a judgment as to infringement or non-infringement for one product does not necessarily assist other generic companies and that a judgment concerning GUK's product may not benefit other generic suppliers if they had a different API supplier (GSK SO Written Response (document 2755), paragraph 8.42).

*as little as 7 months later once relevant marketing authorisations are in place.*¹¹⁶¹

- 7.52 At the time the GUK-GSK Agreement was entered into Alpharma was close to being issued an MA for its generic product, having applied some 10 months earlier (see paragraph 3.323), and [another supplier] was about to submit an application for a UK MA.¹¹⁶² If GUK (along with Ratiopharm and Novartis – see paragraph 3.261) and Alpharma had entered independently, it is also likely that IVAX would have terminated its Agreement with GSK and entered the market. True generic competition, between GSK and a number of generic competitors, was expected to result in substantially lower prices¹¹⁶³ and reduced market shares for GSK (see paragraphs 3.59 to 3.63 and 3.161 to 3.164).
- 7.53 In summary, it would have been reasonable to expect that, had GUK declined to enter into the GUK-GSK Agreement (or an alternative settlement agreement, see paragraphs 7.54 to 7.57) and instead remained a potential competitor that was seeking to enter the UK paroxetine market independently of GSK, the GUK Litigation would have proceeded to trial (scheduled to start the day after the GUK-GSK Agreement was entered into, see paragraph

¹¹⁶¹ [REDACTED]WS1 (GUK) (document 0885), paragraph 7.10.

¹¹⁶² [REDACTED] submitted its UK MA application on 20 March 2002 (MHRA spreadsheet entitled ‘MHRA list of product licences containing paroxetine hydrochloride granted between 1999 and 2005’ dated 11 June 2012 (document 2590)).

¹¹⁶³ The CMA notes that during the GUK Litigation [GUK’s General Manager] suggested that the extent of any price fall following GUK’s independent entry would be limited, as he noted that GUK had offered customers a generic product at a similar price to the parallel import price of £11.50 per pack, and stated that: *‘Parallel imports at this price have not driven down the price of the branded product, so there is no reason to believe that a generic product should do so.’* ([REDACTED]WS (document 0901), paragraph 54). The CMA notes that although the price [GUK’s General Manager] referred to is the price GUK expected to charge on first entering the market, this represents an inappropriate approximation of the impact of GUK’s independent entry and of true generic competition, which would have been expected to result in significant price decreases over time as more generic suppliers entered the market. GUK’s initial price was likely to have been sustained for a short period only (see paragraph 3.59–3.63). For example, the CMA observes that, as predicted by GSK’s own expert witness, independent generic entry resulted in rapid price declines as other generic suppliers entered the market (see paragraph 3.387–3.390). The CMA also observes that the extent to which parallel importers reduce their prices will depend on the price they are able to purchase paroxetine in low-cost member states. For example, in 2002 paroxetine in France (where [GSK’s Finance Director A] estimated most paroxetine imported into the UK was from: see, for example, [REDACTED]WS2 (GUK) (document 0182), paragraph 3.2) cost EUR 0.63 per tablet (see GSK presentation entitled ‘Seroxat Price Strategy Gothenburg 29 August. By [GSK’s Pricing Manager for Europe]’ dated 29 August 2002 (document 0313), slide 16) which equates to £11.80 per pack when converted into pounds sterling using the average exchange rate in the year to August 2002 (the date of document 0313). By contrast, had GUK entered the market independently it faced an initial cost of goods of £4.63 per pack, based on the price at which GUK had been invoiced for the tablets by Alphapharm (paroxetine 20mg packs of 30 were invoiced at \$6.69. See email from [GUK employee] to [the Chief Executive of Merck Generics Group] dated 20 March 2002 (document 1032) and email from [GUK’s Finance Director B] to [GUK’s Commercial Director] dated 19 April 2002 (document 1046). This has been converted from at a rate of USD 1.4434 = GBP 1.00 (the Bank of England’s monthly average rate for April 2002), which indicates a greater scope for price reduction by GUK than by parallel importers who were already (reportedly) pricing around the level of their marginal cost.

3.305). As a consequence, both GSK's expected returns¹¹⁶⁴ and market-wide returns would have been lower due to the threat of GUK's successful independent generic entry. An ongoing litigation process would have preserved (rather than deferred) the potential for true generic competition and the associated price declines.

b) GSK and GUK enter into a settlement agreement on less restrictive terms

- 7.54 The alternative outcome in the counterfactual is that GSK and GUK would have entered into a settlement agreement on less restrictive terms.
- 7.55 For example, had GSK offered a settlement agreement that did not involve the value transfers that GSK made in return for entry restrictions, it is reasonable to expect that GUK would have required an agreement that included other terms that would provide it with sufficient incentive to settle the litigation at the expense of its ongoing efforts to enter the market with generic paroxetine. Absent recourse to value transfers, GSK would have been required to offer more competitive entry terms to GUK to provide GUK with alternative sources of remuneration and a sufficient incentive to settle.¹¹⁶⁵
- 7.56 Any such settlement agreement could have taken one of a number of forms (for example, on the basis of an alternative supply agreement, agreeing a date (prior to the date of patent expiry) on which GUK could launch its generic product¹¹⁶⁶ or allowing GUK to enter on condition that it paid a royalty to

¹¹⁶⁴ That is, the average of its possible profits going forward, taking account of the potential revenue and costs associated with each possible outcome (for example, the success or otherwise of independent generic entry), and the likelihood associated with each.

¹¹⁶⁵ This is consistent with the views of [GSK's Finance Director A] who stated that GSK used the marketing allowance so that a higher supply price could be adopted; one of GSK's objectives was to ensure that list prices in the UK did not deteriorate, because this would also have an impact on the price paid in other countries whose reimbursement systems benchmarked their prices against UK prices: [REDACTED]1 (document 4008R), pages 30–31. GUK submitted that there is no reference to GUK at pages 30–31 of the [REDACTED]1 (GUK Second Letter of Facts Response, document 4162). However, the CMA notes that during the post-SSO witness interview [GSK's Finance Director A] noted that the rationale for the Agreements was common across the Agreements ([REDACTED]1 (document 4008R), page 44), and confirmed that he had no additional comments to make in relation to the promotional allowance in the GUK-GSK Agreement that were distinct from those he had made regarding the IVAX-GSK Agreement (see [REDACTED]1 (document 4008R), page 50). Therefore the CMA considers that although the points referred to were discussed in the context of the IVAX-GSK Agreement, [GSK's Finance Director A's] comments are equally applicable to the GUK-GSK Agreement.

¹¹⁶⁶ GUK has stated that 'An agreement with GSK to wait for a certain period before entering the market was not viable. The important point and the real prize for generic companies was for a 'Day 1' launch. If GUK had agreed to come in at a later date, the market would have changed and may have been dead. GUK wanted to be the first generic to market.' (Note of meeting between the CMA and GUK dated 7 February 2012 (document 1210), paragraph 15). However, the CMA notes that by entering into the GUK-GSK Agreement GUK did give up the prospect of being the first generic to enter the market independently of GSK because as a result of the Agreement GUK's independent entry was delayed until such a time as following the expiry of the Agreement it recommenced its efforts to enter (by which time other generic suppliers may potentially have overtaken GUK in their entry preparations), or the Agreement terminated following successful generic entry by other generic suppliers. In any case, the CMA does not consider that a generic supplier's position of wishing to be first into the

GSK). The CMA is satisfied that the negotiation of an alternative settlement agreement, including more competitive terms, was a realistic outcome in the counterfactual. For example, GUK and Alpharma both internally considered the possibility that a settlement agreement with GSK could include the payment of a royalty to GSK in return for GSK granting it a non-exclusive licence to sell its product (see paragraphs 3.289 and 3.346).¹¹⁶⁷ Alpharma also put to GSK the suggestion that they could agree an appropriate date (prior to the date of patent expiry) on which Alpharma could launch its own product, but such an approach was rejected by GSK (see paragraphs 3.355 to 3.357).¹¹⁶⁸ Moreover, settlement agreements that do not raise competition concerns are common in the pharmaceutical sector. For example, the CMA notes that empirical evidence from the United States supports the proposition that branded and generic suppliers can settle their patent disputes without using payments and similar value transfers that are made in return for entry restrictions.¹¹⁶⁹

market is incompatible with agreeing an appropriate entry date. For example, if the relevant parties had determined that the originator's patent was vulnerable to challenge such that the generic supplier's early entry was a realistic outcome, there would presumably be potential for them to agree to an entry date that still provided the generic supplier with a period in which it was the first generic supplier to enter the market.

Merck submitted that the CMA's view is irrelevant as it was GUK that would have taken this commercial decision, and it has expressly said that it would have rejected an offer containing an agreed entry date (see Merck SO Written Response (document 2764), paragraph 5.71). The CMA does not consider that *ex post* speculation by the Parties as to what they may have been willing to consider is informative in a situation in which it is not possible to state with certainty what, if any, settlement Parties might have reached had it not been possible to use value transfers to induce entry restrictions. The CMA has not sought to do this and has instead contrasted the competitive situation under the terms of the GUK-GSK Agreement with the range of realistic scenarios envisaged in the counterfactual in which the Generic Companies remained potential competitors that were continuing to seek to enter the market independently of GSK. See also paragraphs 1.8–1.13.

¹¹⁶⁷ The CMA notes that agreeing a licencing arrangement as part of a settlement agreement was not uncommon. For example, in a meeting with the OFT on 7 February 2012, GUK noted that: *'it was also quite common for there to be some sort of licence in return for compensation but the terms of the licence would be a matter for negotiation. [GUK's legal representative] thought that the key factors in the negotiation would be: (i) whether GSK believed that they would win/lose; (ii) the strategy with Norton and whether GUK could blow this out of the water; (iii) the cross-undertaking in damages so if GSK lost they would have exposure to pay damages to GUK; and (iv) GSK's ability to supply the product.'* (note of meeting between the OFT and GUK dated 7 February 2012 (document 1210), paragraph 16).

¹¹⁶⁸ The CMA acknowledges that Alpharma's proposal in this example also included the suggestion that GSK make a value transfer to Alpharma as part of the settlement. Without taking a view on the legitimacy of this settlement proposal, the CMA considers that this proposal nonetheless illustrates the principle that Alpharma was open to other types of settlement, and deemed an early entry agreement to be a sufficiently credible option to put to GSK during negotiations.

¹¹⁶⁹ See paragraph 6.25. Moreover, the evidence on settlement agreements concluded in the US indicates that branded and generic companies can settle their patent disputes without using value transfers in return for entry restrictions. For example: *'A third agreement provided for payment of a royalty by the generic to the brand based on the generic company's sales', 'the brand company agreed to license and supply its product to the generic company in exchange for royalties and a share of the generic's profits from marketing the product', Summary of Agreements Filed in FY2004 (available at: <https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/050107medicareactrpt.pdf>), section I.A.1.a. first paragraph, section I.A.1.b. first paragraph, section I.A.1.c.(1) first paragraph, section I.A.1.c.(2) first paragraph, section I.A.1.d. first paragraph; *'Seven of the 11 final settlements did not restrict generic entry either because [...] the agreement included a license to the brand's intellectual property. [...] Three of these seven agreements included no compensation to either party, two required the generic to pay a royalty on its sales to the brand [...].'* Summary of Agreements Filed in FY2005 (available at:*

7.57 In summary, it would have been reasonable to expect in the counterfactual that any agreement that GUK and GSK entered into would not have included restrictions that GUK only accepted in return for value transfers from GSK, and would have provided for more competitive terms as a result.

c) Representations

7.58 The SO Addressees submitted that the CMA has arbitrarily selected only those counterfactuals that would be more competitive than in the case of the Agreements, rather than realistic and likely scenarios.¹¹⁷⁰ The CMA does not accept these submissions, and considers other outcomes to be unrealistic and unlikely.

7.59 For example, at the time the GUK-GSK Agreement was entered into, GUK was a potential competitor that was seeking to enter the market independently of GSK (see paragraph 7.12), and therefore GUK ending the GUK Litigation (and its efforts to enter the UK paroxetine market independently of GSK) does not represent a realistic or likely counterfactual. Contrary to GUK's submissions,¹¹⁷¹ the evidence set out at paragraphs 6.47 to 6.64 indicates

<https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/fy2005drugsettlementsrpt.pdf>), Section C, first paragraph; *'The brand granted the generic a license to enter the market no later than the expiration of the earlier-expiring patent (including paediatric exclusivity) in exchange for a royalty on the generic's sales of the product from entry until the expiration of the later-expiring patents.'* Summary of Agreements Filed in FY2006 (available at: <https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/mmareport2006.pdf>), Section B, first paragraph; *'In three of the eleven settlements, the parties agreed to dismiss the patent litigation, and the brand granted the generic a license to enter as of a certain date prior to patent expiry.'* Summary of Agreements Filed in FY2007 (available at: <https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/mmaact.pdf>), section 1B, first paragraph; *Summary of Agreements Filed in FY2008* (available at: <https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/100113mpdim2003rpt.pdf>), section B, first paragraph; *Overview of Agreements in FY2010* (available at: <https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/1105mmaagreements.pdf>), page 1; *'Despite the record number of potential pay-for delay settlements in FY 2012, the vast majority of patent settlements (greater than 70%) continued to be resolved without compensation to the generic manufacturer.'* Overview of Agreements in FY2012 (available at: <https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf>), page 2; *Overview of Agreements Filed in FY2013* (available at: <https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement/141222mmafy13rpt-1.pdf>), page 2.

¹¹⁷⁰ Merck submitted that the CMA had not considered the full range of scenarios and *'arbitrarily selects [...] only those scenarios that it considers would have led to more competitive outcomes than actually occurred.'* (Merck SO Written Response (document 2764), paragraph 5.13). Teva submitted that the CMA seemed to have *'cherry picked'* its counterfactuals (Teva SO Written Response (document 2750), paragraph 238).

¹¹⁷¹ GUK has stated that *'by the time GUK would have cleared the way and entered the market with its own product, such entry would no longer have been commercially viable.'* (GUK submission to the OFT dated 22 February 2012 (document 1214), paragraph 4.4. The CMA notes that in a meeting with the OFT, GUK's legal representative *'acknowledged that perhaps "not commercially viable" may have been too strong a turn of phrase, and commercially attractive/ "interesting" could have been used instead'* (Note of meeting between the OFT and GUK dated 6 November 2012 (document 2358), paragraph 38). The CMA also observes that GUK subsequently began supplying its own generic paroxetine, both paroxetine 20mg (from February 2005) and paroxetine 30mg (from August 2004). This demonstrates that GUK did not, in the event, take the decision that entry was no longer

that GUK was continuing its strategy of bringing generic paroxetine to market independently of GSK, and that, absent settlement with GSK, GUK would have continued to contest the GUK Litigation¹¹⁷² (for which the hearings were due to commence the day after the GUK-GSK Agreement was entered into (see paragraph 3.305). Furthermore:

- The Parties themselves recognise that continued litigation was an option had an alternative settlement not been reached. For example, GSK stated that if no settlement was reached *‘the result would have been a continued dispute and ultimately litigation.’*¹¹⁷³
- The CMA notes that most of the key investment required in developing and launching a product had already been made prior to entering into the GUK-GSK Agreement, such that this investment represented sunk costs. Sunk costs would not have been relevant to the decision of whether to continue to pursue entry.

7.60 In this context, the CMA considers it highly unlikely and unrealistic that GSK and GUK would have entered into a settlement agreement that provided for a similarly (or more) restrictive outcome than that which resulted from the GUK-GSK Agreement. Absent recourse to value transfers which had the purpose of delaying the potential emergence of true generic competition, GUK would have required alternative more competitive terms to ensure its returns were

commercially attractive or viable (Annex 2 of the response dated 13 July 2012 to part of the Section 26 Notice dated 23 March 2012 sent to GUK, added to on 5 April 2012, and to the Section 26 Notice dated 13 June 2012 sent to GUK (document 1267)).

¹¹⁷² Merck submitted that GUK may not have chosen to proceed with litigation (see Merck SO Written Response (document 2764), paragraphs 5.31–5.44 and Merck’s Economic Annex (the Oxera Report) (document 2766)). For the reasons set out at paragraph 7.59, the CMA does not consider discontinuation of litigation, in the absence of alternative settlement, was a realistic outcome at the time the GUK-GSK Agreement was entered into. As regards the Economic Annex that Merck submitted showing, according to Merck, that under a wide range of reasonable assumptions GUK would not have continued with litigation, the CMA considers that there are a number of assumptions which are unrealistic and likely to significantly understate the potential profits from successful entry. For example, the modelling assumed that GUK would achieve only a 5% market share during widespread generic entry, even though GUK in fact had a share of 19% by volume by 2005. The CMA further notes that the model’s assumptions regarding GUK’s forecast profit levels (of £1.7 million to £1.8 million) during generic entry are not consistent with GUK’s own internal forecasts of such profits. For example, internal emails discussing stock requirements (covering both out-licenced supply and GUK total requirements) assume total supply by GUK of 160,000 packs per month, estimated by GUK to be a 46% market share (See email chain between [a GUK Sales and Marketing employee], [GUK’s General Manager], [GUK’s Sales and Marketing Director] and [GUK’s Head of Contract Sales] dated 30 October 2001 (document 0923) and email chain between [a GUK Sales and Marketing employee], [a GUK Special Projects Manager], [GUK’s Head of Contract Sales], [GUK’s General Manager] and [GUK’s Sales and Marketing Director] dated 31 October to 9 November 2001 (document 0927)). Moreover, [GUK’s General Manager] noted that GUK’s expected profits prior to entering into the GUK-GSK Agreement were in the region of £6 million in the first year, as he stated that the GSK offer *‘would deliver a similar bottom line (£5.6m v’s £6m)’*. (Email chain between [Merck’s Head of Patents and Raw Material Support Group], [the Chief Executive of Merck Generics Group], [GUK’s General Manager], [GUK’s Head of Research and Development], [Head of Merck Operation in Canada], [the Head of Merck Operation in Australia] and [GUK’s Managing Director] dated 31 December 2001 (document 0955)).

¹¹⁷³ GSK SO Written Response (document 2755), paragraph 4.21(c).

sufficient to accept an alternative settlement rather than continuing to pursue litigation and seek independent entry (see also paragraphs 7.54 to 7.57).

d) Conclusion

7.61 The analysis set out at paragraphs 6.84 to 6.141 demonstrated that the purpose of the value transfers (totalling at least £21.3 million to GUK and £50.9 million to the Generic Companies overall) was to induce GUK to defer its efforts to enter the UK paroxetine market independently of GSK. GSK had therefore determined that, if GUK had been permitted to remain a potential competitor that was continuing with its efforts to enter the market, GSK faced the prospect of lower expected profits¹¹⁷⁴ than if GSK were to make value transfers to GUK in return for its acceptance of entry restrictions. Put another way, GSK itself considered that, absent the GUK-GSK Agreement, the competitive outcomes associated with GUK's position as a potential competitor provided for a far greater constraint than GSK faced having entered into the GUK-GSK Agreement.

7.62 Consistent with this, the CMA is satisfied that, absent the GUK-GSK Agreement, GUK would have continued to be a threat, and remained a potential competitor to GSK that was seeking to enter the UK paroxetine market. This would have led to an increase in the competitive constraints being exerted on GSK, either through the process of litigation challenging GSK's patents, or through a less restrictive settlement recognising the uncertainty inherent in that litigation.

iv) *The absence of other relevant sources of competition to GSK meant that the GUK-GSK Agreement assisted GSK in preserving its market power*

7.63 By entering into the GUK-GSK Agreement, GSK materially strengthened its ability to continue to delay the potential emergence of true generic competition, thereby assisting GSK in preserving its market power:

- As set out at paragraph 7.16, at the time the GUK-GSK Agreement was entered into, the only competitive constraints that GSK faced in the UK paroxetine market were provided by parallel importers of its own product and by IVAX as a GSK distributor. However, parallel importers faced several barriers to expansion which limited the extent to which they were capable of challenging GSK's market position (see paragraph 4.113), and IVAX's entry as a distributor for GSK was not likely to materially increase

¹¹⁷⁴ That is, the average of its possible profits going forward, taking account of the potential revenue and costs associated with each possible outcome (for example, the success or otherwise of independent generic entry), and the likelihood associated with each.

the actual competitive constraints faced by GSK (see paragraph B.144). At the time the GUK-GSK Agreement was entered into, there were no independent suppliers of generic paroxetine in the UK paroxetine market.

- At the time the GUK-GSK Agreement was entered into, the GUK Litigation was well advanced and the relevant hearing was due to commence imminently (see paragraph 3.305). Litigation had not commenced in relation to any other generic suppliers, and entering into the GUK-GSK Agreement would therefore ensure that the process that would establish whether generic entry was legal would be delayed, and the uncertainty regarding GSK's patent position would be prolonged.¹¹⁷⁵
- At the time of the GUK-GSK Agreement, GSK was aware that Neolab was intending to launch a paroxetine product in the UK, and it had sent a warning letter accordingly.¹¹⁷⁶ Alpharma was the only other supplier that was close to entering the UK paroxetine market (see paragraph 7.52). This meant that, having entered into the GUK-GSK Agreement, GSK had limited the probability of its patent position being successfully challenged, and of true generic competition emerging. It also ensured that GSK would only need to reach an agreement with two further parties¹¹⁷⁷ to ensure that the potential for independent generic entry was further delayed.¹¹⁷⁸ Doing so would have meant that its patent position would remain unchallenged, and it could continue to commence litigation against (and seek to settle with) other potential competitors should any subsequently emerge. Entering into the GUK-GSK Agreement with one of two of the known potential entrants therefore increased the potential for GSK to continue its strategy of securing agreements that would defer the potential emergence of true generic competition.

7.64 The anti-competitive effects of the GUK-GSK Agreement were reinforced in view of the context: GSK had previously entered into the IVAX-GSK Agreement and subsequently entered into the Alpharma-GSK Agreement and

¹¹⁷⁵ See footnote 1090.

¹¹⁷⁶ GSK Second Response, Part Two (document 0734), paragraph 6.11. GSK also noted that Tillomed had obtained a UK MA. However, the CMA is aware that by the date the GUK-GSK Agreement was entered into, Tillomed had already entered into the IVAX-Tillomed Agreement, granting IVAX exclusive rights to use its MA in the UK, and as such Tillomed was not in a position to imminently enter at the time of the GUK-GSK Agreement.

¹¹⁷⁷ The BASF Litigation was ongoing, and [X] had only just applied for an MA so its market entry was not yet imminent.

¹¹⁷⁸ GUK submitted that this statement indicated that a key element of the CMA's theory of harm is the combined effect of a number of separate agreements (Annex 1 to GUK SO Written Response (document 2753), page 9). The CMA considers that GUK has misconstrued the CMA's case, which is that each Agreement on its own, by removing a potential competitor from seeking to enter the UK paroxetine market, was likely to result in a reduced chance of independent generic entry occurring, and enable GSK to further maintain its strategy of using agreements with potential competitors to delay the threat of true generic competition.

a settlement agreement with [X]. Together these agreements helped to make sure that each threat of potential independent generic entry was deferred, and that there was no material increase in the actual competitive constraints that GSK faced.

D. Assessment of whether the Alpharma-GSK Agreement restricts competition by effect

7.65 In this Section the CMA sets out its detailed assessment of the likely effect of the Alpharma-GSK Agreement¹¹⁷⁹ on competition.

7.66 In summary, the CMA finds that the likely effect of the Alpharma-GSK Agreement was to restrict competition between 12 November 2002 and at least 30 November 2003. In particular, the CMA finds that:

- The context at the time of the Alpharma-GSK Agreement was as follows:
 - As set out at paragraphs 6.65 to 6.82, at the time the Alpharma-GSK Agreement was entered into Alpharma was a potential competitor to GSK in the UK paroxetine market for both paroxetine 20mg and paroxetine 30mg. Alpharma was pursuing entry strategies aimed at entering the market with generic paroxetine sourced independently of GSK;
 - As set out at paragraphs 6.34 to 6.39, had true generic competition emerged, such competition was expected to result in significant decreases in paroxetine prices in the UK and a decline in GSK's market share; and
 - At the time the Alpharma-GSK Agreement was entered into, GSK had market power in the UK paroxetine market.
- The value transfers in the Alpharma-GSK Agreement had the likely effect of inducing Alpharma to accept entry restrictions, thereby delaying its potential independent entry¹¹⁸⁰ and the associated price decreases. As regards the structure of the market, the Alpharma-GSK Agreement also had the likely effect of assisting GSK in preserving the patent entry barriers

¹¹⁷⁹ As set out at paragraph 5.11, the CMA finds that the value transfers were made directly from GSK to Alpharma, pursuant to the Alpharma-GSK Settlement Agreement, with the following exception. The transfer of a restricted volume of paroxetine was made by GSK to Alpharma, indirectly via IVAX pursuant to the IVAX-GSK Agreement and the Alpharma-IVAX Agreement.

¹¹⁸⁰ Moreover, Alpharma was unable to facilitate generic market entry by transferring or assigning its MA to another company.

faced by Alparma and other potential entrants and thereby enabling GSK to maintain its market power.¹¹⁸¹

- Alparma's entry as a distributor of GSK product was not likely to materially increase the actual competitive constraints faced by GSK. As a consequence of the volume restriction Alparma's entry was likely to have no meaningful impact on actual competition in the UK paroxetine market.¹¹⁸²
- Developments observed in the UK paroxetine market during the term of the Alparma-GSK Agreement are consistent with this analysis: (i) Alparma deferred its efforts to enter the market independently of GSK and (ii) Alparma's restricted entry as a GSK distributor had no material impact on market prices.
- Absent the restrictions in the Alparma-GSK Agreement, Alparma would have remained a potential competitor that was pursuing its efforts to enter the market independently of GSK. Alparma's competitive behaviour would not have been distorted by value transfers made in return for entry restrictions. The realistic and likely outcomes are that Alparma would have continued with its efforts to enter the UK paroxetine market independently of GSK, or else it would have settled the litigation on less restrictive terms of entry.
- The absence of other relevant sources of competition to GSK meant that the Alparma-GSK Agreement assisted GSK in preserving its market power, given:
 - that at the time the Alparma-GSK Agreement was entered into, GSK did not face true generic competition;
 - that no other generic suppliers were as advanced in launching generic paroxetine and/or challenging GSK's patent claims; and
 - the limited number of further potential entrants.

¹¹⁸¹ Consistent with this, paragraph 25 of the Commission's Article 101(3) Guidelines notes that: '*Negative effects on competition within the relevant market are likely to occur when the parties individually or jointly have or obtain some degree of market power and the agreement contributes to the creation, maintenance or strengthening of that market power or allows the parties to exploit such market power.*'

¹¹⁸² Even if it had been the case that such entry materially constrained GSK, the CMA considers it likely that in the counterfactual the terms of entry would have been less restrictive. That is because in the absence of a value transfer in return for entry restrictions it is reasonable to expect that Alparma's acceptance of any settlement agreement would have required more competitive terms because GSK would have been required to offer more competitive terms to Alparma to provide Alparma with alternative sources of remuneration and a sufficient incentive to settle (see paragraph 7.107).

7.67 This Section sets out, in relation to the Alpharma-GSK Agreement:

- GSK's competitive position;
- the restrictive effects of the Agreement;
- the counterfactual; and
- other relevant sources of competition to GSK.

7.68 A number of the representations in relation to the effect of the Alpharma-GSK Agreement are discussed in this Section. Representations of relevance to all of the Agreements are presented in Annex I.

i) GSK's competitive position

7.69 As set out at Part 4, the relevant market is the supply of paroxetine in the UK.

7.70 The CMA finds that, at least between January 1998 and November 2003 (the month before independent generic entry began, see paragraph 3.21), GSK had market power in the UK paroxetine market.¹¹⁸³ In particular:

- GSK's market share for the supply of finished product to pharmacies/wholesalers (by volume) was in excess of 60% and it remained the sole manufacturer of paroxetine sold in the UK between January 1998 and November 2003 (with a market share by value or volume of 100% at the production level). Rival suppliers' shares were significantly smaller and not capable of undermining GSK's leading position in the relevant market (see paragraphs 4.105 to 4.110).
- Prior to independent generic entry, GSK was able to sustain prices and profits that were significantly higher than those observed following independent generic entry. Prices were some 90% higher and profits were around 8.5 times higher than those observed following independent generic entry (see paragraph 4.111).

¹¹⁸³ The CMA considers that, irrespective of the conclusion reached in relation to the relevant market, it is in any case clear that GSK had market power at the time it entered into the Alpharma-GSK Agreement. Having sustained comparably higher prices and profits over a number of years prior to independent generic entry, GSK's internal documents indicate that GSK was concerned that generic competition would lead to significant price, profit and market share erosion. Indeed, following the eventual emergence of true generic competition in December 2003, GSK experienced a significant decline in its paroxetine prices, profits and market share. On the basis of these trends, the CMA has concluded that GSK retained market power at least between January 1998 and November 2001 and, as a consequence of the Agreements, until at least November 2003.

- Barriers to expansion were significant in this market. Parallel importers were limited in their ability to expand and exercise a greater competitive constraint on GSK. The volume restrictions imposed by GSK on IVAX and GUK (which had both entered the market as distributors for GSK pursuant to their respective Agreements with GSK) limited the competitive constraints from IVAX and GUK (see paragraphs 4.112 to 4.115).
- GSK's patents in relation to paroxetine represented a barrier to entry, and for as long as they remained unchallenged, enabled GSK to litigate, and seek injunctions, in response to the proposed market entry of potential competitors (see paragraphs 4.116 to 4.123).
- In the Relevant Period, the NHS did not exert countervailing buyer power vis-à-vis GSK for the supply of Seroxat (see paragraphs 4.124 to 4.126).

7.71 In the context of the Alparma-GSK Agreement, GSK had an interest in protecting its position of market power, as there had been no launch of independent generic paroxetine and therefore GSK was able to sustain far higher profits than was likely to be the case following independent generic entry (see paragraphs 3.161 to 3.164).¹¹⁸⁴

ii) The Alparma-GSK Agreement's restrictive effects

a) The likely effect of the value transfers was to induce delays to the potential emergence of true generic competition and to assist GSK in preserving its market power

7.72 As set out at paragraphs 6.152 to 6.154, the Alparma-GSK Agreement included entry restrictions that prevented Alparma, for the term of that Agreement,¹¹⁸⁵ from (i) supplying generic paroxetine sourced independently of GSK, and/or (ii) facilitating generic market entry by transferring or assigning its MA to another company. As set out at paragraphs 6.150 to 6.205, the CMA has considered the purpose of the value transfers from GSK to Alparma, and concluded that they were made in return for Alparma's agreement not to enter the UK paroxetine market independently of GSK.¹¹⁸⁶

7.73 In the absence of the value transfers described above (and in the absence of a more competitive settlement), Alparma would not have been incentivised

¹¹⁸⁴ This is consistent with GSK's strategy regarding defence strategies to protect Seroxat from generic entry (see paragraphs 3.144–3.154).

¹¹⁸⁵ Specifically, for the term of the Alparma-IVAX Agreement.

¹¹⁸⁶ As set out at paragraph 6.152, the entry restrictions also prevented Alparma from assisting others from entering by assigning or transferring its UK MA.

to accept the entry restrictions in the Alparma-GSK Agreement. Alparma was a potential competitor that was otherwise seeking to enter the UK paroxetine market independently of GSK (see paragraphs 6.65 to 6.82), and was unlikely to have accepted the same entry restrictions without sufficient compensation. This analysis is supported by Alparma's internal documents (see paragraphs 6.199 to 6.203) which indicate that absent sufficiently high payments and value transfers from GSK, Alparma was minded to maintain its efforts to enter the market independently of GSK and to continue to contest the Alparma Litigation.

- 7.74 As set out at paragraph 6.154, the CMA observes that the Alparma-GSK Agreement did not resolve the litigation as there was no counterpart to the entry restrictions in the form of any commitment from GSK that it would refrain from patent litigation proceedings if, after the expiry of the Alparma-GSK Agreement, Alparma sought to supply its own generic paroxetine product. In fact, GSK specifically refused to agree to Alparma's request that there be some recognition that it could have entered the UK paroxetine market in future with product sourced from Delta.¹¹⁸⁷ As such, while the threat of Alparma's potential independent entry was delayed by the Alparma-GSK Agreement, the Agreement's terms were such that Alparma would continue to face the prospect of litigation (see paragraphs 4.116 to 4.123) in the event that it sought to enter the UK paroxetine market with a generic paroxetine product sourced independently of GSK, even after the expiry of the Alparma-GSK Agreement.
- 7.75 The likely effect of the Alparma-GSK Agreement, including the value transfers that were used to induce the entry restrictions, was therefore to delay Alparma's potential independent generic entry. By delaying Alparma's potential independent generic entry and associated challenge to GSK's patent position, the likely effect of the Alparma-GSK Agreement was also to assist GSK in preserving the patent entry barriers faced by other potential entrants, which would continue to face the prospect of litigation in the event that they sought to enter the UK paroxetine market with a generic paroxetine product sourced independently of GSK (see also paragraphs 7.116 to 7.117). Indeed, this potential effect of Alparma's entry was acknowledged by GSK: *'Alparma's presence on the market would be a signal that they need no longer fear an injunction.'*¹¹⁸⁸ The Alparma-GSK Agreement therefore made

¹¹⁸⁷ See email from [Alparma ApS's Sales and Marketing Director] to [Alparma Inc's Vice President of Intellectual Property] and others dated 1 October 2002 (document 1356).

¹¹⁸⁸ [redacted]WS2 (Alparma) (document 0289), paragraph 6.2. See also paragraph B.142 in relation to IVAX.

the independent entry of competitors onto the market more difficult, thereby interfering with the structure of competition on the market.

b) *The likely effect of Alharma's entry as a GSK distributor was no material increase to the actual competitive constraints faced by GSK*

7.76 The transfer of a restricted volume of product from GSK to Alharma was not likely to materially increase the actual competitive constraints faced by GSK in the supply of paroxetine in the UK.

7.77 As set out at paragraph 6.163, under the terms of the Alharma-GSK Agreement, GSK transferred value to Alharma by supplying it with a restricted volume of paroxetine and Alharma was initially able to purchase no more than 500,000 packs of GSK product each year.¹¹⁸⁹ For the reasons set out at paragraph 6.164, the transfer of a restricted volume of product itself represented a value transfer that involved GSK transferring to Alharma the margin that it would otherwise have earned on such volumes.¹¹⁹⁰ In the same way as a payment, GSK was able to use this mechanism to make a value transfer to Alharma through a means that would not meaningfully increase the price competition it was facing on the market. Consistent with this, the likely effect of the transfer of a restricted volume of paroxetine¹¹⁹¹ was no material increase in the actual competitive constraints faced by GSK and therefore no meaningful impact on the degree of actual competition in the UK paroxetine market:

- In the event that Alharma reduced its prices to a level that was materially below the level of its competitors in the UK paroxetine market (namely GSK, IVAX, GUK and parallel importers of Seroxat), the associated increase in its orders would have resulted in Alharma quickly reaching the volume restriction of 500,000 packs of paroxetine 20mg, thereby harming

¹¹⁸⁹ In 2003, in return for extinguishing a debt from GSK for £500,000 value (pursuant to clause 6 of the Alharma-GSK Settlement Agreement (document 0356)), Alharma successfully negotiated to increase the volume restriction from 500,000 units per year to 620,000 units per year (see the Alharma-GSK Settlement Agreement amendment (document 0441)).

¹¹⁹⁰ GSK submitted that the volume restriction was not restrictive in the way the CMA contends, and that there was no evidence that the Generic Companies sought additional supplies (GSK SO Written Response (document 2755), paragraphs 1.142 and 8.52). See paragraph 7.87 for the CMA's responses to these points.

¹¹⁹¹ The CMA notes that as IVAX supplied Alharma with paroxetine, IVAX was therefore aware of the supply terms that Alharma faced, in particular the supply price and volume restriction clauses. As such, IVAX would have known that Alharma faced no incentive to meaningfully compete with GSK, for the reasons established in paragraphs 7.77–7.78. Therefore, IVAX's awareness of the terms of the Alharma-GSK Agreement and its knowledge that Alharma did not pose a competitive threat ensured that there was no incentive for IVAX to reduce its price or end its Agreement with GSK and seek to enter independently.

its reputation with customers by not being able to meet customers' orders.¹¹⁹²

- Were Alparma to lower its prices to materially below prevailing levels, its profits would be lower than would have otherwise been the case, because Alparma would be making a lower mark-up on each pack sold without being able to sell additional packs. As a result of the volume restriction, Alparma's incentive to reduce prices below the prevailing price at the time, of approximately £13,¹¹⁹³ would have been minimal.
- As Alparma could not sell more than 500,000 packs,¹¹⁹⁴ it could not expand its market share by volume¹¹⁹⁵ beyond 8% of the UK paroxetine market,¹¹⁹⁶ and GSK's distributors (IVAX, GUK and Alparma) between them could supply no more than 31% of the UK paroxetine market. Therefore, having secured customers to whom it would make its allocation of paroxetine sales, Alparma would have had no incentive to compete for other customers to whom GSK was supplying Seroxat.¹¹⁹⁷ As a result, the impact that sales by Alparma could have on GSK's market share was limited, helping to protect GSK's share of the UK paroxetine market.
- As the restricted product volumes that were supplied to Alparma were limited to paroxetine 20mg packs, under the terms of the Alparma-GSK Agreement Alparma was unable to supply any paroxetine 30mg packs. Prior to entering into the Alparma-GSK Agreement, Alparma was a potential competitor with respect to both 20mg and 30mg tablets (see

¹¹⁹² Alparma's volume restriction was increased in 2003 to 620,000 packs (see footnote 1189), which represented a market share by volume of 12% (based on market size in the year to October 2003). Although this meant that Alparma could potentially supply to a larger share of the UK paroxetine market, the level of the volume restriction is still not great enough to alter the analysis presented, namely that Alparma had no incentive to reduce its prices to the extent that doing so would result in it being unable to satisfy the resulting increase in demand.

¹¹⁹³ Email from [Alparma Ltd's Director of Sales and Marketing] to [Alparma ApS's Sales and Marketing Director] and others dated 14 October 2002 (document 1361), which stated that '*UK price referred [to] by GSK of £13.15 per pack is an accurate reflection of current retail prices.*'

¹¹⁹⁴ As described in paragraph 3.226, to allow for Alparma's supply, GSK increased the overall quantities that IVAX could supply to 2,020,000 packs in the Third Addendum (document 1807), an increase to the previous addendum of 500,000 packs.

¹¹⁹⁵ Alparma estimated that its share of 500,000 units would equate to a 15% market share – see email from [Alparma Ltd's Director of Sales and Marketing] to [Alparma ApS's Sales and Marketing Director] and others dated 14 October 2002 (document 1361).

¹¹⁹⁶ Calculated based on the market size in the 12 months to October 2002, based on data supplied by relevant parties.

¹¹⁹⁷ This impact of the volume restriction was recognised by [Alparma ApS's Sales and Marketing Director]: '*Being supplied with a fixed, limited, volume of stock of 500,000 packs would have affected Alparma's incentives to discount the GSK-sourced product or the retail price. For some UK customers, to win business you would have to offer a very low price. Clearly, given that only a limited supply of product was available, Alparma was not in a position to compete for these customers, as GSK would have known well. It therefore would have been better from GSK's perspective to pay a higher lump sum to Alparma to cover all of Alparma's upfront costs, and effectively buy off some of our risk, rather than supplying more packs to Alparma.*' [§]WS (document 3172), paragraph 8.14.

paragraph 7.66). Therefore, GSK, in providing for Alpharma to sell only 20mg tablets, removed the threat of independent generic entry by a potential competitor in relation to sales of 30mg packs.

- Because of the volume restriction, Alpharma's potential market shares were capped.

7.78 As a further consequence of the volume restriction, GSK would have had little incentive to respond to Alpharma's entry (or, for the same reasons, the earlier entries of IVAX and GUK) by competing on price:

- The majority of GSK's existing customers were unlikely to be the subject of an approach from Alpharma (or GUK or IVAX) given the volume restrictions that the Generic Companies were subject to and the expectation that IVAX's and GUK's sales would in part replace those of parallel importers (see paragraph B.149 and 7.32).
- GSK's own pricing policy was not to pre-emptively decrease its price to gain market share: *'Experience shows that GSK should not drop prices pre-emptively. This only forces a price war. Optimal strategy for branded products generally to follow price reduction rather than lead.'*¹¹⁹⁸ Consistent with this, it was likely that GSK would not drop its prices below those charged by Alpharma as it would have been aware that, had it done so, Alpharma and the other Generic Companies would continue to match GSK's prices until prices were competed down close to approximately £8.45 per pack (that is, the cost per pack for the Generic Companies) such that GSK would make substantially lower profits overall. Moreover, had the Generic Companies' prices, and specifically GUK's price, fallen below £12.25 per pack, GSK would have lost further profits through its contractual requirement to make payments (of up to £2.85 million) to GUK as required by the profit guarantee clause in the GUK-GSK Agreement. GSK's most profitable response to the restricted entry of the Generic Companies was therefore to preserve its prices at prevailing levels. Consistent with this, prices remained broadly constant during the term of the Alpharma-GSK Agreement (see paragraph 7.97).

¹¹⁹⁸ Seroxat Brand Planning Europe December 2002 (document D124), page 34. [GSK's Finance Director A's] witness statements during the Alpharma Litigation also imply that GSK would react to price falls rather than leading them: *'A further result of the price of Generic Paroxetine falling substantially would be that GSK would be obliged to respond by increasing its brand equalisation discounts for as many of its customers as possible.'* ([REDACTED]WS1 (Alpharma) (document 0241), paragraph 9.8) and *'GSK's brand equalisation discounts are only offered in reaction to market pressures, principally the prices charged by parallel importers. [...] It is bizarre to suggest that GSK would offer such discounts without having to do so.'* (emphasis in original) ([REDACTED]WS2 (Alpharma) (document 0289), paragraph 2.2).

- Had GSK instigated price cuts that limited the margins available to Alparma, Alparma would (other things being equal) have a decreased incentive to extend its Agreement beyond the relevant expiry date.
- Were GSK to reduce its prices to a level below £8.45, the Generic Companies would have been entitled to terminate their Agreements with GSK and continue their efforts to enter the UK paroxetine market independently of GSK.¹¹⁹⁹

7.79 Consistent with this, contemporaneous evidence¹²⁰⁰ demonstrates that both Alparma and GSK considered that the expected impact of a supply agreement¹²⁰¹ containing volume restrictions would be continued price stabilisation:¹²⁰²

¹¹⁹⁹ As set out at paragraphs B.108–B.131, IVAX was incentivised by the IVAX-GSK Agreement to delay its efforts to enter the market independently of GSK.

¹²⁰⁰ This is also consistent with [Alparma ApS's Sales and Marketing Director]'s witness statement in which he noted the limited scope for Alparma to lower its retail price: '*...Alparma knew the cost of goods under a supply arrangement with GSK would be the transfer price of £8.45, and Alparma could effectively assume a retail price. Even in a very tough competitive situation you could try to assume a retail price. Here, GSK would of course still be in a very strong position because it is literally supplying all of the paroxetine going into the UK market. The transfer price proposed by GSK was not exactly low, which of course limited the scope that existed for Alparma to lower the retail price at which it supplied the GSK-produced product. I can't recall exactly what IVAX's position was in this regard, but I would assume that IVAX was similarly limited in terms of scope to supply at a lower retail price as a result of GSK's high supply price.*' [§]WS (document 3172), paragraph 8.6.

¹²⁰¹ This is also consistent with evidence that GSK's expectation was that the supply agreements would lead to price stabilisation. For example, in 2001, a GSK internal presentation considering the 'Seroxat Patent Challenge' concluded that entering into a supply agreement would lead to a '*Generic price 75% MSP to compete with PI [Parallel Imports]*' (GSK presentation entitled 'Seroxat Patent Challenge' dated 5 February 2001 (document 0123), page 4) and [GSK's Finance Director A] confirmed in a post-SSO witness interview that in planning it was assumed that the generic selling price would be 75% of the MSP ([§]1 (document 4008R), page 32). In GSK Third Response (document 0750) GSK indicated that 'MSP' referred to the list price at the time of £17.76. In relation to the latter document, Actavis submitted that the paragraph in question made no reference to Alparma (Actavis response dated 5 October 2015 to the Second Letter of Facts, document 4164). The CMA notes, however, that [GSK's Finance Director A] was explicit that the rationale for the Agreements was common across the Agreements ([§]1 (document 4008R), page 44), and therefore the CMA considers that although the points referred to were discussed in the context of the IVAX-GSK Agreement, [GSK's Finance Director A's] comments are equally applicable to the Alparma-GSK Agreement.

Consistent with this, a GSK document from December 2002 noted, for the UK, that: '*GSK-Norton co-marketed version of Seroxat available with a price of approx. 70% of branded version. [...] Early indications are that total Seroxat revenues are holding up well.*' (Seroxat Brand Planning Europe December 2002 (document D 124), page 25). [GSK's Finance Director A] further stated that the intention of the supply agreements was to allow GSK to meet its budget agreed over a three-year planning horizon. [GSK's Finance Director A] stated that GSK was not anticipating multiple generics entering the market and competing on price for several years, and it sought to maintain that position of '*some level of certainty*' ([§]1 (document 4008R), pages 15-16). Consistent with this, an internal GSK document dated January 2004 indicated that unrestricted competition independently of GSK would result in substantial price declines: '*The Apotex court ruling means the UK competitive environment is significantly altered. We now expect the [sic] to face a generic not supplied by GSK, leading to aggressive price competition*' (Synthon STP dated 16 January 2004 (document 0456)).

¹²⁰² GSK submitted that witness statements in patent litigation suggesting that the impact of the IVAX-GSK or GUK-GSK Agreements was not, or was not likely to be, substantial are of no evidential value. GSK stated that the relevant comments were made by comparison to true generic competition and the associated irreversible price decline, whereas the relevant counterfactual is the maintenance of a presumptively valid patent. (GSK SO Written Response (document 2755), paragraphs 8.28–8.29). The CMA does not agree that these points undermine the statements' evidential value because: (i) the statements in question directly relate to the impact of the Agreements, and as such are therefore relevant, and (ii) the CMA does not consider that the context

- For example, GSK anticipated that the appointment of sub-distributors by IVAX would not result in greater competition in the UK paroxetine market or in Alparma competing meaningfully on price, as noted by [GSK's Finance Director A]:¹²⁰³

'Whom Ivax appoints and on what commercial terms is entirely up to Ivax. However, GSK concluded, since Ivax's selling price to its sub-distributors is likely to be above the price which Ivax pays to GSK, any sub-distributors' prices to their customers are unlikely greatly to undercut Ivax's own and, therefore, the financial impact on GSK would, again, be minimised.'

- When discussing GUK's entry as a sub-distributor, GSK's skeleton argument in the GUK Litigation states that GUK could enter the market and supply product at the prevailing price (the parallel import price). The anticipated price impact applies equally to Alparma given that both the GUK-GSK Agreement and Alparma-GSK Agreement contained similar volume restriction terms:¹²⁰⁴

*'it is clear [...] that [IVAX] is willing for GUK to be a sub-distributor. **This would enable GUK to mitigate its loss by selling paroxetine at the parallel import price. It would not enable it to severely undercut this price and de-stabilize the market.**'* (emphasis added)

- A strategy document dated December 2002 indicates that GSK considered that the expected impact of the Agreements would be price stabilisation at prevailing price levels:¹²⁰⁵

'Price Defence Strategy: Defences undertaken to date are crucial to protect Seroxat prices:

*...Co-marketing strategies avoid generic reference pricing (e.g. UK, Ger, Den, Netherlands, and Spain) and **allow participation in generic market without undermining Seroxat price.**'* (emphasis added)

- In an internal email, dated 29 October 2002, [Alparma employee] appears to confirm that GSK and Alparma shared an understanding that

undermines the statements as they merely articulate that the impact of the Agreements was expected to be minimal compared to the situation at the time (that is, prior to any independent generic entry having taken place).

¹²⁰³ [REDACTED] WS1 (Alparma) (document 0241), paragraph 6.6.

¹²⁰⁴ GSK skeleton argument in the GUK Litigation dated 23 October 2001 (document 0910), paragraph 54.

¹²⁰⁵ Seroxat Brand Planning Europe December 2002 (document D 124), page 34. As set out at paragraph 3.147, GSK also referred to 'supply agreements' as 'co-marketing agreements'.

the volume restriction would have the effect of maintaining prices at the prevailing level:¹²⁰⁶

'The Sales price of £13,7 reflects what the negotiation ended up with – a sales price which GSK and [redacted] [Alpharma Ltd's Director of Sales and Marketing], I believe, agreed on would be the correct one to be able to sell 500 packs.'

- During the Alpharma Litigation [Alpharma Ltd's Director of Sales and Marketing] indicated that he considered that IVAX and GUK, in distributing paroxetine pursuant to Agreements with GSK, would be unable to impose competitive constraints on other competitors, which Alpharma could take advantage of:¹²⁰⁷

'Although Generics UK and Ivax are already on the market, everyone is aware that their product is in fact sourced from GSK and is therefore not a true developed generic product. [...] The market will be aware that there are constraints imposed by GSK on Ivax and Generics UK relating to their supply of paroxetine. Being truly independent will mean that Alpharma's product will be viewed to be a true alternative to Seroxat, which will help us not only enter the market but also maintain our usual market share.'

- [Alpharma Ltd's Marketing Manager] explained in her witness statement that taking supply from a non-GSK source would result in greater flexibility with respect to volumes and prices:¹²⁰⁸

'By the phrase "true generic distributor", I was referring to the situation if Alpharma were the only party distributing paroxetine in the UK that was sourced from someone other than GSK. [...] I would have expected that taking supply from a non-GSK source would enable a generic supplier more flexibility 1) in terms of volume (i.e. the generic

¹²⁰⁶ In response to [Alpharma employee's] email [Alpharma Ltd's Managing Director] appeared to confirm the understanding that prices would be maintained, as he stated that: *'In discussions with [Alpharma Ltd's Marketing Manager] the now model is based on an ASP of £10.50 and holding for the year [...] This takes us back to the original plan from a GM perspective, however, we need to get more discussion on this to come to a correct ASP. Somewhere between £13.15 and £10.50.'* The CMA notes that it is apparent from the email chain that the reference to Alpharma's average selling price being at £10.50 per pack is not a reference to market prices falling, but rather reflects that Alpharma expected to primarily sell to wholesalers (for whom the price is lower than the market price to pharmacies). In particular, [Alpharma Ltd's Marketing Manager] stated that: *'As we only expect to have 500,000 packs made available to us through the agreement this would require selling each pack at £13.40. PI's are already available at £12.90 in the UK and as most of our business will be through wholesale we cannot expect to earn more than £10.00 per pack maximum.'* Email chain between [Alpharma employee], [Secretary of Alpharma] and others dated 1 November 2002 (document 1380).

¹²⁰⁷ [redacted]WS2 (document 1325), paragraph 37.

¹²⁰⁸ [redacted]WS (document 1587), paragraph 3.19.

would have greater control over volumes it could order) and also in terms of 2) price/cost of goods depending on what we could negotiate with our supplier.'

7.80 The evidence indicates that Alpharma ordered from IVAX (as GSK's distributor) the maximum number of packs that it was entitled to under the volume restriction for the duration of the Alpharma-GSK Agreement (prior to independent generic entry taking place).¹²⁰⁹ Data on the volume of product that IVAX supplied to Alpharma shows that, during the Alpharma-GSK Agreement, Alpharma received 416,666 packs in the first contract year (that is, for the term of the Alpharma-GSK Agreement prior to independent generic entry taking place)¹²¹⁰ which equates to 100%¹²¹¹ of the restricted volume available to Alpharma in that year.

¹²⁰⁹ The CMA notes that GSK stated, in respect of the total restricted volumes available to the Generic Companies, that: *'It is important to appreciate that Ivax only ever asked for a fraction of this entitlement. In other words, far from being restricted, Ivax had available to it far greater volumes than it actually called for. The volume quota in the agreement therefore did not have the effect of a "restriction" on quantities available.'* (GSK Second Response, Part Two (document 0734), paragraph 11.3). GSK subsequently provided data which showed that this was not the case, such that the Generic Companies did order the full allocation of volumes available to them in 2002 and 2003 (source: CMA calculations based on PDF 'Apotex damages disclosure document 171' undated (document 2525), attached to the response dated 30 January 2013 to the Section 26 Notice dated 18 December 2012 sent to GSK (document 2515)).

¹²¹⁰ Part two of the response dated 4 May 2012 to the Teva Second Section 26 Notice, with Annexes 1–3 (documents 2049 and 2050). Additionally, Alpharma received 95,484 packs in the second contract year which equates to 62% of the restricted volume available to Alpharma. The CMA notes that the second contract year began in December 2003 which is the same month in which independent generic entry began. The volume restriction was higher for the second year of the Alpharma-GSK Agreement at 620,000 packs and the higher volume restriction came into effect at the same time as independent generic entry occurred, and, as set out at paragraphs 3.391–3.393, the UK paroxetine market was contracting at this time. The last orders Alpharma made pursuant to the Agreement were in January 2004. Although Actavis also provided data on Alpharma's sales of paroxetine, the CMA considers that it is order data which is important to an assessment of whether the volume restriction was binding because Alpharma was restricted in the amount it could purchase from GSK under the Alpharma-GSK Agreement.

The CMA notes that GSK stated that the increase to Alpharma's volumes in the second year of the Agreement was effectively agreed as part of the original settlement, but that Alpharma had previously exercised an option to consider whether it would prefer to have access to some end-of-line products which GSK was prepared to divest (GSK SO Written Response (document 2755), paragraph 7.126 (d)). The CMA does not consider that the timing of the relevant negotiations alters the fact that Alpharma was subject to a volume restriction. Moreover, the fact that Alpharma could only receive an increase in volumes by foregoing the option to access some of GSK's end-of-line products supports the CMA's case that Alpharma was subject to a volume restriction. If there was no volume restriction (such that Alpharma was free to order whatever volumes it required), there would have been no value to Alpharma in negotiating the increase in its allowance, and it would have had no reason to accept an increase in volumes in place of the payment it was otherwise due.

¹²¹¹ The effective date of the Alpharma-IVAX Agreement was 1 December 2002. However, Alpharma received no packs until February 2003 (part two of the response dated 4 May 2012 to the Teva Second Section 26 Notice, with Annexes 1–3 (documents 2049 and 2050)). The CMA considers that it is appropriate to pro-rate the volumes available to Alpharma over the 10 months in the first contract year that it actually received packs. This is on the basis that clause 5.1 in the IVAX-Alpharma Agreement provided for Alpharma to receive £200,000 per month in the event that IVAX was unable to deliver product. Alpharma received this payment for at least December 2002 and January 2003 (see Teva Response dated 15 October 2015 to the Section 26 Notice dated 1 October 2015 (document 4081) and the accompanying Annexes (documents 4082, 4083 and 4084), and part one of the response (dated 10 October 2011) to the Section 26 Notice dated 12 August 2011 sent to Teva, consolidated in the Section 27 Notice dated 6 October 2011 sent to Teva (document 1983), Annex 3, page 10). As Alpharma appears to have interpreted this clause as a *'profit compensation for any delays after December 1st'* (see email from [Alpharma ApS's Sales and Marketing Director] to [Alpharma Ltd's Director of Sales and Marketing] and

7.81 Consistent with this, when planning its own independent entry, Alparma had been planning to supply a greater volume of paroxetine than it could supply pursuant to the Alparma-GSK Agreement:

- [Alparma Ltd's Director of Sales and Marketing] stated in an email that entering into the Alparma-GSK Agreement would mean that Alparma would tender for fewer contracts due to limited supply: *'As %GPM [gross profit margin] now tighter than available via Delta and no longer separate source of product, we would probably not tender for Boots, Lloyds, Moss business. This would clearly limit our market share capabilities but the risk of renegeing on supply and penalty claims would be too great'*.¹²¹²
- In preparation for the launch of its paroxetine product, Alparma had ordered stocks of paroxetine from Delta, comprising some 360,000 packs of 20mg tablets and 138,000 packs of 30mg tablets.¹²¹³ This stock was described by [Alparma Ltd's Marketing Manager] as being *'opening order quantities'*¹²¹⁴ and once Alparma had launched it would be expected that further orders would have followed.

7.82 The evidence indicates that without the volume restriction Alparma would have been able to sell higher quantities of paroxetine during the period of the Alparma-GSK Agreement:

- In an internal email dated 20 May 2003 regarding stock levels for paroxetine, [Alparma's Distribution Manager] stated: *'Paroxetine –*

others entitled 'Quick note on UK settlement for Paroxetine – meeting October 23 2002' dated 24 October 2002 (document 1364)), the CMA understands this term to mean that Alparma was unable to order the missed volume in the event of a delay in supply.

GSK stated that as Alparma sold 83% of its allocation in the first year of the Alparma-GSK Agreement, this indicates that the volume restriction was not binding (GSK SO Written Response (document 2755), paragraph 8.52). The CMA notes that the figure of 83% to which GSK refers is in fact the proportion of orders Alparma made, rather than its sales data. However, in making such a submission GSK has overlooked the CMA's explanation in this footnote that the reason Alparma ordered less than its full allocation of 500,000 packs is that it did not receive any packs during the first two months due to a delay in supply from IVAX. GSK further submitted that as Alparma ordered double the normal monthly volume once supply commenced this suggests it was not the case that Alparma was unable to order additional volume (GSK SO Written Response (document 2755), paragraphs 8.52 and 7.126(g)). The CMA considers that Alparma placing a larger order for its first month of supply does not imply that the volume restriction was not binding upon Alparma, and notes that in any case Alparma was subject to an annual not a monthly volume restriction.

¹²¹² Email from [Alparma Ltd's Director of Sales and Marketing] to [Alparma ApS's Sales and Marketing Director] dated 14 October 2002 (document 1361).

¹²¹³ Email chain between [Alparma Ltd's Marketing Manager], [Alparma Ltd's Director of Sales and Marketing] and others dated 25 April 2002 (document 1308).

¹²¹⁴ Email chain between [Alparma Ltd's Marketing Manager], [Alparma Ltd's Director of Sales and Marketing] and others dated 25 April 2002 (document 1308).

already on the case – if anything we could sell a lot more (Boots looking for supply – but volume circa 54K / month).¹²¹⁵

- [✂], Alharma [Ltd]'s Managing Director, responded by saying: *'Paroxetine, we won't get any more at this stage – GSK are "quite happy" with limiting the market – but we should be getting our agreed share. This needs to be continually pointed out to Ivax. [...] Trick is to make sure that we are allocating our limited volume wisely to the customers'*.¹²¹⁶
- In a further email dated 22 May 2003 on paroxetine supply [Alharma Ltd's Managing Director] stated: *'The products we can sell we can't get enough stock: [...] Paroxetine – we could sell double the monthly allowance we have from IVAX/GSK'*.¹²¹⁷
- In an email to [Alharma Ltd's Marketing Manager] and others (setting out some thoughts on negotiating a new deal with GSK) on 25 June 2003 [Alharma Ltd's Managing Director] stated: *'Look at volumes we could sell if not 'restricted' in supply – as current.*¹²¹⁸
- Alharma had communicated the supply limitations to potential customers. For example in 2003, Moss Pharmacy reportedly requested that *'IVAX write to Moss stating that there are supply limitations in the market and that a letter from Alharma had already been sent stating that this was the case.*¹²¹⁹

7.83 The evidence confirms that price stability was in fact observed:

- As explained in paragraph 7.97, the Alharma-GSK Agreement did not have a material impact on prices in the market: there was no material fall

¹²¹⁵ Email chain between [Alharma's Sales Support Supervisor], 'Company Day Figures', [Alharma Ltd's Managing Director], [Alharma's Distribution Manager], [Alharma Ltd's Marketing Manager], [Alharma's Product Sourcing Manager], [Alharma's Finance Director], [a Third Party Planner of Alharma], 'Re: Paroxetine/ Vancomycin/ New Pdts' dated 20 – 22 May 2003 (document 1424).

¹²¹⁶ Email chain between [Alharma's Sales Support Supervisor], 'Company Day Figures', [Alharma Ltd's Managing Director], [Alharma's Distribution Manager], [Alharma Ltd's Marketing Manager], [Alharma's Product Sourcing Manager], [Alharma's Finance Director], [a Third Party Planner of Alharma], 'Re: Paroxetine/ Vancomycin/ New Pdts' dated 20 – 22 May 2003 (document 1424).

¹²¹⁷ Email chain between [Alharma's Sales Support Supervisor], 'Company Day Figures', [Alharma Ltd's Managing Director], [Alharma's Distribution Manager], [Alharma Ltd's Marketing Manager], [Alharma's Product Sourcing Manager], [Alharma's Finance Director], [a Third Party Planner of Alharma], 'Re: Paroxetine/ Vancomycin/ New Pdts' dated 20 – 22 May 2003 (document 1424).

¹²¹⁸ Email chain between [Alharma Ltd's Managing Director], [Alharma Inc's Chief Financial Officer], [Alharma Inc's Chief Legal Officer], [Alharma Inc's Vice President of Intellectual Property], [Alharma ApS's Sales and Marketing Director], [Alharma Ltd's Marketing Manager], [Alharma's Head of Sales & Marketing], [Alharma's Product Sourcing Manager], [Alharma's Head of Purchasing], [Director, Regulatory Affairs of Alharma], [Alharma's Finance Director] dated 23 – 25 June 2003 (document 1428).

¹²¹⁹ Moss Pharmacy contact report dated 20 March 2003 (document 1827).

in prices following either the introduction of the Agreement or during its term. For example, average paroxetine 20mg prices were 2% higher and Seroxat 20mg prices were 2% lower in the three months after Alpharma's entry pursuant to the Alpharma-GSK Agreement compared to the three months before Alpharma's entry.

- [GSK's Finance Director A] indicated in a witness statement dated 22 October 2002 that prices had not fallen after IVAX, GUK and Tillomed had entered the UK paroxetine market as GSK sub-distributors:¹²²⁰ *'Ivax would be unlikely to want to undercut the existing price paid by customers for parallel imported paroxetine. This is the price to which GSK was already discounting a number of brand equalisation deals [...] I believe the current situation, therefore, is that the price at which both Ivax and its sub-distributors sell Distributed Paroxetine has remained stable since the coming into effect of the Ivax Agreement.'*

7.84 The evidence also confirms that, as anticipated in paragraph 7.77, the volume restriction ensured that the impact on GSK's market share of UK supplied product was limited (see also paragraph 7.96).¹²²¹

Parties' Representations

7.85 GSK,¹²²² Actavis,¹²²³ and Xellia-Zoetis¹²²⁴ submitted that the Alpharma-GSK Agreement resulted in Alpharma's early entry into the market and introduced more price competition into the supply of paroxetine in the UK. The Parties

¹²²⁰ [REDACTED]WS1 (Apotex) (document 0333), paragraphs 6.5 and 6.7. GSK submitted that what was meant by this statement was that the price had not decreased further since the original low prices at which IVAX and GUK respectively had sold authorised generic paroxetine into the market, and the focus of this witness statement, given that it was made in litigation during October 2002, was on the lack of further price decreases rather than the original price decrease (GSK SO Written Response (document 2755), paragraph 8.38). The CMA considers that the interpretation it has given to this statement remains accurate given both: (i) the context in which this statement was made that GSK considered that IVAX would be unlikely to undercut prices as compared to existing levels; and (ii) the evidence presented at paragraph B.166 that paroxetine prices did not fall materially following IVAX's entry as a GSK distributor.

¹²²¹ The CMA notes that during the GUK Litigation, [GSK's Finance Director A] stated that *'a substantial proportion (about 40%) of the SEROXAT (paroxetine) dispensed in the UK is in the form of parallel imports'* ([REDACTED]WS1 (GUK) (document 0885), paragraph 3.3). This implies that GSK's market share (for the supply of finished product to pharmacists/wholesalers) was 60% during 2001. However, as set out in Tables 3.4 and 3.5, GSK's market share, based on data submitted by GSK (see IMS diagnostics data dated 6 December 2011, supplied by GSK in response to the GSK Section 27 Notice (document 0680)), was significantly higher than this, 79% by value and 77% by volume in 2001. At this time GSK remained the sole manufacturer of paroxetine sold in the UK (with a market share by value or volume of 100% at the production level).

¹²²² For example, GSK stated *'Far from restricting competition, the GSK Agreements accelerated early entry of generic paroxetine to the UK market'*. See GSK SO Written Response (document 2755), page 142; see also paragraph 4.6, paragraph 4.15, page 158, paragraph 6.111, paragraph 6.119, page 257 summary box and paragraph 8.58. See also GSK submission to the OFT dated 27 June 2012 (document 0746), section 5.

¹²²³ Actavis SO Written Response (document 2754), paragraphs 1.47 and 4.14. See also Note of meeting between the OFT and Actavis dated 16 October 2012 (document 2357), paragraph 17.

¹²²⁴ Xellia-Zoetis SO Written Response (document 2767), paragraph 170.

stated that for this reason the effect of the Alparma-GSK Agreement cannot have been to restrict competition. This sub-section addresses those submissions.

Volume restrictions

7.86 GSK's and Actavis's submissions regarding the volume restrictions were as follows:¹²²⁵

- The volume restrictions were not restrictive because the volumes supplied to the Generic Companies were substantial,¹²²⁶ and were not binding, based on there being no evidence that Alparma requested an increase in volumes subsequent to the signing of the Alparma-GSK Agreement.¹²²⁷
- The volumes Alparma could supply under the Alparma-GSK Agreement were 'very close' to the volumes of independent generic product which Alparma proposed to supply, and the figure of 500,000 packs was a reasonable forecast level.¹²²⁸
- It is not correct that Alparma could have sold more paroxetine during the initial launch period because it was not Alparma's strategy to flood the market with product.¹²²⁹

7.87 The CMA remains satisfied that the volume restriction was binding, in the sense that Alparma ordered the maximum number of packs which it was contractually entitled to, for the reasons set out at paragraph 7.80, and makes the following additional points:

¹²²⁵ Xellia-Zoetis stated that analysis of the volume restrictions was irrelevant on the basis that early entry on the basis of the patent holder's supply is the most pro-competitive outcome possible for a party seeking entry when the patent holder is exercising its right to exclude potentially infringing suppliers (Xellia-Zoetis SO Written Response (document 2767), paragraph 166). The CMA's responses regarding the counterfactual are discussed at paragraphs 1.8–1.27.

¹²²⁶ GSK SO Written Response (document 2755), paragraphs 1.142, 8.19, 8.52.

¹²²⁷ GSK SO Written Response (document 2755), paragraph 8.52, with reference to paragraph 7.126.

¹²²⁸ GSK SO Written Response (document 2755), paragraph 8.52, with reference to paragraph 7.126.

¹²²⁹ Actavis SO Written Response (document 2754), paragraphs 1.36, 4.16, 5.19–5.20, GSK SO Written Response (document 2755), paragraph 7.126(f). Actavis and GSK noted that [Alparma Ltd's Director of Sales and Marketing] confirmed in a witness statement that Alparma did not intend to sell greater volumes by selling to Boots: '*Alparma has no intention of supplying the Boots pharmacy chain.*' ([redacted]WS2 2002 (document 1325), paragraph 9). The CMA notes that the email dated 14 October 2002 relied upon by the CMA in paragraph 7.81 suggests that Alparma's position over whether to supply Boots was revised after the time of the witness statement cited by Actavis and GSK, dated 24 July 2002, and implies that the decision not to supply Boots was as a result of the proposed agreement with GSK and not, as submitted by Actavis and GSK, Alparma's intention anyway. Regardless of whether the Alparma-GSK Agreement affected Alparma's incentives to supply Boots, the CMA notes that this does not imply that supply could not otherwise have been expanded to other customers.

- The CMA observes that the volume restrictions were binding and that the Generic Companies would have taken more product had it been offered to them. The CMA considers that GSK found no evidence that the Generic Companies requested additional volumes because the Generic Companies understood, given that the volume restrictions were terms required by GSK in the Agreements, that they could not expect any request for additional volumes to be granted. For example, [X], Alpha Pharma [Ltd]'s Managing Director, stated in an email: *'Paroxetine, we won't get any more at this stage – GSK are "quite happy" with limiting the market'*.¹²³⁰ The CMA infers that Alpha Pharma was only granted a higher volume allowance in return for extinguishing a debt from GSK to Alpha Pharma of £500,000 (see paragraph 3.374).
- The CMA does not consider that the volumes agreed were *'very close'* to volumes which Alpha Pharma proposed to supply under independent entry. For example, [Alpha Pharma Ltd's Marketing Manager] noted that further orders would have followed Alpha Pharma's opening order of 360,000 packs, which was estimated to provide for approximately the first six months' supply.¹²³¹ In any case, the CMA considers that the key distinction is that under the terms of the Agreements the volume restrictions provided for a *'managed'* market in which the Generic Companies were allocated a maximum market share, whereas entry without volume restrictions would have been characterised by uncertainty¹²³² and unrestricted competition that was expected to result in substantial price declines. Moreover, under the Alpha Pharma-GSK Agreement, Alpha Pharma could not sell any packs of 30mg paroxetine, whereas it had placed an opening order of 138,000 packs of 30mg paroxetine (see paragraph 7.81).
- The CMA does not consider it credible to argue that, had Alpha Pharma not been subject to a volume restriction, it would not have sought to expand volumes beyond 500,000 packs. First, the CMA observes that, in lieu of a

¹²³⁰ Email chain between [Alpha Pharma's Sales Support Supervisor], 'Company Day Figures', [Alpha Pharma Ltd's Managing Director], [Alpha Pharma's Distribution Manager], [Alpha Pharma Ltd's Marketing Manager], [Alpha Pharma's Product Sourcing Manager], [Alpha Pharma's Finance Director], [a Third Party Planner of Alpha Pharma], 'Re: Paroxetine/ Vancomycin/ New Pdts' dated 20–22 May 2003 (document 1424).

¹²³¹ [X]WS (document 1587), paragraph 3.23.

¹²³² Such uncertainty was referred to by [Alpha Pharma Ltd's Marketing Manager] in her witness statement: *'... I have explained that stock requirements and sales levels could be quite unpredictable. This is because, at times the market could be unpredictable, and prices could drop sharply or stock could become difficult to sell, depending, for example, on whether there was additional market entry.'* [X]WS (document 1587), paragraph 3.23. Contrary to GSK's suggestion in the GSK SO Written Response (document 2755), paragraph 7.126(e), the CMA does not agree that this statement is evidence that Alpha Pharma may not have sold additional stock had it been provided under the Alpha Pharma-GSK Agreement. The context of [Alpha Pharma Ltd's Marketing Manager's] statement is referring to Alpha Pharma's opening order quantities under independent generic entry, and makes no reference to conditions in a *'managed'* market created by the volume restrictions, which would not be characterised by the unpredictability to which [Alpha Pharma Ltd's Marketing Manager] referred.

payment of £500,000, Alparma accepted the transfer of an additional volume allowance of 120,000 packs over and above the initial allowance of 500,000 packs (see paragraph 3.374). Such a decision would evidently have made no sense if Alparma was not confident that its sale of the additional packs could achieve comparable returns. More generally, given that (as a consequence of volume restrictions) market prices and profit margins remained high prior to the entry of Apotex (through its distributors), it was evident that absent the restriction there would have been significant scope for Alparma to increase its sales volumes while still achieving healthy profit margins.

Supply Price

7.88 The Parties submitted that the supply price was at a level such that Alparma was able to compete effectively with GSK:

- The Parties stated that the supply price allowed for a substantial margin compared to prevailing prices, to enable the Generic Companies to exert downward pressure on prices, which they did.¹²³³ GSK submitted that the Generic Companies had the ability to sell at competitive prices, on the basis of: (i) the supply price allowing for margins of 35 to 45% against prevailing prices, and (ii) marketing allowances being available for discounting against the supply price.¹²³⁴ Actavis submitted that Alparma's cost of paroxetine under the Agreement (taking into account the monthly marketing payment) was comparable to the cost of independent generic paroxetine for Alparma.¹²³⁵
- Actavis stated that Alparma's average selling price under the Agreement of £12.02 per pack in 2003 was at a lower level than Alparma intended to launch its own generic, on the basis of it being below: (i) Alparma's proposed retail price for its own product (£14.20), (ii) the average generic selling price reported to Alparma by GSK during settlement negotiations (£13.15), and (iii) GSK's average selling price for its branded product (list price of £17.76, subsequently reduced to £15.66).¹²³⁶

7.89 Regarding the submissions in relation to the supply price being at a competitive level:

¹²³³ GSK SO Written Response (document 2755), summary box page 257.

¹²³⁴ GSK SO Written Response (document 2755), paragraphs 8.24–8.26.

¹²³⁵ Actavis SO Written Response (document 2754), paragraphs 1.34–1.35, 1.47, 4.14, 4.16–4.17.

¹²³⁶ Actavis SO Written Response (document 2754), paragraphs 1.33–1.34, 1.47, 4.14, 5.18, 11.1.

- The CMA does not accept that the margins available could reasonably have been expected to be used for discounting. As explained above (see paragraph 7.77) the CMA finds that, as a consequence of the binding volume restriction, Alpharma was not incentivised to charge a price that was materially below prevailing levels. In particular, given that Alpharma was able to sell its full volume at prevailing prices, there was no reason to offer a discount (as doing so would mean lower profits on the units it sold, and lost reputation with customers as a result of being unable to fulfil orders due to the volume restriction). Instead, as explained at paragraph 6.163, the transfer of a restricted volume of paroxetine and the associated margins constituted a value transfer. For the reasons set out at paragraph 6.161 the CMA considers that the marketing allowance did not increase Alpharma's incentive to offer lower prices (and this analysis of Alpharma's pricing incentives is not affected by the approach that Alpharma took to comparing the average per pack profitability of the Alpharma-GSK Agreement and independent generic entry). Consistent with these analyses, the CMA observes that the Alpharma-GSK Agreement did not have a material impact on prevailing prices in the relevant market (see paragraph 7.97).
- Neither Alpharma's expected initial selling price under independent entry¹²³⁷ or the prevailing average generic selling price represent a sustainable price under conditions of independent generic entry, and these prices are not therefore appropriate benchmarks against which to measure the impact of the Alpharma-GSK Agreement (see paragraphs 3.59 to 3.63). For example, Alpharma anticipated a price decrease of around 45% in its first year of entry in its own forecasts.¹²³⁸ Consistent with this, the CMA observes that, as predicted by GSK's own expert witness, [X], there were rapid price declines (of 52% in the first six months following independent entry) as the independent entry of Apotex (through its distributors) was followed by the entry of other generic suppliers (see paragraph 3.21).

¹²³⁷ The CMA further notes that the price which Actavis cited as being GSK's selling price was in fact GSK's list price. At that time, GSK's list price was £17.76 and its average selling price was £13.99 (the weighted average Seroxat 20mg pack price between September to November 2003).

¹²³⁸ See Alpharma spreadsheet entitled 'paroxSep02: Alpharma new product business case' dated 13 September 2002 (document 1348).

Competitive pressure on GSK

7.90 GSK, Actavis and Xellia-Zoetis submitted that the decline in GSK's market share was evidence of increased competitive pressure due to the Agreements on the basis that:

- The Generic Companies more than displaced parallel imports, and took 20 percentage points of 20mg volume share from GSK.¹²³⁹
- Even if the volume restrictions were binding, the additional sales would have increased competition faced by parallel importers and put downwards pressure on prices, resulting in more pressure for brand equalisation deals or switching away from GSK.¹²⁴⁰
- Alharma must have been pricing at some discount to existing players as it gained a non-negligible market share.¹²⁴¹
- GSK's profits from sales of Seroxat 20mg fell.¹²⁴²

7.91 The CMA accepts that sales by the Generic Companies more than displaced parallel imports, but does not consider that GSK's falling share of sales volumes, and the associated decline in profits, can be attributed to an increase in competitive pressure. The market share losses suffered by GSK were the consequence of its allocation of volumes to the Generic Companies. However, the adoption of these volume restrictions ensured that a meaningful increase in the competitive constraints GSK faced was not likely to (and did not) emerge following the Generic Companies' entry as suppliers of GSK product and that the Generic Companies did not face incentives to price below prevailing levels (see paragraph 7.77). Moreover, the evidence indicates that there was in fact no material price fall during the Agreements (see paragraph 7.97).

7.92 By contrast, it is consistent with the volume restrictions being a mechanism to transfer value to Alharma (and the other Generic Companies) that GSK's market share and profits¹²⁴³ fell, that Alharma would gain a market share permitted by its volume allowance, and that Alharma's entry as a supplier of GSK product would have no material impact on prevailing market prices.

¹²³⁹ GSK SO Written Response (document 2755), paragraphs 8.18–8.20.

¹²⁴⁰ GSK SO Written Response (document 2755), paragraphs 8.16–8.17.

¹²⁴¹ Xellia-Zoetis SO Written Response (document 2767), paragraphs 270, 282.

¹²⁴² Xellia-Zoetis SO Written Response (document 2767), paragraphs 270, 282.

¹²⁴³ The CMA also notes that overall paroxetine volumes were falling at the relevant time (see paragraphs 3.391–3.393) which will have contributed to GSK's falling profits.

- 7.93 Actavis and Xellia-Zoetis further submitted that the Alpharma-GSK Agreement was pro-competitive because it allowed Alpharma to enter the market immediately¹²⁴⁴ and resulted in generic competition from Alpharma as a GSK distributor.¹²⁴⁵ For the reasons set out at paragraph 7.84, the CMA does not consider that Alpharma's entry as a GSK distributor was likely to result in a material increase in the competitive constraints which GSK faced.
- 7.94 Actavis submitted that the Alpharma-GSK Agreement was pro-competitive because it was time limited and provided Alpharma with the ability to terminate and launch its own independent generic product at the earliest opportunity.¹²⁴⁶ The CMA considers that, by entering into the Alpharma-GSK Agreement, Alpharma agreed to delay its efforts to enter the UK paroxetine market independently of GSK. Doing so ensured that its potential independent market entry was delayed until such time as another generic supplier chose not to accept value transfers offered by GSK and continued with its efforts to enter the market independently of GSK. The fact that Alpharma could subsequently launch its product (at the expiry of the Alpharma-GSK Agreement or if other generic suppliers entered the market) does not make its Agreement pro-competitive, as it does not alter the analysis that Alpharma, as one of a finite number of potential competitors and the one that had progressed furthest in its preparations to enter the market at the time of entering the Agreement, accepted value transfers to defer its own efforts to enter the market independently of GSK and instead enter on the restricted terms offered by GSK.

c) *The market developments observed during the Alpharma-GSK Agreement*¹²⁴⁷

- 7.95 Although not a necessary part of the analysis of the likely effect of the Alpharma-GSK Agreement, the CMA considers that the developments observed during the term of the Agreement reveal that there was no material increase in the actual competitive constraints faced by GSK, and the threat of true generic competition was deferred. Developments in the UK paroxetine

¹²⁴⁴Actavis SO Written Response (document 2754), paragraphs 1.47, 4.14 and 11.1, and Xellia-Zoetis SO Written Response (document 2767), paragraph 269.

¹²⁴⁵Xellia-Zoetis submitted that *'the [CMA] cannot discount entry on the basis of the supply from GSK as if this had no effect on pricing or availability of generic alternatives to Seroxat.'* (Xellia-Zoetis SO Written Response (document 2767), paragraph 170). Xellia-Zoetis also stated that entry by a generic that leads to price decreases is pro-competitive, and introducing an additional competitor is also pro-competitive (Xellia-Zoetis SO Written Response (document 2767), paragraph 265). The CMA notes that Xellia-Zoetis's assertion that prices decreased is not supported by the pricing evidence presented at paragraph 7.97.

¹²⁴⁶Actavis SO Written Response (document 2754), paragraphs 1.47 and 4.14.

¹²⁴⁷The CMA is not required, and has not sought, to assess or quantify the actual effects on competition. See paragraph 7.6.

market during the period of the Agreements are set out at paragraphs 3.380 to 3.398.¹²⁴⁸

- 7.96 In relation to the deferral of potential competition, the evidence set out at paragraphs 3.382 to 3.383 demonstrates that, as a consequence of the AlphaPharma-GSK Agreement, AlphaPharma deferred its efforts to enter the UK paroxetine market. In particular, AlphaPharma did not supply generic paroxetine that was sourced independently of GSK in the period 12 November 2002 to 13 February 2004.¹²⁴⁹ Further, having entered into the AlphaPharma-GSK Agreement, AlphaPharma did not go ahead with its launch of the generic paroxetine product which it had sourced from Delta, the AlphaPharma Product (see paragraphs 3.324 to 3.325). AlphaPharma's independent generic entry did not take place until after Apotex had eventually prevailed in litigation with GSK in December 2003.
- 7.97 The evidence also demonstrates that, as a consequence of the AlphaPharma-GSK Agreement, GSK did not face an increase in the actual competitive constraints it faced until independent generic entry took place in December 2003:
- AlphaPharma's entry as a GSK distributor had no meaningful impact on paroxetine 20mg price levels. During the term of the AlphaPharma-GSK Agreement, AlphaPharma priced at, or very close to, prevailing levels and price levels of paroxetine 20mg stayed fairly constant both immediately following AlphaPharma's entry¹²⁵⁰ and throughout the period when AlphaPharma was supplying paroxetine pursuant to the Agreement, until December 2003

¹²⁴⁸ In considering developments in prices throughout the term of the Agreements, the CMA has used data provided by the relevant parties on the actual prices, net of discounts and rebates where available, at which branded and generic paroxetine was sold. The CMA does not consider that assessing Drug Tariff reimbursement prices would be sufficient for this purpose given that the Drug Tariff is not necessarily an accurate reflection of actual prices, as it does not take into account, for example, discounts and rebates or parallel import prices (see also paragraphs 1.2–1.7). For a fuller description of the data used, see footnote 611.

¹²⁴⁹ During February 2004 and March 2004, AlphaPharma sold both paroxetine sourced from GSK and paroxetine sourced independently, and AlphaPharma subsequently continued to sell paroxetine sourced independently of GSK thereafter (see Annex 4.1 entitled 'UK sales of paroxetine between January 2000 and December 2005' undated (document 1293) to part two of the response dated 30 April 2012 to the Section 26 Notice dated 23 March 2012 sent to Actavis, added to on 5 April 2012 (document 1539)).

¹²⁵⁰ Xellia-Zoetis submitted that as AlphaPharma's entry involved competition against multiple parties it contributed to a decrease in price of paroxetine 20mg (Xellia-Zoetis SO Written Response (document 2767), paragraph 158), and that the CMA did not present evidence to show that higher levels of price decrease would have been observed under an alternative (Xellia-Zoetis SO Written Response (document 2767), paragraph 271). Xellia-Zoetis further submitted that it is quite likely that the price reduction at the end of 2003, or some material proportion of it, actually resulted from the AlphaPharma-GSK Agreement some 14 months earlier (Xellia-Zoetis SO Written Response (document 2767), paragraph 284). The CMA notes that these suppositions are not supported by the evidence presented in this paragraph that 20mg prices remained broadly constant. Moreover, there is no evidence suggesting that a price fall would take 14 months to be observed, and in fact, to the contrary, the evidence indicates that a price fall would take place substantially faster than this, for example, see paragraph 3.63 setting out [GSK's independent expert's] expectation of price falls following the generic entry of multiple suppliers of around 30% within 6 months and 45 to 50% after 12 months.

when independent generic entry began.¹²⁵¹ For example, average paroxetine 20mg prices were 2% higher and Seroxat 20mg prices were 2% lower in the three months after Alpharma's entry pursuant to the Alpharma-GSK Agreement compared to the three months before Alpharma's entry.¹²⁵²

- Alpharma's entry as a GSK distributor had no impact on paroxetine 30mg price levels. The price of paroxetine 30mg remained broadly constant throughout the Alpharma-GSK Agreement and GSK remained the sole supplier of paroxetine 30mg in the UK until after independent generic entry in February 2004.¹²⁵³
- GSK did not face any actual competition at the manufacturer level. GSK remained the sole manufacturer of paroxetine sold in the UK throughout the term of the Agreements and prior to independent generic entry which began in December 2003 (with a market share by value or volume of 100% at the production level).

7.98 The impact of Alpharma's entry on GSK's market share was very limited as a consequence of the volume restriction included in the Alpharma-GSK Agreement. Following Alpharma's entry under the Alpharma-GSK Agreement, GSK retained an average market share for the supply of finished product to pharmacies/wholesalers of 68% by value (or 63% by volume).¹²⁵⁴ During the period between its entry under the Alpharma-GSK Agreement in February 2003 and November 2003, the last month prior to independent generic entry, Alpharma achieved an average market share for the supply of finished product to pharmacies/wholesalers of 8% by value (or 9% by volume).¹²⁵⁵

iii) The counterfactual

7.99 This sub-section examines the competitive landscape that was likely to have existed in the absence of the Alpharma-GSK Agreement.

¹²⁵¹ The CMA notes that Alpharma's sales price during its initial month of sales (February 2003) was substantially higher than its sales price in the subsequent months during the Agreement. It also appears that this sales price was higher than that of other companies selling paroxetine, including IVAX and GUK, and was also higher than GSK's own price for Seroxat.

¹²⁵² This is based on a comparison of weighted average paroxetine 20mg and Seroxat 20mg prices in the period November 2002 to January 2003 with February 2003 to April 2003.

¹²⁵³ As set out at paragraph 3.383, independent generic entry as regards paroxetine 30mg began later than as regards paroxetine 20mg.

¹²⁵⁴ Calculated as GSK's average market share in the UK paroxetine market between November 2002 and November 2003, based on data submitted by relevant parties.

¹²⁵⁵ There was no market expansion following Alpharma's entry into the UK paroxetine market as a GSK distributor, and nor could GSK have reasonably expected it to result in expansion (see paragraph 6.167).

7.100 Absent the Alparma-GSK Agreement, Alparma would have continued to be a competitive threat and remained a potential competitor to GSK that was pursuing its efforts to enter the market independently of GSK.¹²⁵⁶ Alparma's competitive behaviour would not have been distorted by value transfers made in return for entry restrictions. The realistic and likely outcomes are that Alparma would have pursued its challenge to GSK's patent claims or, alternatively, that Alparma would have entered into a settlement on terms that were not 'bought' using the value transfers, and that legitimately reflected the uncertainty regarding GSK's patent claims.

a) *Alparma seeks to enter the UK paroxetine market independently of GSK*

7.101 Had Alparma not entered into the Alparma-GSK Agreement (or an alternative settlement agreement, see paragraphs 7.107 to 7.110), the prospect of Alparma's potential independent entry would have been maintained (see paragraph 7.66). In the absence of the Alparma-GSK Agreement, it would have been open to Alparma to reject other settlement proposals, to continue with its efforts to enter the UK paroxetine market independently of GSK and to continue to defend the Alparma Litigation. In that case, the prospect of Alparma's independent entry, and of true generic competition, would have been maintained and the processes necessary to determining whether Alparma could have entered the UK paroxetine market would have continued.

7.102 Had Alparma declined to settle, the Alparma Litigation would have continued and the process necessary to determining the validity of the relevant patent claims, and whether the Alparma Product was non-infringing, would have continued.¹²⁵⁷

¹²⁵⁶ As explained at paragraph 7.66, at the time the Alparma-GSK Agreement was entered into, the CMA finds that Alparma was a potential competitor to GSK.

¹²⁵⁷ In a meeting with the OFT, Actavis stated that the counterfactual to the Alparma-GSK Agreement was that litigation would have prevented Alparma from entering the UK paroxetine market for a considerable time. For example, '[Actavis's legal representative] said that the counterfactual Alparma expected was therefore, that if Alparma did not settle and went to trial there would be a substantial delay in Alparma entering the market and it may not have been in a position to launch prior to the Apotex judgement in late 2003.' (Note of meeting between the OFT and Actavis of 16 October 2012 (document 2357), paragraph 15). [Alparma ApS's Sales and Marketing Director] stated in an internal email to [Alparma Ltd's Director of Sales and Marketing], [Alparma ApS's patent attorney], [Alparma Inc's Chief Legal Officer] and others that a key issue to evaluate was: '*The earliest possible time we can have the tableting patent invalidated. As long as that patent is in place we cannot launch any way. If my understanding is correct it will be impossible to launch before well into 2003 due to that patent.*' (email chain entitled 'UK settlement negotiations for Paroxetine – meeting October 11, 2002' dated 14 October 2002 (document 1361)). On that basis, Actavis's statement implies that the Alparma-GSK Agreement could be no less restrictive than the counterfactual, in which case no competition could emerge until such time as the litigation was determined.

- 7.103 The progression of that litigation would have been of relevance to other potential competitors, in addition to Alpharma, as it would have provided greater clarity as to the validity of the Anhydrate Patent, and the terms on which a generic product was found to be non-infringing.¹²⁵⁸ Further, it would also have affected GSK's incentive to pursue litigation against other companies that sought to supply generic paroxetine in the UK. For example, IVAX noted that if it was successful in patent litigation with GSK the relevant *[p]rinciples will be established for all*¹²⁵⁹ and similarly GSK acknowledged, with respect to Alpharma, that independent entry by a generic supplier would lower entry barriers for other generic suppliers: *'Alpharma's presence on the market would be a signal that they need no longer fear an injunction.'*¹²⁶⁰
- 7.104 It is therefore likely that, had the litigation progressed and had Alpharma successfully defended its product launch before the Courts, other generic suppliers would have entered soon after.¹²⁶¹ For example, GSK expected that

The CMA notes that Alpharma agreed not to enter the UK paroxetine market for the duration of the Agreement (see paragraphs 6.152–6.154) and that, in the event that it then launched its own generic paroxetine product after the expiry of the Agreement, Alpharma would have continued to face the prospect of litigation from GSK. To that extent, the Alpharma-GSK Agreement served to delay the processes relevant to resolving the dispute (including the entirety of the litigation process that Actavis refers to), whereas in the counterfactual that process had already been commenced. To that extent, the Alpharma-GSK Agreement delayed the potential emergence of true generic competition.

Actavis stated that while the litigation process may have been delayed as compared to the counterfactual, this did not mean the 'potential emergence of competition' was delayed because Alpharma could have lost the litigation, or not entered until after judgment in an appeal. (Actavis SO Written Response (document 2754), paragraphs 10.20–10.23). The CMA considers that, as set out at paragraphs 7.102–7.106, Alpharma's entry into the Alpharma-GSK Agreement served to delay the relevant litigation process, and as such delayed Alpharma's efforts to enter the market independently of GSK. The CMA notes that the ultimate outcome of any subsequent litigation, when assessed *ex post*, does not alter that position. Moreover, the CMA sets out at paragraph 1.22 that the delay to the potential emergence of true generic competition exists regardless of whether Alpharma would ultimately have entered 'at risk'.

¹²⁵⁸ By way of example, after the Apotex Parties successfully demonstrated a product was non-infringing, several generic suppliers entered the UK paroxetine market (see paragraph 3.21).

¹²⁵⁹ Seroxat (paroxetine): 14th March 2001' dated 14 March 2001 (document 1699).

¹²⁶⁰ [§]WS2 (Alpharma) (document 0289), paragraph 6.2.

¹²⁶¹ Although a judgment may have related only to whether Alpharma's product infringed valid patent claims, a judgment in Alpharma's favour was likely to prompt further entry and to substantially limit GSK's incentive to pursue further litigation. For example, Alpharma sub-licensed the Alpharma Product from Medis, so were this product found to be non-infringing, at least Alpharma and [§] would be able to enter the market. Their independent generic entry would have been expected to result in the substantial price declines that GSK was seeking to avoid by pursuing litigation, limiting GSK's incentive to pursue further litigation in response to further entry. Other generic suppliers could also choose to enter 'at risk', particularly if the decision was taken that the risks and exposure to damages had been reduced by the favourable judgment and subsequent entry (indeed Actavis stated it was the level of risk and exposure to damages which was the key consideration for Alpharma in determining whether to launch (Actavis SO Written Response (document 2754), paragraphs 10.20–10.23)). For these reasons the CMA rejects GSK's and Actavis's submissions that a judgment as to infringement or non-infringement for one product does not necessarily assist other generic suppliers or that early entry by Alpharma would not necessarily have resulted in early entry by other generic suppliers because the Alpharma Litigation related to infringement rather than validity of the Anhydrate Patent, and GSK would have continued to seek injunctions against other potential entrants. (GSK SO Written Response (document 2755), paragraph 8.55, Actavis SO Written Response (document 2754), paragraph 1.17).

Conversely, had GSK prevailed in litigation, this had the potential to disincentivise other generic companies from pursuing independent entry. This is consistent with the views of [GSK's Finance Director A], who explained that: *'[t]he market could continue as it was if GSK won litigation but if it lost the patent then everything would go. There would be intense competition from the generics in the near future. GSK therefore decided, to provide for some*

entry by one generic supplier would *'result in the introduction of other generic products onto the marketplace shortly thereafter with a further wave following as little as 7 months later once relevant marketing authorisations are in place.'*¹²⁶²

7.105 At the time the Alpharma-GSK Agreement was entered into both Apotex and [X] had obtained a UK MA, and both Sandoz and Ratiopharm had applied for an MA.¹²⁶³ If Alpharma had entered independently, it is also likely that IVAX and GUK would have terminated their Agreements with GSK and entered the market.¹²⁶⁴ True generic competition,¹²⁶⁵ between GSK and a number of generic competitors, would inevitably have resulted in substantially lower prices and reduced market shares for GSK (see paragraphs 3.59 to 3.63 and 3.161 to 3.164).

period of certainty, to enter into supply agreements (Note of meeting between the OFT and GSK dated 19 December 2011 (document 0688), paragraphs 18 and 20). Similarly, a note in which IVAX considered its options for the launch of paroxetine, dated 14 March 2001, states that one benefit of entering into an agreement along the lines of the IVAX-GSK Agreement is that *'every one [sic] else has to start again'*. In contrast if it did choose to test the patent *'[p]rinciples will be established for all'*. (*Seroxat* (paroxetine): 14th March 2001' dated 14 March 2001 (document 1699)).

Further, Actavis submitted that the CMA did not provide evidence that [X] would have entered, given that had it done so it would have been competing with its own product. (Actavis SO Written Response (document 2754), paragraph 10.26). The CMA notes that in-licensing arrangements between generic suppliers were common during the period (see paragraph 3.188). Moreover, contrary to Actavis' suggestion that [X] would not have launched its own product, the CMA observes that [X] entered into a settlement agreement with GSK undertaking *'that it will not launch its paroxetine product onto the UK market'* which implies that it had been intending to launch a product (see Letter of Agreement re Paroxetine Hydrochloride Patents between GSK and [X] dated 14 February 2003 (document 0381)).

¹²⁶² [X]WS1 (GUK) (document 0885), paragraph 7.10.

¹²⁶³ Apotex received its MA on 30 July 2002, [X] received its MA on 10 October 2002, and Sandoz and Ratiopharm both applied for MAs on 31 July 2002 (MHRA spreadsheet entitled 'MHRA list of product licences containing paroxetine hydrochloride granted between 1999 and 2005' dated 11 June 2012 (document 2590)).

¹²⁶⁴ Actavis submitted that there is no evidence to support the CMA's assertion that it is likely that IVAX and GUK would have entered the market given that the Alpharma Litigation did not include an assessment as to invalidity and therefore IVAX and GUK would need to receive Delta product from Alpharma in order to enter the market. (Actavis SO Written Response (document 2754), paragraph 10.26). See footnote 1261 for the CMA's response to points regarding possibilities for entry by other generic suppliers following independent entry by one entrant.

¹²⁶⁵ The CMA notes that [Alpharma Ltd's Director of Sales and Marketing] made arguments in a witness statement during the Alpharma Litigation which suggested that the extent of any price fall following Alpharma's independent entry would be limited ([X]WS2 (document 1325), paragraphs 4–34). Some of these arguments are presented as follows:

- *'Seroxat is already sold at a reduced price'*. The CMA notes that this does not in itself explain why prices could not reduce further. [GSK's Finance Director A] submitted in response that the part of the UK paroxetine market to which GSK supplies brand equalisation discounts is influenced by prices to the rest of the UK paroxetine market, and GSK would lose existing customers if it did not increase brand equalisation discounts to match the prices offered by other suppliers. ([X]WS2 (Alpharma) (document 0289), paragraphs 3.1 and 3.2).
- *'GSK will retain its monopoly on some versions of the product and in some markets.'* In response to this, [GSK's Finance Director A] submitted that GSK's ability to retain supply to retailers such as Boots was dependent on offering brand equalisation discounts, which is a defensive pricing strategy offered in reaction to market pressures ([X]WS2 (Alpharma) (document 0289), paragraphs 4.1–4.3). Therefore, if prices were to fall resulting from generic competition, GSK would either lose the relevant business, or need to respond by offering greater discounts.

In any case, the CMA notes that Alpharma's internal expectation, as presented at paragraph 3.321, was that prices would decline following independent generic entry by Alpharma and others.

7.106 In summary, it would have been likely that, had Alparma declined to enter into the Alparma-GSK Agreement (or an alternative settlement agreement, see paragraphs 7.107 to 7.110) and instead remained a potential competitor that was seeking to enter the UK paroxetine market independently of GSK, the Alparma Litigation would have proceeded to trial. As a consequence, both GSK's expected returns¹²⁶⁶ and market-wide returns would have been lower due to the threat of Alparma's successful independent generic entry. An ongoing litigation process would have preserved (rather than deferred) the potential for true generic competition and the associated price declines.

b) GSK and Alparma enter into a settlement agreement on less restrictive terms

7.107 The alternative outcome in the counterfactual is that GSK and Alparma would have entered into a settlement agreement on less restrictive terms.

7.108 For example, had GSK offered a settlement agreement that did not involve the value transfers that GSK made in return for Alparma's acceptance of the entry restrictions, it is reasonable to expect that Alparma would have required an agreement that included other terms that would provide it with sufficient incentive to settle the litigation at the expense of its ongoing efforts to enter the market with generic paroxetine. Absent recourse to value transfers which had the purpose of delaying the potential emergence of true generic competition, GSK would have been required to offer more competitive entry terms to Alparma to provide Alparma with alternative sources of remuneration and a sufficient incentive to settle.¹²⁶⁷

7.109 Any such settlement agreement could have taken one of a number of forms (for example, on the basis of an alternative supply agreement, agreeing a date (prior to the date of patent expiry) on which Alparma could launch its generic product or allowing Alparma to enter on condition that it paid a

¹²⁶⁶ That is, the average of its possible profits going forward, taking account of the potential revenue and costs associated with each possible outcome (for example, the success or otherwise of independent generic entry), and the likelihood associated with each.

¹²⁶⁷ This is consistent with the views of [GSK's Finance Director A] who stated that GSK used the marketing allowance so that a higher supply price could be adopted. One of GSK's objectives was to ensure that list prices in the UK did not deteriorate, because this would also have an impact on the price paid in other countries whose reimbursement systems benchmarked their prices against UK prices. [§]1 (document 4008R), pages 30–31. Actavis submitted that there is no reference to Alparma at pages 30-31 of the interview transcript (Actavis response dated 5 October 2015 to the Second Letter of Facts, document 4164). However, during the witness interview [GSK's Finance Director A] noted that the rationale for the Agreements was common across the Agreements (see [§]1 (document 4008R), pages 44 and 53), and further, [GSK's Finance Director A] confirmed in relation to the Alparma-GSK Agreement that the supply price was set slightly higher to ensure that GSK did not run into problems with reference pricing ([§]1 (document 4008R), page 56). Therefore although the points referred to were discussed in the context of the IVAX-GSK Agreement, [GSK's Finance Director A's] comments are equally applicable to the Alparma-GSK Agreement.

royalty to GSK).¹²⁶⁸ The CMA is satisfied that the negotiation of an alternative settlement agreement, including more competitive terms, was a realistic outcome in the counterfactual. For example, GUK and Alharma both internally considered the possibility that a settlement agreement with GSK could include the payment of a royalty to GSK in return for GSK granting it a non-exclusive licence to sell its product (see paragraphs 3.289 and 3.346).¹²⁶⁹ Alharma also put to GSK the suggestion that they could agree an appropriate date (prior to the date of patent expiry) on which Alharma could launch its own product, but such an approach was rejected by GSK (see paragraphs 3.355 to 3.357).¹²⁷⁰ Moreover, settlement agreements that do not raise competition concerns are common in the pharmaceutical sector. For example, the CMA notes that empirical evidence from the United States supports the proposition that branded and generic suppliers can settle their patent disputes without using payments and similar value transfers that are made in return for entry restrictions.¹²⁷¹

7.110 In summary, it would have been reasonable to expect in the counterfactual that any agreement that Alharma and GSK entered into would not have included restrictions that Alharma only accepted in return for value transfers from GSK, and would have provided for more competitive terms as a result.

c) Representations

7.111 The SO Addressees submitted that the CMA has arbitrarily selected only those counterfactuals that would be more competitive than in the case of the Agreements, rather than realistic and likely scenarios.¹²⁷² The CMA does not

¹²⁶⁸ Actavis submitted that the termination provisions in the Agreement ensured that Alharma could enter at the first available opportunity (Actavis SO Written Response (document 2754), paragraphs 10.30–10.35). See paragraph 7.94 for the CMA's response to this point.

¹²⁶⁹ The CMA notes that agreeing a licencing arrangement as part of a settlement agreement was not uncommon. For example, in a meeting with the OFT on 7 February 2012, GUK noted that: *'it was also quite common for there to be some sort of licence in return for compensation but the terms of the licence would be a matter for negotiation. [GUK's legal representative] thought that the key factors in the negotiation would be: (i) whether GSK believed that they would win/lose; (ii) the strategy with Norton and whether GUK could blow this out of the water; (iii) the cross-undertaking in damages so if GSK lost they would have exposure to pay damages to GUK; and (iv) GSK's ability to supply the product.'* (note of meeting between the OFT and GUK dated 7 February 2012 (document 1210), paragraph 16).

¹²⁷⁰ The CMA acknowledges that Alharma's proposal in this example also included the suggestion that GSK make a value transfer to Alharma as part of the settlement. Without taking a view on the legitimacy of this settlement proposal, the CMA considers that this proposal nonetheless illustrates the principle that Alharma was open to other types of settlement, and deemed an early entry agreement to be a sufficiently credible option to put to GSK during negotiations.

¹²⁷¹ See paragraph 6.25.

¹²⁷² Merck submitted that the CMA had not considered the full range of scenarios and *'arbitrarily selects [...] only those scenarios that it considers would have led to more competitive outcomes than actually occurred.'* (Merck SO Written Response (document 2764), paragraph 5.13). Teva submitted that the CMA seemed to have *'cherry picked'* its counterfactuals (Teva SO Written Response (document 2750), paragraph 238).

accept these submissions, and considers other outcomes to be unrealistic and unlikely.

7.112 For example, at the time the Alparma-GSK Agreement was entered into, Alparma was a potential competitor (see paragraph 7.66), and therefore Alparma ending the Alparma Litigation (and its efforts to enter the market independently of GSK) does not represent a realistic or likely counterfactual. The evidence set out at paragraphs 6.65 to 6.82 indicates that Alparma was continuing its strategy of bringing generic paroxetine to market independently of GSK, and that absent a settlement agreement with GSK, Alparma would have continued to contest the relevant litigation. Furthermore:

- The Parties themselves recognise that continued litigation was an option had an alternative settlement not been reached. Indeed, Actavis stated that the only alternative to the Alparma-GSK Agreement was continued litigation¹²⁷³ and Xellia-Zoetis also posited continued litigation as one of the options available to Alparma,¹²⁷⁴ but neither submitted that Alparma would have walked away from litigation. Similarly, GSK stated that if no settlement was reached *‘the result would have been a continued dispute and ultimately litigation.’*¹²⁷⁵
- The CMA notes that most of the key investment required in developing and launching a product had already been made prior to entering into the Alparma-GSK Agreement, such that this investment represented sunk costs. Sunk costs would not have been relevant to the decision of whether to continue to pursue entry.

7.113 In this context, the CMA considers it highly unlikely and unrealistic that GSK and Alparma would have entered into a settlement that provided for a similarly (or more) restrictive outcome than that which resulted from the Alparma-GSK Agreement. Absent recourse to value transfers which had the purpose of delaying the potential emergence of true generic competition, Alparma would have required alternative more competitive terms to ensure its returns were sufficient to accept an alternative settlement rather than continuing to pursue litigation and seek independent entry (see also paragraphs 7.107 to 7.110).

¹²⁷³ Actavis SO Written Response (document 2754), paragraph 10.39.

¹²⁷⁴ Xellia-Zoetis SO Written Response (document 2767), paragraph 124. See also transcript of Xellia-Zoetis SSO Oral Hearing dated 10 December 2014 (document 3878), page 32 lines 16–19.

¹²⁷⁵ GSK SO Written Response (document 2755), paragraph 4.21(c).

d) Conclusion

7.114 The analysis set out at paragraphs 6.150 to 6.205 demonstrated that the purpose of the value transfers (totalling £11.8 million to Alparma and at least £50.9 million to the Generic Companies overall) was to induce Alparma to defer its efforts to enter the UK paroxetine market independently of GSK. GSK had therefore determined that, if Alparma had been permitted to remain a potential competitor that was continuing with its efforts to enter the market, GSK faced the prospect of lower expected profits,¹²⁷⁶ than if GSK were to make value transfers to Alparma in return for its acceptance of entry restrictions. Put another way, GSK itself considered that, absent the Alparma-GSK Agreement, the competitive outcomes associated with Alparma's position as a potential competitor provided for a far greater constraint than GSK faced having entered into the Alparma-GSK Agreement.

7.115 Consistent with this, the CMA is satisfied that, absent the Alparma-GSK Agreement, Alparma would have continued to be a threat, and remained a potential competitor to GSK that was seeking to enter the UK paroxetine market. This would have led to an increase in the competitive constraints being exerted on GSK, either through the process of litigation challenging GSK's patents, or through a less restrictive settlement recognising the uncertainty inherent in that litigation.

iv) *The absence of other relevant sources of competition to GSK meant that the Alparma-GSK Agreement assisted GSK in preserving its market power*

7.116 By entering into the Alparma-GSK Agreement, GSK materially strengthened its ability to continue to delay the potential emergence of true generic competition, thereby assisting GSK in preserving its market power:

- As set out at paragraph 7.70, at the time the Alparma-GSK Agreement was entered into, the only competitive constraints that GSK faced in the UK paroxetine market were provided by parallel importers of its own product and by IVAX and GUK as GSK distributors. However, parallel importers faced several barriers to expansion which limited the extent to which they were capable of challenging GSK's market position (see paragraph 4.113) and IVAX's and GUK's entry as distributors for GSK was not likely to materially increase the actual competitive constraints faced by

¹²⁷⁶ That is, the average of its possible profits going forward, taking account of the potential revenue and costs associated with each possible outcome (for example, the success or otherwise of independent generic entry), and the likelihood associated with each.

GSK (see paragraphs 7.25 to 7.34 and B.143 to B.151). At the time the AlphaPharma-GSK Agreement was entered into, there were no independent suppliers of generic paroxetine in the UK paroxetine market.¹²⁷⁷

- At the time of entering into the AlphaPharma-GSK Agreement, the AlphaPharma Litigation had progressed by some five months having begun on 11 June 2002. Although the Apotex Litigation had commenced on 22 October 2002, it was around four months behind the start of the AlphaPharma Litigation and was therefore likely to conclude later than the AlphaPharma Litigation would have done.¹²⁷⁸ Entering into the AlphaPharma-GSK Agreement would therefore ensure that the process by which GSK's patent position would be examined by the courts would be delayed, and the uncertainty regarding GSK's patent position would be prolonged.
- At the time the AlphaPharma-GSK Agreement was entered into, Neolab and Waymade were parties to the Apotex Litigation¹²⁷⁹ and, as set out in paragraph 7.105, [X] and Apotex had obtained a UK MA.¹²⁸⁰ This meant that, having entered into the AlphaPharma-GSK Agreement, GSK had limited the probability of its patent position being successfully challenged, and of true generic competition emerging. It also ensured that GSK would only need to reach an agreement with two further parties (Apotex¹²⁸¹ and [X]) to ensure that the potential for independent generic entry was further

¹²⁷⁷ The CMA notes that during the AlphaPharma Litigation, [GSK's Finance Director A] [in relation to other generic competition] stated that '*GUK, Tillomed and Ivax are free at any time to sell their own generic products in the UK*' ([X]WS2 (AlphaPharma) (document 0289), paragraph 6.2). However, the CMA finds that IVAX and GUK had agreed or been incentivised not to enter the UK paroxetine market (see paragraphs B.131 and 6.140) and Tillomed had already entered into the IVAX-Tillomed Supply Agreement (document 1751), granting IVAX exclusive rights to use its MA in the UK, and as such, Tillomed was not in a position to imminently enter at the time of the AlphaPharma-GSK Agreement.

¹²⁷⁸ Although the BASF Litigation had ended, the CMA notes that the judgment in the BASF Litigation was that of the various claims in the Anhydrate Patent, only claim 10(i) and claim 11 were valid, and GSK continued to challenge generic entry after this judgment. In particular, GSK varied the case against AlphaPharma to allege that the remaining claim was infringed and issued proceedings against the Apotex Parties. It was not until the Apotex Litigation when a finding was made on a product not infringing that generic entry occurred.

¹²⁷⁹ See paragraph 3.135.

¹²⁸⁰ During the AlphaPharma Litigation, [GSK's Finance Director A] reported that '*GSK has also been approached by APS regarding the possible sale by APS [Approved Prescription Services] of paroxetine in the UK. At present, APS does not have the necessary marketing authorisation but its approach to GSK would seem to indicate that it has applied or is applying for one.*' ([X]WS2 (AlphaPharma) (document 0289), paragraph 6.3). However, the CMA has not listed APS as ready to enter because GSK stated in its Second Response, Part Two (document 0734), paragraph 6.21, that '[t]here was insufficient evidence to justify sending warning letters to any other generic producers', which implies that APS was not at a sufficiently advanced stage in its entry preparations for GSK to perceive that it posed it a significant threat. The CMA notes that although GSK entered into an agreement with [X] in February 2003, GSK did not become aware that [X] had obtained an MA until after it had entered into the AlphaPharma-GSK Agreement.

¹²⁸¹ As Neolab and Waymade were distributors for Apotex (see *SmithKline Beecham Plc v Apotex Europe Limited* [2003] EWHC 2939 (Ch)), reaching an agreement with Apotex would delay the potential entry of Apotex, Neolab and Waymade.

delayed.¹²⁸² Doing so would mean that its patent position would remain unchallenged, and it could continue to commence litigation against (and seek to settle with) other potential competitors should any subsequently emerge. Entering into the Alpharma-GSK Agreement with one of the known potential entrants therefore increased the potential for GSK to continue its strategy of securing agreements that would defer the potential emergence of true generic competition.

7.117 The anti-competitive effects of the Alpharma-GSK Agreement were reinforced in view of the context: GSK had previously entered into the IVAX-GSK and GUK-GSK Agreements, and subsequently entered into a settlement agreement with [redacted].¹²⁸³ Together these agreements helped to make sure that each threat of potential independent generic entry was deferred, and that there was no material increase in the actual competitive constraints that GSK faced.

¹²⁸² Moreover, although Sandoz and Ratiopharm had applied for an MA, they had not yet received it, so there would have been a delay until the time of their potential entry.

¹²⁸³ Alpharma understood GSK's strategy was to seek to enter into similar settlement agreements with other potential competitors such that the potential for true generic competition to emerge would continue to be delayed. For example, [Alpharma ApS's Sales and Marketing Director] stated in an email on 11 October 2002: 'GSK consider us the only serious threat right now, but will be ready to consider similar deals if others make a similar threat.' (Email chain between [Alpharma Ltd's Director of Sales and Marketing], [Alpharma ApS's Sales and Marketing Director], [Alpharma Inc's Vice President of Intellectual Property], [Alpharma Inc's President (Human Generics)], [Alpharma ApS's patent attorney], [VP New Products – FP at Alpharma ApS], [Alpharma Inc's Chief Financial Officer], [Alpharma Inc's Chief Legal Officer], entitled 'UK settlement negotiations for Paroxetine – meeting October 11, 2002' dated 14 October 2002 (document 1361)). Similarly, in an email dated 1 October 2002, [Alpharma ApS's Sales and Marketing Director] stated: 'GSK wants to supply product to us if we enter. They want to attack all non-GSK product entering the market, and he [GSK's Finance Director A] stated that he would struggle to get a contract approved by the legal department in which we can launch a Delta product at a later stage'. (Email from [Alpharma ApS's Sales and Marketing Director] to [Alpharma Inc's Vice President of Intellectual Property] and others entitled 'Today's meeting with [GSK's Finance Director A], GSK, re. settlement possibilities for Paroxetine' dated 1 October 2002 (document 1356)).

8. ABUSE OF A DOMINANT POSITION

A. Overview

- 8.1 The CMA's assessment of GSK's dominant market position is set out in Part 4, Section E. As described in that Part the CMA finds that GSK held a dominant market position from at least January 1998 to November 2003.
- 8.2 In this Part, the CMA finds that GSK abused its dominant position (in contravention of Chapter II of the Act) by making value transfers to induce the Generic Companies to delay their potential entry (independently of GSK) to the market for the supply of paroxetine in the UK. GSK did not comply with its special responsibility not to allow its conduct to impair genuine undistorted competition.
- 8.3 In particular, the CMA finds that:
- (a) The purpose of GSK committing to make cash payments and other value transfers to the Generic Companies was to induce the Generic Companies to delay their efforts to enter the market independently of GSK and thereby protect GSK from such competition. That conduct did not constitute 'normal competition' or 'competition on the merits'.
 - (b) GSK's conduct also had the likely effect of restricting competition.
 - (c) GSK has not demonstrated that its conduct was objectively justified.
- 8.4 The CMA has applied the Chapter II prohibition to GSK's conduct (as well as applying the Chapter I prohibition and Article 101 TFEU in relation to the GUK-GSK Agreement and the Chapter I prohibition in relation to the AlphaPharma-GSK Agreement) because that conduct formed part of GSK's overall strategy to delay potential competition from generic undertakings, and fell outside the scope of competition on the merits.¹²⁸⁴
- 8.5 The remainder of this Part is structured as follows:
- Section B summarises the legal test for finding an abuse of a dominant position.

¹²⁸⁴ Paragraphs 6.4–6.9 explained the CMA's concerns with the reverse payment settlement agreements. That analysis is also relevant to the circumstances in which a dominant company makes value transfers to induce a potential competitor to defer its efforts to enter the market independently of the dominant company.

- Section C explains why GSK's conduct did not constitute 'normal competition' or 'competition on the merits'.
- Section D sets out the CMA's analysis of the likely anti-competitive effects of GSK's conduct on the UK paroxetine market.
- Section E presents the CMA's response to GSK's submissions that there was an objective justification for its conduct.
- GSK's representations on this Part are set out and responded to at Annex J.

B. The legal test for an abuse of a dominant position

- 8.6 Section 18(1) of the Act imposes the Chapter II prohibition¹²⁸⁵ which provides that any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the UK.¹²⁸⁶
- 8.7 It has been consistently held that an undertaking holding a dominant position has a special responsibility not to allow its conduct to impair genuine undistorted competition.¹²⁸⁷ The scope of that responsibility must be considered in light of the circumstances of each case which show a weakened competitive situation.¹²⁸⁸
- 8.8 The CJ has defined the concept of abuse as:¹²⁸⁹

‘an objective concept relating to the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to

¹²⁸⁵ The Chapter II prohibition does not apply in cases in which it is excluded pursuant to section 19 of the Act. None of the excluded cases is applicable in respect of the Infringements that are the subject of this Decision.

¹²⁸⁶ Section 18(3) of the Act provides that, for the purposes of section 18, a 'dominant position' means 'a dominant position in the United Kingdom' and 'the United Kingdom' means 'the United Kingdom or any part of it'.

¹²⁸⁷ Case 322/81 *Michelin v Commission* EU:C:1983:313, paragraph 57. See also Judgment of 7 October 1999 in, *Irish Sugar v Commission*, T-228/97, ECR, EU:T:1999:246, paragraph 112. See also *Aberdeen Journals Ltd v Office of Fair Trading* [2003] CAT 11, at [350] in which, in relation to the Chapter II prohibition, the CAT referred to 'the special responsibility of a dominant firm not to impair genuine undistorted competition'.

¹²⁸⁸ Case C-333/94 P *Tetra Pak v Commission* EU:C:1996:436, paragraph 24; *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1 at [219].

¹²⁸⁹ Judgment of 6 December 2012 in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 74.

Judgment of 13 February 1979 in *Hoffmann-La Roche v Commission*, C-85/76, EU:C:1979:36, paragraph 91. This passage has since often been cited in the European Courts and in the CAT. For example, see *Genzyme Ltd v Office of Fair Trading* [2004] CAT 4, at [482]-[484]. See also the Court of Appeal in *Napp Pharmaceuticals Holdings Ltd v Director General of Fair Trading* [2002] EWCA Civ 796, paragraphs 22–24.

methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.'

- 8.9 In order to determine whether there has been recourse to methods different from those which condition normal competition, regard must be had to all the relevant circumstances of the individual case.¹²⁹⁰ It is well established that a dominant undertaking must not resort to methods falling outside the scope of 'competition on the merits' and must not adopt a strategy of using its economic strength and/or strong market position to impair undistorted competition, including competition which still remains in the market or the growth of that competition in future.¹²⁹¹
- 8.10 Whilst anti-competitive intent is not a prerequisite to establish an abuse, it is one of the facts that may be taken into account when determining whether a dominant position has been abused.¹²⁹²
- 8.11 For the purposes of establishing an abuse of a dominant position within the meaning of the Chapter II prohibition, it is sufficient to show that the abusive conduct of the undertaking in a dominant position tends to restrict competition or that the conduct is capable of having that effect.¹²⁹³ Conduct of a dominant undertaking is capable of having that effect when it makes the entry of competitors onto the market more difficult, or impossible, thereby interfering with the structure of competition on the market.¹²⁹⁴ The '*anti-competitive nature of [the dominant undertaking's] acts must be evaluated at the time when those acts were committed*'.¹²⁹⁵
- 8.12 A dominant undertaking may defend behaviour that would otherwise be abusive by showing either that it is objectively necessary or that the exclusionary effect produced by that behaviour is counterbalanced by advantages in terms of efficiency gains that also benefit consumers.¹²⁹⁶
- 8.13 The concept of objective justification is to be applied in terms of the general interest, and in particular the interests of customers and consumers that the

¹²⁹⁰ Judgment in *Tomra Systems ASA v Commission*, C-549/10 P, EU:C:2012:221, paragraph 18.

¹²⁹¹ Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraphs 74–75. See also Judgment in *Hoffmann-La Roche v Commission*, 85/76, EU:C:1979:36, paragraph 91.

¹²⁹² Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraphs 359, upheld by the CJ in Judgment in *AstraZeneca AB and AstraZeneca v Commission* C-457/10, EU:C:2012:770.

¹²⁹³ Judgment in *Tomra Systems v Commission*, C-549/10 P, EU:C:2012:221, paragraph 68.

¹²⁹⁴ Judgment in *TeliaSonera Sverige AB*, C-52/09, EU:C:2011:83, paragraph 63.

¹²⁹⁵ Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 110.

¹²⁹⁶ Judgment in *Post Danmark A/S*, C-209/10, EU:C:2012:172, paragraphs 40–41.

Chapter II prohibition is intended to protect, and not in terms of the benefits that accrue to the dominant undertaking.¹²⁹⁷

- 8.14 If objective justification is relied on to justify what would otherwise be prohibited conduct, it is necessary to consider '*whether the conduct in question is indispensable and proportionate to the goal allegedly pursued by the dominant undertaking*'.¹²⁹⁸
- 8.15 The existence of an objective justification may be tested by seeing whether the evidence shows that it was the actual basis on which the dominant company acted. If it appears that the justification relied on was not really why the dominant company behaved as it did, this can shed light on the strength of the justification.¹²⁹⁹
- 8.16 The CJ has also recognised that the exclusionary effect produced by the conduct of a dominant undertaking may be counterbalanced or outweighed by advantages in terms of efficiency that also benefit consumers. The CJ has held:¹³⁰⁰

'In that last regard, it is for the dominant undertaking to show that the efficiency gains likely to result from the conduct under consideration counteract any likely negative effects on competition and consumer welfare in the affected markets, that those gains have been, or are likely to be, brought about as a result of that conduct, that such conduct is necessary for the achievement of those gains in efficiency and that it does not eliminate effective competition, by removing all or most existing sources of actual or potential competition.'

- 8.17 It is sufficient for one of the four conditions not to be met in order for an efficiency defence to be rejected. It is incumbent upon the dominant undertaking to provide all the evidence necessary to demonstrate that its conduct is objectively justified. It then falls to the CMA to make an assessment of whether the conduct in question is not objectively necessary and, based on a weighing up of any apparent anti-competitive effects against

¹²⁹⁷ *Genzyme v Office of Fair Trading* [2004] CAT 4, at [583].

¹²⁹⁸ Commission Communication: Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty (now Article 102 TFEU) to abusive exclusionary conduct by dominant undertakings OJ C 45/7, 24.2.2009, paragraph 28, last sentence.

¹²⁹⁹ *Arriva the Shires Ltd v London Luton Airport Operations Ltd* [2014] EWHC 64 (Ch), paragraphs 134, 148.

¹³⁰⁰ Judgment in *Post Danmark A/S*, C-209/10, EU:C:2012:172, paragraph 42. Commission Communication: Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty (now Article 102 TFEU) to abusive exclusionary conduct by dominant undertakings OJ C 45/7, 24.2.2009, paragraph 30.

any advanced and substantiated efficiencies, is likely to result in consumer harm.¹³⁰¹

C. GSK's conduct did not constitute normal competition

8.18 Under the terms of its Agreements with the Generic Companies, GSK committed to make cash payments and other value transfers totalling at least £50.9 million to the Generic Companies (see paragraph B.47), including at least £17.9 million in transfers to IVAX (see paragraph B.63), at least £21.3 million in transfers to GUK (see paragraph 6.91), and £11.8 million in transfers to AlphaPharma (see paragraph 6.155).

8.19 The CMA observes that, at the time that GSK committed to make those value transfers to the Generic Companies, the relevant context was as follows:

- (a) the Generic Companies were all potential competitors to GSK in the supply of paroxetine in the UK; there were real concrete possibilities for the Generic Companies to enter the market independently of GSK and compete with GSK;¹³⁰² and
- (b) had true generic competition emerged, such competition was expected to result in significant decreases in paroxetine prices in the UK and a decline in GSK's market share.¹³⁰³ GSK's own expert forecasted that, if successful, generic entry would result in price decreases of around 60% within two years.¹³⁰⁴

j) The purpose of the value transfers that GSK made to the Generic Companies

8.20 The main economic purpose of the value transfers was to induce the Generic Companies to delay their potential independent generic entry:

- (a) GSK's agreement to make value transfers to each of GUK and AlphaPharma was conditional on GUK and AlphaPharma accepting and adhering to entry restrictions. The IVAX-GSK Agreement was designed to be an alternative

¹³⁰¹ Guidance on Article 102 TFEU, page 7, paragraphs 30-31. See also Judgment of 17 September 2007 in, *Microsoft v Commission*, T-201/04, ECR, EU:T:2007:289, paragraph 688.

¹³⁰² See paragraphs B.3–B.60 for IVAX, paragraphs 6.47–6.64 for GUK, and paragraphs 6.65–6.82 for AlphaPharma.

¹³⁰³ See paragraphs 6.34–6.39 and B.61–B.62.

¹³⁰⁴ In particular, [GSK's independent expert's] expectation, based on four case studies, was that '*generics will probably undercut the pre-generic price of Seroxat by around 30% within 6 months of launch, by 45 to 50% after 12 months and by 60% after 24 months.*' [§]WS dated 13 September 2001, paragraph 20 (document 0143). See also paragraph 3.63.

to IVAX's independent generic entry and the value transfers from GSK necessarily incentivised IVAX to defer its own potential generic entry.

- (b) GSK's decision to make each value transfer cannot be explained on the basis of their stated purpose in the respective Agreements.
- (c) The overall level of the value transfers cannot be explained on any other commercial basis that was not anti-competitive, and the value transfers were commercially rational for GSK only on the basis that they would induce the Generic Companies to delay their potential independent market entry.

a) *The contractual terms on which GSK committed to make value transfers to the Generic Companies*

8.21 As set out in Part 6, the CMA finds that the respective value transfers that GSK made to GUK and Alpharma were contractually linked to each of GUK's and Alpharma's acceptance of entry restrictions:

- under the GUK-GSK Agreement, GUK accepted the value transfers and committed not to make, import, supply or offer to supply paroxetine in the UK save as purchased from IVAX pursuant to the GUK-IVAX Agreement or otherwise manufactured or marketed by GSK¹³⁰⁵ (see paragraphs 6.93 and 6.88 to 6.90); and
- under the Alpharma-GSK Agreement, Alpharma accepted the value transfers and committed not to import, supply or offer to supply paroxetine in the UK save as purchased from IVAX pursuant to the Alpharma-IVAX Agreement or otherwise manufactured or marketed by GSK¹³⁰⁶ (see paragraphs 6.157 and 6.152 to 6.154).

8.22 In the case of IVAX, the IVAX-GSK Agreement was designed to be an alternative to IVAX's independent generic entry, such that, by incentivising IVAX to enter into and sustain the IVAX-GSK Agreement, the value transfers necessarily incentivised IVAX to defer its own potential generic entry (see paragraphs B.100 to B.101 and B.108 to B.131).

¹³⁰⁵ Specifically, for the term of the GUK-IVAX Agreement.

¹³⁰⁶ Specifically, for the term of the Alpharma-IVAX Agreement.

b) GSK's decision to make each value transfer cannot be explained on the basis of their stated purpose in the respective Agreements

8.23 Part 6 and Annex B include an assessment of whether, from GSK's perspective, the payments within the Agreements were for their stated purpose.

8.24 In relation to the value transfers that GSK made to IVAX, the CMA finds that:

- The purpose of the promotional allowance could not have been to fund marketing to be carried out by IVAX, or to fund discounts to its resale price, and IVAX had no reason to use the marketing allowances for marketing or for discounting. There were no legitimate benefits to GSK that can explain GSK transferring the marketing allowances to IVAX (see paragraphs B.64 to B.68).
- The '*transfer of a restricted volume of paroxetine*' constituted a value transfer. There were no legitimate benefits to GSK of transferring a restricted volume of paroxetine to IVAX (see paragraphs B.69 to B.79).

8.25 In relation to the value transfers that GSK made to GUK, the CMA finds that:

- The purpose of the marketing allowance could not have been to fund marketing to be carried out by GUK, or to fund discounts to its resale price, and GUK had no reason to use the marketing allowances for marketing or for discounting. There were no legitimate benefits to GSK that can explain GSK transferring the marketing allowances to GUK (see paragraphs 6.94 to 6.98).
- GSK did not make payments for GUK's stock for the purpose of its profitable resale, and there were no legitimate benefits to GSK that can explain GSK's payments to acquire that stock (see paragraphs 6.99 to 6.102).
- The '*transfer of a restricted volume of paroxetine*', and the associated profit guarantee clause, constituted a value transfer. There were no legitimate benefits to GSK that can explain GSK transferring a restricted volume of paroxetine to GUK (see paragraphs 6.103 to 6.110).¹³⁰⁷

¹³⁰⁷ As set out paragraphs 5.9 and 6.92, the transfer of a restricted volume of paroxetine, and the associated profit guarantee, was made by GSK to GUK, indirectly via IVAX pursuant to the IVAX-GSK Agreement and the GUK-IVAX Agreement.

8.26 In relation to the value transfers that GSK made to Alpharma, the CMA finds that:

- The purpose of the marketing allowance could not have been to fund marketing to be carried out by Alpharma, or to fund discounts to its resale price, and Alpharma had no reason to use the marketing allowances for marketing or for discounting. There were no legitimate benefits to GSK that can explain GSK transferring marketing allowances to Alpharma (see paragraphs 6.158 to 6.162).
- The ‘transfer of a restricted volume of paroxetine’ constituted a value transfer. There were no legitimate benefits to GSK that can explain GSK transferring a restricted volume of paroxetine to Alpharma (see paragraphs 6.163 to 6.171).¹³⁰⁸
- There were no legitimate benefits that can explain GSK’s payments for Alpharma’s legal, production and preparation costs to Alpharma (see paragraphs 6.172 to 6.174).

8.27 The CMA therefore finds that, when considered objectively, the value transfers made by GSK were not for the purposes as stated in the relevant Agreements.

- c) *The overall level of the value transfers cannot be explained on any other commercial basis that was not anti-competitive, and the value transfers were commercially rational for GSK only on the basis that they would induce the Generic Companies to delay their potential independent market entry***

8.28 The CMA observes, first, that entering into the Agreements with IVAX, GUK and Alpharma could not have been expected to provide for legitimate benefits that could explain GSK’s decision to commit to make value transfers totalling at least £50.9 million:

- There were no gains from entering into the Agreements (or transferring the associated¹³⁰⁹ sums), and supplying restricted volumes of paroxetine to

¹³⁰⁸ As set out at paragraphs 5.11 and 6.156, the transfer of a restricted volume of paroxetine was made by GSK to Alpharma, indirectly via IVAX pursuant to the IVAX-GSK Agreement and the Alpharma-IVAX Agreement.

¹³⁰⁹ See, for example, GSK presentation entitled ‘Seroxat Patent Challenge’ by [GSK’s Finance Director A] and [GSK’s Head of Regulatory Affairs] dated 5 February 2001 (document 0123), and [GSK]WS2 (GUK) (document 0182).

the Generic Companies, that can explain the level of value transfers that GSK made, because:

- at the time the Agreements were entered into, GSK was already able to distribute paroxetine throughout the UK, so the additional sub-distribution agreements did not provide for any opportunities to increase supply or to lower GSK's distribution costs;¹³¹⁰ and
- any strategy aimed at increasing the supply of paroxetine was reliant on persuading GPs to issue more prescriptions for paroxetine, and could not be achieved by changes to GSK's distribution model.
- Consistent with this, the CMA infers that, by imposing volume restrictions on the purchases that the Generic Companies could make from GSK, the intention was not to encourage the development of a supply channel involving them, but rather to transfer value from GSK to each of the Generic Companies (see paragraphs B.69 to B.79 (IVAX), paragraphs 6.103 to 6.110 (GUK) and paragraphs 6.163 to 6.171 (Alpharma)).

8.29 As set out above, the CMA has also considered whether the avoidance of litigation costs, damages exposure pursuant to the GUK Interim Injunction or Alpharma Undertaking, or the risks of irreversible damages (in the case of IVAX) could plausibly explain the level of value transfers that GSK committed to make to each of IVAX, GUK and Alpharma (see paragraphs B.84 to B.99 (IVAX), 6.111 to 6.133 (GUK), 6.175 to 6.196 (Alpharma)). For the reasons set out in those sub-sections, the CMA does not consider any of these factors to be capable of explaining the level of value transfers made to each Generic Company. For the same reasons, the CMA does not consider that the overall level of value transfers that GSK made to IVAX, GUK and Alpharma can be explained by the avoidance of those costs.

8.30 Moreover, although GSK was committed to making value transfers totalling at least £50.9 million on entering into the Alpharma-GSK Agreement (and having already entered into the IVAX-GSK and GUK-GSK Agreements), the litigation costs that it deferred were unlikely to include all of the costs that GSK had estimated that it would have incurred in relation to the Alpharma, GUK and IVAX disputes. This is because, as was ultimately the case following GSK's dispute with Apotex, one concluded case was likely to have provided clarity as

¹³¹⁰ GSK documents that discuss entry into sub-distribution agreements make no reference to efficiencies or gains to be made through increased distribution, but rather, focus on the need to protect GSK's price and patent position. See, for example, GSK presentation entitled 'Seroxat Patent Challenge' by [GSK's Finance Director A] and [GSK's Head of Regulatory Affairs] dated 5 February 2001 (document 0123), and [REDACTED]WS2 (GUK) (document 0182)/ [REDACTED]WS2 (Alpharma) (document 0289).

to whether and on what terms generic entry was possible without infringing valid patent claims, and had the potential to prompt the widespread generic entry that would have disincentivised GSK from pursuing further litigation (see paragraphs 6.119 and 6.183).

- 8.31 Furthermore, in the context of a market with a total sales value of £91 million in 2001¹³¹¹ and that was expected to be the subject of substantial price declines had generic entry taken place (see paragraph 8.19), the CMA considers that GSK would, on an objective basis, have been aware that offering value transfers of at least £50.9 million¹³¹² between 2001 to 2005 in total to the Generic Companies would significantly increase the Generic Companies' incentives to delay their potential generic entry.
- 8.32 The CMA therefore finds GSK's decision to transfer value to the Generic Companies was commercially irrational were it not for the gains that GSK expected to derive from delaying the potential emergence of true generic competition. The purpose of the value transfers was to delay true generic competition, as the payment of value transfers would have made no economic sense if this were not the case.

ii) *GSK had the intention of restricting competition*

- 8.33 This Section considers GSK's intention on making the value transfers to IVAX, GUK and Alharma and entering into the associated Agreements, and whether or not GSK's intention supports the analysis outlined above. As summarised below, the evidence obtained from GSK indicates that it transferred value to the Generic Companies as part of its overall strategy to maintain its monopolistic position on the UK paroxetine market for as long as possible.
- 8.34 As described in paragraphs 3.144 to 3.154, GSK's rationale for entering into supply agreements with generic suppliers in relation to paroxetine generally is set out in documents relating to Project Dyke. GSK intended to '*maintain [GSK's] monopolistic position*' by a combination of either: (i) suing potential entrants for infringement of GSK's patent rights; or (ii) cooperating with potential generic entrants by entering into '*supply agreements*' (also called '*co-marketing agreements*') with them.¹³¹³ GSK expected that these steps would postpone the significant price falls and market share decreases that it

¹³¹¹ CMA's calculations, based on data provided by relevant parties.

¹³¹² See paragraph B.47 for a breakdown of value transfers between the Generic Companies, and for calculations.

¹³¹³ GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100).

anticipated would otherwise occur if generic competitors entered the market.¹³¹⁴ Further examples are considered at paragraphs 6.134 to 6.135 and 6.198.

- 8.35 Taken together, the evidence regarding intentions confirms that GSK's intention was to use value transfers as a means of securing entry restrictions and deferring the threat of true generic competition. This evidence supports the CMA's findings outlined at paragraphs 8.18 to 8.32.

iii) Conclusion

- 8.36 For the reasons set out at paragraphs 8.18 to 8.32, the CMA finds that the purpose of GSK's value transfers to IVAX, GUK and Alparma was to induce them to delay their efforts to enter the UK paroxetine market independently of GSK; indeed that was GSK's intention (see paragraphs 8.33 to 8.35). In having recourse to methods different from those which condition 'normal competition', GSK's conduct tended to restrict competition or was capable of having that effect, and deviated from GSK's special responsibility not to allow its conduct to impair genuine undistorted competition. Absent an objective justification, GSK's conduct therefore constituted an abuse of a dominant position in contravention of the Chapter II prohibition.

D. Likely effect on competition

i) Introduction

- 8.37 The CMA finds that the reasons set out above (at paragraphs 8.18 to 8.36) are sufficient to demonstrate that GSK's conduct (absent an objective justification) constituted an abuse of a dominant position in contravention of the Chapter II prohibition. However, for completeness, the CMA sets out in this Section its detailed analysis of the likely effect of GSK's conduct on competition.¹³¹⁵

- 8.38 As set out in detail below, the CMA finds that the likely effect of value transfers made by GSK to the Generic Companies was to restrict or distort competition:

- At the time that GSK committed to make the value transfers, GSK held a dominant position in the UK paroxetine market.

¹³¹⁴ See [REDACTED]WS1 (document 0241), paragraph 9.2 and [REDACTED]WS2 (GUK) (document 0182), paragraph 2.4..

¹³¹⁵ A number of the representations in relation to the effects of the individual Agreements are discussed in the relevant effects Sections. Representations of relevance to all of the Agreements are presented in Annex I.

- At the time the Agreements were entered into, the Generic Companies were each potential competitors to GSK in the UK paroxetine market. Each of the Generic Companies was pursuing an entry strategy aimed at entering the market with generic paroxetine sourced independently of GSK.
- The value transfers in the Agreements had the likely effect of inducing the Generic Companies to delay their potential independent entry and the associated price decreases. As regards the structure of the market, the Agreements therefore had the likely effect of assisting GSK in preserving the patent entry barriers faced by the Generic Companies and other potential entrants and thereby enabling GSK to maintain its dominant position.
- Entry by the Generic Companies as distributors of GSK product was not likely to materially increase the actual competitive constraints faced by GSK. As a consequence of the volume restrictions, their entry would have no meaningful impact on actual competition in the UK paroxetine market.¹³¹⁶
- Developments observed in the UK paroxetine market during the term of the Agreements are consistent with this analysis: (i) the Generic Companies deferred their efforts to enter the market independently of GSK and (ii) their restricted entry as GSK distributors had no material impact on market prices.
- Absent the values transfers made to induce a delay to each Generic Companies' potential independent generic entry, the Generic Companies would have remained potential competitors to GSK that were pursuing their efforts to enter the market independently of GSK. GSK's competitive behaviour would not have been distorted by value transfers made to induce a delay to their potential independent entry. The realistic and likely outcomes are that the Generic Companies would have continued with their efforts to enter the UK paroxetine market independently of GSK or else they would have settled their disputes on less restrictive terms.

¹³¹⁶ Even if it had been the case that such entry materially constrained GSK, the CMA considers it likely that in the counterfactual the terms of entry and/or supply would have been less restrictive. That is because in the absence of a value transfer in return for entry restrictions, or made to induce a potential entrant to defer its efforts to enter the market independently, it is reasonable to expect that each Generic Company's acceptance of any settlement agreement would have required more competitive terms because GSK would have been required to offer more competitive terms to the Generic Companies to provide the Generic Companies with alternative sources of remuneration and a sufficient incentive to settle.

- The absence of other relevant sources of competition to GSK meant that the Agreements assisted GSK in preserving its dominant position.

ii) GSK's competitive position

8.39 As set out at Part 4, the CMA finds that, at least between January 1998 and November 2003, GSK held a dominant position in the UK paroxetine market.

8.40 In the context of the value transfers made to the Generic Companies, and the delay to independent entry that they induced, GSK had an interest in protecting its dominant position, as there had been no entry into the UK paroxetine market by companies supplying paroxetine sourced independently of GSK and therefore GSK was able to sustain far higher profits than was likely to be the case following independent generic entry (see paragraphs 3.161 to 3.164).

iii) The Generic Companies were potential competitors to GSK

8.41 For the reasons set out at paragraphs B.3 to B.60 (IVAX), 6.47 to 6.64 (GUK), and 6.65 to 6.82 (Alpharma), the CMA finds that each Generic Company was a potential competitor to GSK in the UK paroxetine market at the time it entered into its respective Agreement with GSK. Each of the Generic Companies was pursuing an entry strategy aimed at entering the market with generic paroxetine sourced independently of GSK.

iv) The likely effect of the value transfers was to induce delays to the potential emergence of true generic competition, and to assist GSK in preserving its dominant position

8.42 As set out at paragraphs B.63 to B.131 (IVAX), 6.86 to 6.141 (GUK) and 6.150 to 6.205 (Alpharma), GSK made value transfers to induce the Generic Companies to delay their efforts to enter the market independently of GSK. IVAX entered into the IVAX-GSK Agreement as an alternative to independent generic entry (see paragraphs B.108 to B.131), and GUK and Alpharma accepted entry restrictions (see paragraphs 6.88 to 6.90 (GUK) and 6.152 to 6.154 (Alpharma)).

8.43 As set out at paragraphs 7.18 to 7.24 (GUK), 7.72 to 7.75 (Alpharma) and B.139 to B.142 (IVAX), in the absence of the value transfers described above (and in the absence of more competitive settlement terms from GSK), the Generic Companies would not have been incentivised to enter into their respective Agreements with GSK and to defer their efforts to enter the market independently of GSK.

- 8.44 As set out at paragraphs B.82 (IVAX), 6.90 (GUK) and 6.154 (Alpharma), the CMA observes that the Agreements did not resolve the relevant disputes as GSK provided no commitment that it would refrain from patent litigation proceedings if any of the Generic Companies sought to enter the UK paroxetine market independently with generic paroxetine after the expiry of the Agreement. As such, while the threat of each Generic Company's potential independent entry was delayed as a consequence of the actions that the value transfers incentivised, the Agreements' terms were such that each of the Generic Companies would continue to face the prospect of litigation (see paragraphs 4.116 to 4.123) in the event that it entered the UK paroxetine market with a generic paroxetine product sourced independently of GSK, even after the expiry of the Agreement.
- 8.45 The Agreements, including the value transfers that were used to induce their acceptance, had the likely effect of deferring the potential market entry of each of IVAX, GUK and Alpharma. In doing so, GSK's conduct assisted GSK in preserving the patent entry barriers faced by other potential entrants, who would continue to face the prospect of litigation in the event that they sought to enter the UK paroxetine market with a generic paroxetine product sourced independently of GSK (see also paragraphs 8.55 to 8.56). GSK's conduct therefore made the independent entry of competitors onto the market more difficult, thereby interfering with the structure of competition on the market.
- v) ***The likely effect of the Generic Companies' entry as GSK distributors was no material increase to the actual competitive constraints faced by GSK***
- 8.46 The transfer of a restricted volume of product from GSK to each Generic Company was unlikely to materially increase the actual competitive constraints faced by GSK in the supply of paroxetine in the UK.
- 8.47 As set out at paragraphs B.69 to B.70 (IVAX), 6.103 to 6.104 (GUK) and 6.163 to 6.164 (Alpharma), under the terms of the Agreements, GSK transferred value to each Generic Company by supplying it with a restricted volume of paroxetine. For the reasons outlined at those paragraphs, the transfer of a restricted volume of product itself represented a value transfer that involved GSK transferring to each Generic Company the margin it would otherwise have earned on such volumes. In the same way as a payment, GSK was able to use this mechanism to make a value transfer to each Generic Company through a means that would not meaningfully increase the price competition it was facing on the market. Consistent with this and as set out at paragraphs 7.25 to 7.41 (GUK), 7.76 to 7.94 (Alpharma) and B.143 to B.161 (IVAX), the likely effect of the transfer of a restricted volume of

paroxetine was no material increase in the actual competitive constraints faced by GSK and therefore no meaningful impact on the degree of actual competition in the UK paroxetine market:

- In the event that a Generic Company reduced its prices to a level that was materially below the level of its competitors in the UK paroxetine market (namely GSK, parallel importers of Seroxat and the other Generic Companies where relevant), the associated increase in its orders would have resulted in it quickly exceeding the volume restriction.
- Were the Generic Company to lower its prices to below prevailing levels in the market at the time, its profits would be lower than would have otherwise been the case,¹³¹⁷ because it would be making a lower mark-up on each pack sold without being able to sell additional packs. As a result of the volume restriction, its incentive to reduce prices below prevailing levels at the time would have been minimal.¹³¹⁸
- Because of the volume restriction, the Generic Companies' potential market shares were each capped.

vi) *Market developments following GSK's commitment to make the value transfers*

8.48 Although not a necessary part of the analysis of the likely effect of GSK's conduct, the CMA considers that the developments observed during the term of the Agreements reveal that there was no material increase in the actual competitive constraints faced by GSK, and the threat of true generic competition was deferred. Developments in the UK paroxetine market during the period of the Agreements are set out at paragraphs 3.380 to 3.398 and see also paragraphs 7.42 to 7.45 (GUK), paragraphs 7.95 to 7.98 (Alpharma) and B.162 to B.170 (IVAX).

8.49 In relation to the deferral of potential competition, the evidence demonstrates that as a consequence of the Agreements, each of the Generic Companies deferred their efforts to enter the relevant market (see Table 3.3). Independent generic entry did not take place until after Apotex had eventually prevailed in litigation with GSK in December 2003.

¹³¹⁷ In the case of GUK, as a result of the profit guarantee clause, such a price reduction would either have no impact on, or reduce, the profits it was able to make (see paragraph 7.26).

¹³¹⁸ Consistent with this paragraphs B.143–B.161 (IVAX), 7.25–7.41 (GUK) and 7.76–7.94 (Alpharma) set out analysis of each Generic Company's limited incentive and ability to compete effectively with GSK while being supplied with a restricted volume of GSK product.

8.50 The evidence also demonstrates that, as a consequence of the Agreements, GSK did not face an increase in the actual competitive constraints it faced until independent generic entry took place in December 2003:

- The Generic Companies' entry as GSK distributors had no meaningful impact on paroxetine 20mg price levels. While the Agreements were in place, the Generic Companies priced at, or very close to, prevailing levels. Paroxetine Seroxat 20mg price levels remained fairly constant both immediately following the entry of each of the Generic Companies and throughout the period when the Generic Companies were supplying paroxetine pursuant to the Agreements until December 2003 when independent generic entry began.
- GSK did not face any actual competition at the manufacturer level. GSK retained a market share at the production level of 100% throughout the Agreements and prior to independent generic entry which began in December 2003. Each of the Generic Companies deferred its efforts to enter the market independently of GSK.¹³¹⁹

8.51 The impact of the Generic Companies' entry on GSK's market share was limited as a consequence of the volume restrictions included in the Agreements. During the Agreements, GSK retained an average market share of 71% by value (or 66% by volume).¹³²⁰ During the period between each respective entry under the Agreement and December 2003, when independent generic entry began, the Generic Companies obtained market shares as follows:¹³²¹ IVAX achieved an average share of 11% by value (or 12% by volume); GUK achieved an average market share of 11% by value (or 14% by volume); and Alpharma achieved an average market share of 8% by value (or 9% by volume). At the same time, as set out at paragraphs 3.397 to 3.398, sales of parallel imports declined substantially, from a market share by volume of 23% in November 2001 to 2% in January 2003.

vii) Counterfactual

8.52 As set out at paragraphs B.171 to B.185 (IVAX), 7.46 to 7.62 (GUK) and 7.99 to 7.113 (Alpharma), the CMA finds that, absent the Agreements, the Generic

¹³¹⁹ As set out at paragraph B.114, during the course of the IVAX-GSK Agreement, IVAX made no further efforts to enter the UK paroxetine market independently of GSK, either with its own product or with a product supplied by a third party. Neither GUK nor Alpharma entered independently during the term of their respective Agreements, in accordance with the entry restrictions set out within those Agreements.

¹³²⁰ Calculated as GSK's share of the UK paroxetine market between December 2001 and November 2003, based on data supplied by relevant parties.

¹³²¹ There was no market expansion following the Generic Companies' entry into the UK paroxetine market as GSK distributors, and nor could GSK have reasonably expected their entry to result in expansion (see paragraphs B.69 (IVAX), 6.103 (GUK) and 6.163 (Alpharma)).

Companies would have continued to be competitive threats and remained potential competitors to GSK that were pursuing efforts to enter the UK paroxetine market independently of GSK. The Generic Companies' competitive behaviour would not have been distorted by value transfers to induce delays to their independent entry. The realistic and likely outcomes are that the Generic Companies would have pursued their strategy of independent entry (including their challenges to GSK's patent claims) or, alternatively, that the Generic Companies would have entered into a settlement on terms that were not 'bought' using the value transfers, and that legitimately reflected the uncertainty regarding GSK's patent claims.

8.53 The analysis set out at paragraphs B.63 to B.131 (IVAX), 6.86 to 6.141 (GUK) and 6.150 to 6.205 (Alpharma) demonstrates that the purpose of the value transfers GSK committed to make (totalling at least £50.9 million to the Generic Companies overall) was to induce the Generic Companies to delay their efforts to enter the market independently of GSK. GSK had therefore determined that, if the Generic Companies were permitted to remain as potential competitors that were continuing with their efforts to enter the market, GSK faced the prospect of lower expected profits¹³²² than if GSK were to make value transfers to induce the Generic Companies to delay their efforts to enter independently. Put another way, GSK itself considered that, absent the Agreements, the competitive outcomes associated with the Generic Companies' positions as potential competitors provided for a far greater constraint than GSK faced having entered into the Agreements.

8.54 Any alternative counterfactual scenarios (such as GSK and the Generic Companies entering into a settlement agreement that provided for a similarly or more restrictive outcome as each of the respective Agreements, or the Generic Companies ending their efforts to enter the market independently of GSK) are highly unlikely, and not sufficiently realistic, as set out at paragraphs B.183 to B.185 (IVAX), 7.58 to 7.60 (GUK) and 7.111 to 7.113 (Alpharma).¹³²³

viii) *The absence of other relevant sources of competition to GSK meant that the Agreements assisted GSK in preserving its dominant position*

8.55 As set out at paragraphs 7.63 to 7.64 (GUK), 7.116 to 7.117 (Alpharma) and B.188 to B.189 (IVAX), by entering into the Agreements, GSK materially

¹³²² That is, the average of its possible profits going forward, taking account of the potential revenue and costs associated with each possible outcome (for example, the success or otherwise of independent generic entry), and the likelihood associated with each.

¹³²³ GSK's representations on the counterfactual largely repeat those in relation to the Chapter I/Article 101 findings outlined above (GSK SO Written Response (document 2755), paragraphs 9.16–9.21). The CMA has considered each of these submissions at paragraphs I.8–I.27. For the reasons set out in the relevant sections, the CMA does not consider that GSK's submissions undermine the findings presented above.

strengthened its ability to continue to delay the potential emergence of true generic competition, thereby enabling GSK to preserve its dominant position.

- 8.56 The anti-competitive effects of the Agreements were reinforced because together they helped to make sure that each threat of potential independent generic entry was deferred, and that there was no material increase in the actual competitive constraints that GSK faced.

E. Objective justification

i) Introduction

- 8.57 It is for the dominant undertaking to raise any objective justification and to support it with arguments and evidence.¹³²⁴ (See paragraphs 8.12 to 8.17 for the approach followed by the CMA).

- 8.58 GSK submitted that its conduct was objectively justified because it:

- constituted the legitimate defence of its patent rights (including settlement of anticipated and actual litigation to that effect);¹³²⁵
- created efficiencies in the form of reduced prices that could be expected to be passed on, and were in fact passed on, to consumers.¹³²⁶

- 8.59 For the reasons set out below, the CMA finds that GSK has not demonstrated the existence of any objective justification for its conduct or that its conduct produced advantages in terms of efficiencies that also benefit consumers.

ii) GSK's representation that its conduct was a legitimate defence of its intellectual property rights and necessary for business planning

- 8.60 GSK submitted that any abuse allegations were misplaced in the real commercial and economic context of the Agreements because '[t]hey were settlements of genuine disputes over patents',¹³²⁷ and GSK's conduct was objectively justified on the basis that it legitimately defended its patent rights. GSK made the following points:

¹³²⁴ Case T-201/04 *Microsoft v Commission* EU:T:2007:289, para 688.

¹³²⁵ GSK SO Written Response (document 2755), paragraphs 9.23 and 9.28–9.49.

¹³²⁶ GSK SO Written Response (document 2755), paragraphs 9.23 and 9.50–9.53.

¹³²⁷ GSK SO Written Response (document 2755), paragraph 9.28.

- the EU Courts have accepted that the legitimate defence of an undertaking's commercial position is an objective justification;¹³²⁸
- the situation in this case is different to that observed in *AstraZeneca*,¹³²⁹ in that there has been no misuse of patent powers or administrative and judicial processes;¹³³⁰
- a dominant company cannot infringe Chapter II of the Act where it is pursuing litigation that is not manifestly unfounded;¹³³¹
- its actions were within its legal rights to defend its patents and the settlement terms were reasonable;¹³³² and
- GSK made the value transfers it did for the legitimate purpose of avoiding risky, expensive and time consuming litigation,¹³³³ and avoiding disruption to the business to the detriment of research and development.¹³³⁴

8.61 The CMA does not consider any of the foregoing points demonstrate an objective justification for GSK transferring value to each of the Generic Companies to induce them to delay their efforts to enter the relevant market independently of GSK. The CMA addresses each of the points in turn below.

8.62 GSK's first point is that an undertaking in a dominant position has the right to take such reasonable steps as it deems appropriate to protect its own commercial interests. The CJ has held, however, that such behaviour cannot be countenanced if its actual purpose is to strengthen this dominant position and abuse it.¹³³⁵ Such behaviour must also be proportionate.¹³³⁶ In the present case, however, the purpose of GSK's conduct was to make value

¹³²⁸ GSK referred to the CJ's judgment in *United Brands* '...the fact that an undertaking is in a dominant position cannot disentitle it from protecting its own commercial interests if they are attacked, and that such an undertaking must be conceded the right to take such reasonable steps as it deems appropriate to protect its said interests...' See GSK SO Written Response (document 2755), paragraph 9.29, and Judgment in *United Brands v Commission*, 27/76, EU:C:1978:22, paragraph 189. The CMA notes that GSK has selectively quoted the *United Brands* judgment by not including the final line in the paragraph: '...such behaviour cannot be countenanced if its actual purpose is to strengthen this dominant position and abuse it.'

¹³²⁹ Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770. The CMA accepts that GSK's conduct is distinct to that observed in *AstraZeneca*. Nevertheless, for the reasons set out (at paragraphs 8.18–8.36), the CMA finds that, in having recourse to methods different from 'normal competition', GSK's conduct tended to restrict competition or was capable of having that effect, and deviated from GSK's special responsibility not to allow its conduct to impair genuine undistorted competition.

¹³³⁰ GSK SO Written Response (document 2755), paragraphs 9.30–9.31.

¹³³¹ GSK SO Written Response (document 2755), paragraph 9.32. GSK cited the judgment of 17 July 1998, *ITT Promedia v Commission*, T-111/96, ECR, EU:T:1998:183. The CMA notes that it has not objected in this case to the fact of GSK pursuing the GUK Litigation or Alpharma Litigation per se.

¹³³² GSK SO Written Response (document 2755), paragraph 9.33.

¹³³³ GSK SO Written Response (document 2755), paragraphs 9.37–9.46.

¹³³⁴ GSK SO Written Response (document 2755), paragraphs 9.44–9.46.

¹³³⁵ Judgment in *United Brands v Commission* 27/76, EU:C:1978:22, paragraph 189.

¹³³⁶ Judgment in *United Brands v Commission* 27/76, EU:C:1978:22, paragraph 190; see also paragraph 182.

transfers to induce potential market entrants to delay their legitimate efforts to enter the market independently, thereby protecting its dominant position. That was manifestly anti-competitive and not a legitimate way to defend GSK's patent rights. Further and in any event, GSK's value transfers were neither reasonable nor proportionate steps to protect its commercial interests. As already noted,¹³³⁷ there were less anti-competitive alternatives to the value transfers that would have enabled GSK to seek to defend the patent challenges it faced.

- 8.63 Secondly, GSK refers to the judgment in *AstraZeneca v Commission* where the CJ re-affirmed that Article 102 TFEU prohibits a dominant undertaking from strengthening its position by using methods other than those which come within the scope of competition on the merits.¹³³⁸ That proposition of law applies in this case: GSK made value transfers to induce delays to the competitive threat from three potential competitors and its conduct did not constitute competition on the merits. It is not relevant to the CMA's findings that the facts of this case differ from the facts of *AstraZeneca*.¹³³⁹
- 8.64 GSK's third submission that a dominant undertaking cannot infringe the Chapter II prohibition where it is pursuing non-frivolous litigation is unfounded. This Decision does not object to a patentee, such as GSK, commencing and pursuing proceedings for patent infringement. GSK refers to the conditions set out by the Commission in *ITT Promedia v Commission*, but those conditions are not relevant as they relate to the different situation of a dominant undertaking misusing its right to bring proceedings against a competitor.¹³⁴⁰ They do not relate to the use of value transfers to induce delays to the potential independent market entry of a rival.
- 8.65 GSK's fourth submission is that it had acted within its legal rights (to defend its patents) and that all of the terms of the Agreements were reasonable.¹³⁴¹ This submission is unfounded. For the reasons set out above, the CMA finds that GSK's conduct went beyond the legitimate exercise of its patent rights to oppose alleged infringements. GSK's conduct was to make value transfers with the purpose of inducing delays to the potential independent market entry

¹³³⁷ See paragraphs 8.52–8.54.

¹³³⁸ Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 75.

¹³³⁹ It is not necessary, for example, to show that administrative and/or judicial processes have been misused in order for a dominant position to have abused its position.

¹³⁴⁰ See similarly judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraph 363.

¹³⁴¹ GSK SO Written Response (document 2755), paragraph 9.33.

of IVAX, GUK and Alparma. That conduct is not part of the specific subject-matter of a patent and was anti-competitive (see paragraphs 6.19 to 6.22).

- 8.66 Furthermore, GSK has not shown that its conduct was indispensable and proportionate to the enforcement of its patents. As set out above,¹³⁴² in the absence of GSK's conduct, there were less anti-competitive alternatives available to GSK. Either GSK could have enforced its patents in the courts or it could have entered into settlements with the Generic Companies on less restrictive terms than the Agreements (for example, by agreeing to more competitive entry/supply terms).
- 8.67 GSK's fifth submission is that it committed to transfer value to the Generic Companies to avoid the costs of litigation. Also, GSK refers to the importance to it of avoiding patent litigation that could disrupt its business, and in particular its research and development activities.¹³⁴³ The CMA rejects this point as being unfounded on the facts for the reasons set out at paragraphs 6.115 to 6.126, 6.179 to 6.190 and B.84 to B.96. Further the CMA considers that:
- the value transfers that GSK committed to make to each of IVAX (at least £17.9 million), GUK (at least £21.3 million) and Alparma (£11.8 million) significantly exceeded the litigation cost savings that GSK estimated to be around £5.8 million;
 - the litigation costs estimated by GSK are a significant overstatement of the litigation costs that GSK avoided by entering into the Agreements (see 6.117 to 6.120 (GUK) and 6.181 to 6.184 Alparma));
 - GSK was not incentivised to pass any such litigation costs savings on to consumers. The volume restrictions contained in the Agreements meant that the distribution of GSK's paroxetine by IVAX, GUK and Alparma could not reasonably have been expected to result (and did not result) in any meaningful or positive impact upon competition or prevailing prices.
 - The combined likely effect of the entry/supply terms that GSK's value transfers induced was to preserve the patent-related barriers to entry, thereby protecting GSK's dominant position. Given this, GSK's submission based on objective necessity cannot be accepted.

¹³⁴² See paragraphs 8.52–8.54.

¹³⁴³ GSK SO Written Response (document 2755), paragraphs 9.41–9.43.

8.68 The CMA does not accept GSK's other submissions that '[s]ettling litigation frees up resources to refocus on research and development to the benefit of GSK and future patients alike'¹³⁴⁴ because:

- GSK has not substantiated the likelihood and magnitude of these alleged freeing up of resources;
- GSK has not demonstrated a sufficient causal link between any resource savings and its investments in research and development;
- GSK has not adduced any evidence existing at the time of the Agreements that indicates that GSK behaved as it did in order to achieve such benefits; and
- in the case of the GUK-GSK and Alharma-GSK Agreements, the litigation with GSK had already progressed to such an extent that the necessary experiments and testing would have already been largely completed, thereby reducing the value of any such (putative) benefit (see paragraphs 6.124 and 6.188). Moreover, in relation to any residual impact that litigation might have had on GSK's R&D efforts, the patent litigation would have merely deferred any related benefits, and not deprived GSK of them.

iii) *GSK's representation that its conduct resulted in new entry and reduced prices for the NHS*

8.69 GSK also submitted that its conduct was objectively justified on the basis that the Agreements created efficiencies, in terms of new entry resulting in reduced prices for the NHS, which were passed on to consumers. In this regard, GSK referred to analysis¹³⁴⁵ which claimed that, as a consequence of the workings of the Drug Tariff, the Agreements delivered savings of £15.6 million for the NHS, and that authorised independent early entry would not have delivered greater savings.¹³⁴⁶

8.70 As explained at paragraph 8.50, there was no meaningful impact on the actual prices at which paroxetine was sold to pharmacies, either directly or indirectly through wholesalers, as a consequence of GSK's conduct and the commencement of the Agreements. The fact that paroxetine reimbursement prices fell is a consequence of the way that the Drug Tariff and PPRS price mechanisms functioned (specifically that a generic product being available

¹³⁴⁴ GSK SO Written Response (document 2755), paragraphs 9.44–9.46.

¹³⁴⁵ Annex 3 to GSK SO Written Response (document 2757), Consumer welfare analysis – Impact of the supply agreements on the NHS: A report by Charles River Associates dated 6 August 2013.

¹³⁴⁶ GSK SO Written Response (document 2755), paragraph 9.50.

caused a reduction in the Drug Tariff reimbursement price).¹³⁴⁷ In fact, any decrease in the Drug Tariff reimbursement price did not reflect efficiencies generated by GSK's conduct, which did not cause prices to pharmacies to fall, but instead related to the allocation of monies between the NHS and pharmacies.¹³⁴⁸ Further, as the reimbursement systems designed by DH¹³⁴⁹ are intended to ensure that any decrease in the price paid by pharmacies is passed on to the NHS, a decrease in the Drug Tariff in the absence of a price decrease to pharmacies does not indicate that there was an overall saving for the NHS.

- 8.71 Further, for the reasons described in Part 8, Section D, the CMA is satisfied that, in the counterfactual, the outcome would have been more competitive and could therefore have been expected to provide for more favourable prices to pharmacies overall.
- 8.72 GSK also submitted that its conduct did not remove any source of existing competition for paroxetine products, as no such competition existed at the time.¹³⁵⁰
- 8.73 The CMA considers that GSK's submission overlooks the competitive constraint exerted by the Generic Companies as potential competitors.¹³⁵¹
- 8.74 Further and in any event, the CMA considers that anti-competitive conduct that helps to protect and maintain a dominant position cannot normally be justified on the grounds that it also creates efficiency gains.¹³⁵² Such conduct is not consistent with competition on the merits and the special responsibility on a dominant firm not to allow its conduct to impair genuine undistorted competition. The CMA has found (see Sections 8C and 8D) that the combined likely effect of the Agreements that the value transfers induced was to assist GSK in preserving the entry barriers faced by Generic Companies and other potential entrants, thereby enabling GSK to maintain its dominant position.

¹³⁴⁷ Indeed, GSK acknowledged the latter point in its representations by stating that because of the way the NHS reimbursement system operated, the reduction in the Drug Tariff price in June 2002 would have resulted from the Agreements even if the Agreements had no effect on the prices paid by pharmacies (GSK Written SO Response (document 2755), paragraph 8.13).

¹³⁴⁸ For example, an argument that NHS list prices decreased while prices to pharmacies remained the same implies that any benefits to the NHS would be at the expense of pharmacies, who would be worse off. This is not an efficiency caused by GSK's conduct, but rather a reallocation of monies from pharmacies to the NHS.

¹³⁴⁹ In particular, as explained at paragraphs 3.110 and 3.111, DH uses a mechanism referred to as 'clawback' to regulate pharmacy buying profits, which works by providing pharmacies with an initial reimbursement price (set by reference to the Drug Tariff in relation to generic medicines), but then using 'discount inquiries' to determine what pharmacies have spent on medicines, and how much of their buying profits DH should take back through 'clawback'.

¹³⁵⁰ GSK SO Written Response (document 2755), paragraphs 9.51–9.53.

¹³⁵¹ GSK's submission that the relevant market was at least as wide as SSRIs is considered in Annex C.

¹³⁵² See Guidance on Article 102 TFEU, page 7, paragraph 30.

iv) Conclusion

8.75 In view of all of the foregoing, the CMA finds that GSK has not demonstrated that its conduct was objectively justified or that its conduct produced advantages in terms of efficiency that also benefit consumers. Consequently, GSK's conduct constituted an abuse of a dominant position in contravention of the Chapter II prohibition.

9. ATTRIBUTION OF LIABILITY

9.1 This Part sets out the CMA's approach to attributing liability for the Infringements and the CMA's assessment in respect of each Party.

A. CMA's approach to attribution of liability

9.2 Competition law refers to the activities of undertakings.¹³⁵³ Where an undertaking infringes the competition rules, it falls, according to the principle of personal responsibility, to that undertaking to answer for that infringement.¹³⁵⁴

9.3 An undertaking may consist of several persons, legal or natural.¹³⁵⁵ Given the requirement to impute an infringement to a legal entity or entities on whom fines may be imposed and to whom an infringement decision is to be addressed,¹³⁵⁶ it is necessary to identify the relevant legal persons that form part of the undertaking in question.

9.4 In determining which entities are liable for an infringement in this case, the CMA has identified, for each undertaking that it has found to have infringed the competition rules (that is, GSK, GUK and Alpharma), the relevant legal entities which form part of those undertakings.

i) *Parent/subsidiary liability*

9.5 It is settled in EU case law that the conduct of a subsidiary may be imputed to its parent company in particular where, although having a separate legal personality, that subsidiary does not decide independently upon its own conduct on the market, but carries out, in all material respects, the instructions given to it by the parent company, having regard in particular to the economic, organisational and legal links between those two legal entities.¹³⁵⁷ In such a situation, since the parent company and its subsidiary form a single undertaking, the CMA may address a decision imposing fines on the parent company, without having to establish the personal involvement of the latter in the infringement.¹³⁵⁸

¹³⁵³ Judgment in *Akzo Nobel v Commission*, C-97/08 P, EU:C:2009:536, paragraph 54.

¹³⁵⁴ Judgment in *Akzo Nobel v Commission*, C-97/08 P, EU:C:2009:536, paragraph 56.

¹³⁵⁵ Judgment in *Akzo Nobel v Commission*, C-97/08 P, EU:C:2009:536, paragraph 55.

¹³⁵⁶ Judgment in *Akzo Nobel v Commission*, C-97/08 P, EU:C:2009:536, paragraph 57.

¹³⁵⁷ Judgment in *Akzo Nobel v Commission*, C-97/08 P, EU:C:2009:536, paragraph 58. See also *Alliance One & Others v Commission* joined cases C-628/10 P and C-14/11 P, EU:C:2012:479, paragraph 43.

¹³⁵⁸ Judgment in *Akzo Nobel v Commission*, C-97/08 P, EU:C:2009:536, paragraph 59. See also *Alliance One & Others v Commission* joined cases C-628/10 P and C-14/11 P, EU:C:2012:479, paragraph 44.

9.6 The CJ has held that where a parent company has a 100% shareholding in a subsidiary which has infringed the competition rules:

- that parent company is able to exercise ‘decisive influence’ over the conduct of its subsidiary; and
- there is a rebuttable presumption that the parent company does in fact exercise a decisive influence over the conduct of its subsidiary,

such that the two entities can be regarded as a single economic unit and thus jointly and severally liable.¹³⁵⁹ Where a parent company exercises ‘decisive influence’ over its subsidiary, the CMA has discretion to address an infringement decision relating to the conduct of the subsidiary to the parent company, the subsidiary, or both.¹³⁶⁰

9.7 As to the interpretation of ‘decisive influence’, the CAT noted in *Durkan* (referring to *Akzo*) that the European Courts have established, among other things, that:¹³⁶¹

‘(a) The fact that the parent owns all the shares in the subsidiary means that it has the ability to exert influence; this does not automatically mean that it actually exerts that influence but it creates a rebuttable presumption that influence was actually exercised.

(b) The exercise of influence can be indirect and may be established even if the parent does not interfere in the day to day business of the subsidiary and even if the influence is not reflected in instructions or guidelines emanating from the parent to the subsidiary.

(c) It is not necessary to show that any influence was actually exercised as regards the infringement in question: one must look generally at the relationship between the two entities.

(d) The factors to which the court may have regard, when considering the issue of decisive influence, are not limited to commercial conduct but cover a wide range’

¹³⁵⁹ Judgment in *Akzo Nobel v Commission*, C-97/08 P, EU:C:2009:536, paragraph 60-61. *Alliance One & Others v Commission*, Joined cases C-628/10 P and C-14/11 P, EU:C:2012:479, paragraph 46–47.

¹³⁶⁰ Judgment in *Akzo Nobel v Commission*, C-97/08 P, EU:C:2009:536, paragraph 61. See also *Alliance One & Others v Commission* joined cases C-628/10 P and C-14/11 P, EU:C:2012:479, paragraph 47 and *RWE v Commission*, T-543/08, EU:T:2014:627, paragraph 136.

¹³⁶¹ *Durkan Holdings Ltd v Office of Fair Trading* [2011] CAT 6, at [22].

9.8 It is thus sufficient for the CMA to prove that the subsidiary is wholly-owned by the parent company in order to presume that the parent exercises decisive influence over the conduct of that subsidiary, unless the parent company, which has the burden of rebutting that presumption, adduces sufficient evidence to show that its subsidiary acts independently on the market.¹³⁶² This also applies to situations where the parent company indirectly holds a 100% ownership in a subsidiary, for example, via one or more intermediary companies.¹³⁶³

ii) Corporate changes

9.9 The CJ has confirmed that events such as corporate changes should not enable liability for competition law breaches to be avoided.¹³⁶⁴ For example, a change in the legal form and name of an undertaking does not create a new undertaking free of liability for the anti-competitive behaviour of its predecessor when, from an economic point of the view, the two are identical.¹³⁶⁵

9.10 Where the original entity is still in existence, it remains liable for the infringement. Even if the original entity no longer carries out activities on the relevant market or the relevant business has been transferred to another undertaking, under the doctrine of personal liability, the original entity may still be held liable for an infringement of competition law that occurred whilst the entity was active on the relevant market.¹³⁶⁶

9.11 Where the original entity responsible no longer exists in law or has been transferred to another entity, the CMA has considered whether there is functional and economic continuity between the original infringer and the undertaking into which it was merged.¹³⁶⁷

B. The CMA's assessment in respect of each Party

9.12 For each Party that the CMA finds has infringed the Act and/or Article 101 TFEU, the CMA has first identified the legal entity/entities that were directly

¹³⁶² Judgment in *Akzo Nobel v Commission*, C-97/08 P, EU:C:2009:536, paragraph 61. Judgment in *Alliance One & Others v Commission*, Joined cases C-628/10 P and C-14/11 P, EU:C:2012:479, paragraph 47.

¹³⁶³ See for instance Judgment in *General Química and Others v Commission*, C-90/09 P, EU:C:2011:21, paragraphs 86–88.

¹³⁶⁴ Judgment in *ETI and Others*, Case C-280/06, EU:C:2007:775, paragraphs 41–43.

¹³⁶⁵ See Judgment in *CRAM and Rheinzink v Commission*, Joined cases 29/83 and 30/83, EU:C:1984:130, paragraph 9.

¹³⁶⁶ Judgment of 30 September 2009, *Hoechst v Commission*, Case T-161/05, ECR, EU:T:2009:366, paragraph 50. Judgment in *Alliance One & Others v Commission*, Joined cases C-628/10 P and C-14/11 P, EU:C:2012:479, paragraph 42.

¹³⁶⁷ Commission Decision of 21 December 1988, PVC, OJ [1989] L 74/1, paragraph 42. Commission Decision of 2 August 1989, Welded Steel Mesh, OJ [1989] L 260/1, paragraph 194.

involved in the Infringement(s), and has attributed liability for the Infringement(s) to it/them according to the principle of personal responsibility. In each case, the CMA has then determined whether liability for the Infringement(s) should be on a joint and several basis with another legal entity that formed part of the same undertaking.

i) GSK

9.13 In respect of GSK, the CMA attributes liability to the following legal entities:

- GlaxoSmithKline Plc;
- GlaxoSmithKline UK Limited;
- SmithKline Beecham Limited (formerly SmithKline Beecham Plc); and
- Beecham Group Plc.

a) *GlaxoSmithKline UK Limited, SmithKline Beecham Limited (formerly SmithKline Beecham Plc) and Beecham Group Plc*

9.14 The CMA finds that each of GlaxoSmithKline UK Limited, SmithKline Beecham Limited (formerly SmithKline Beecham Plc during the Relevant Period) and Beecham Group Plc, which were all subsidiaries of GlaxoSmithKline Plc during the Relevant Period,¹³⁶⁸ was directly involved in at least one of the Infringements. This is demonstrated by the following facts:

- (a) The GUK-GSK Settlement Agreement was entered into by SmithKline Beecham Plc and Beecham Group Plc.¹³⁶⁹
- (b) The Alpha-GSK Settlement Agreement was entered into by GlaxoSmithKline UK Limited and SmithKline Beecham Plc.¹³⁷⁰

9.15 GlaxoSmithKline UK Limited, SmithKline Beecham Limited and Beecham Group Plc continue to remain active entities as of the date of this Decision.¹³⁷¹

¹³⁶⁸ GlaxoSmithKline Plc Annual Report for the year ended 31 December 2003 (document 2576), page 146 (as printed), under Note 37 to the financial statements listing GlaxoSmithKline UK Limited and SmithKline Beecham Plc (now re-registered as SmithKline Beecham Limited) as principal group companies. Beecham Group Plc Annual Report for the year ended 31 December 2003, (document 4070), page 11 (as printed), under Note 19 to the financial statements listing GlaxoSmithKline Plc as the ultimate parent.

¹³⁶⁹ GUK-GSK Settlement Agreement (document 0995). For an analysis of the GUK-GSK Agreement, see paragraphs 3.249–3.318.

¹³⁷⁰ Alpha-GSK Settlement Agreement (document 0356). For an analysis of the Alpha-GSK Agreement, see paragraphs 3.319–3.379.

¹³⁷¹ GlaxoSmithKline Plc Annual Report 2014 for the year ended 31 December 2014 (document 3671), page 204 (as printed), under Note 44 to the financial statements listing GlaxoSmithKline UK Limited and SmithKline

SmithKline Beecham Plc was re-registered as SmithKline Beecham Limited, a private limited company, on 27 October 2009.¹³⁷² The change in legal form and name of this entity did not create a new undertaking free from liability for the anti-competitive behaviour of its predecessor.¹³⁷³ In particular, at the time of this change, there were no consequent changes in the company number or the identities of its directors. In light of the functional and economic continuity between SmithKline Beecham Plc and SmithKline Beecham Limited, the CMA finds SmithKline Beecham Limited jointly and severally liable for the Infringements. This Decision is therefore addressed to GlaxoSmithKline UK Limited, SmithKline Beecham Limited and Beecham Group Plc in respect of their participation in the relevant Infringement(s).

b) *GlaxoSmithKline Plc*

9.16 In addition, applying the presumption referred to in paragraph 9.6, the CMA finds that GlaxoSmithKline Plc exercised decisive influence over the conduct of GlaxoSmithKline UK Limited, SmithKline Beecham Plc, and Beecham Group Plc during the Relevant Period in light of its 100% ownership of those entities. The CMA has not been provided with any evidence from GSK to rebut the presumption that GlaxoSmithKline Plc exercised decisive influence over the conduct of those entities during the Relevant Period.

c) *Conclusion on attribution of liability to the GSK entities*

9.17 In light of the above, this Decision is addressed to GlaxoSmithKline Plc, GlaxoSmithKline UK Limited, SmithKline Beecham Limited (formerly SmithKline Beecham Plc) and Beecham Group Plc.

ii) *GUK-Merck*

9.18 In respect of GUK-Merck, the CMA attributes liability to the following legal entities:

- Generics (UK) Limited¹³⁷⁴ ('GUK'); and

Beecham Limited as principal group companies. Beecham Group Plc Annual Report for the year ended 31 December 2014 (document 4009), page 11 (as printed), under Note 17 to the financial statements listing GlaxoSmithKline Plc as the ultimate parent.

¹³⁷² See SmithKline Beecham Limited (formerly SmithKline Beecham Plc) annual report and financial statements for the year ended 31 December 2009 (document 2577).

¹³⁷³ Judgment in *CRAM and Another v Commission*, Joined cases 29/83 and 30/83, EU:C:1984:130, paragraph 9.

¹³⁷⁴ Company number 1558756, registered address: Station Close, Potters Bar, Hertfordshire, EN6 1TL.

- Merck KGaA¹³⁷⁵ ('Merck').

a) GUK

9.19 GUK was directly involved in the Infringement in respect of the GUK-GSK Agreement.

(a) The GUK-GSK Settlement Agreement and GUK-IVAX Agreement were entered into by GUK.¹³⁷⁶

(b) Individuals involved in the negotiation and implementation of the GUK-GSK Agreement were employees of GUK.¹³⁷⁷

9.20 As noted at paragraph 3.6, Merck sold GUK in 2007, to Mylan Inc, and GUK has continued to exist (as a separate legal entity with its own turnover and assets) and to remain active in the supply of generic pharmaceutical products.¹³⁷⁸ This Decision is therefore addressed to GUK in respect of its participation in the Infringement in respect of the GUK-GSK Agreement.

b) Merck

9.21 As described at paragraph 3.5, GUK was, in the Relevant Period, an indirect 100% owned subsidiary of Merck. The CMA does not consider that Merck was directly involved in the relevant Infringement in respect of the GUK-GSK Agreement.¹³⁷⁹ Applying the presumption referred to in paragraph 9.6, the CMA finds that Merck exercised decisive influence over the conduct of GUK during the Relevant Period, in light of its 100% ownership of GUK. For the reasons given below, the CMA finds that Merck has not adduced sufficient evidence to rebut the presumption referred to in paragraph 9.6.

¹³⁷⁵ Merck KGaA is incorporated in Germany.

¹³⁷⁶ GUK-GSK Settlement Agreement (document 0995); GUK-IVAX Agreement (document 1765). For an analysis of the GUK-GSK Agreement, see paragraphs 3.249–3.318.

¹³⁷⁷ For example, [GUK's Managing Director] and [GUK's General Manager] were involved in the negotiation of the GUK-GSK Agreement (see paragraphs 3.287–3.304).

¹³⁷⁸ Generics (UK) Limited Directors' report and financial statements dated 31 December 2014 (document 4072), page 19 of which lists GUK as being ultimately controlled by Mylan Inc.

¹³⁷⁹ Merck submitted that [the Chief Executive of Merck Generics Group] was not employed by Merck, and that no employee of Merck was directly involved in negotiating the GUK-GSK Agreement: Merck SO Written Response (document 2764), paragraphs 6.22–6.49 and 9.32–9.36; Transcript of Merck SO Oral Hearing dated 17 October 2013 (document 3028), page 12, line 2 to page 15, line 8; transcript of Merck DPS Oral Hearing dated 17 September 2015 on the GUK DPS (document 4105), page 7, line 15 to page 8, line 4. The CMA has therefore concluded that there is no sufficient basis on which to find that Merck was directly involved in the Infringement in respect of the GUK-GSK Agreement.

Merck's representations in rebuttal of the presumption of decisive influence

- 9.22 In order to rebut the presumption that Merck exercised decisive influence over the conduct of GUK (in light of its 100% ownership of GUK) during the Relevant Period, Merck made a number of submissions, as summarised below.
- 9.23 Merck submitted that the Merck Generics Group (including GUK) was an entirely separate business group within Merck and that there were no structural, organisational or economic links between Merck and the Merck Generics Group at any time during the period of Merck's ownership of GUK. In addition, Merck submitted that GUK, and the Merck Generics Group, had their own personnel and were separated operationally from Merck. Merck stated that it was a mere financial investor in GUK, and that it did not exert decisive influence over GUK's business.¹³⁸⁰
- 9.24 For the reasons set out below, the CMA finds that Merck has not adduced sufficient evidence to rebut the presumption that Merck exercised decisive influence over the conduct of GUK during the Relevant Period. The evidence indicates the Merck Generics Group (including GUK) was part of the overall Merck group and did not, during the Relevant Period, determine its conduct on the market independently of the Merck group, but carried out, in all material respects, the instructions given to it, having regard in particular to the economic, organisational and legal links between them.
- 9.25 Merck's position is inconsistent with Merck's 2001 Annual Report which states that: *'Ethicals used in the treatment of metabolic and cardiovascular diseases [and ...] generics [...] are the core of our pharmaceuticals business.'* The report further refers to *'our [Merck's] strategic plans for long-term growth'*.¹³⁸¹ Merck's 2002 Annual Report states that: *'We achieved the highest growth in the United Kingdom, with a climb in sales of 121% that was encouraged by*

¹³⁸⁰ Merck SO Written Response (document 2764), paragraphs 6.50–6.76 and 9.37–9.42; Transcript of Merck SO Oral Hearing dated 17 October 2013 (document 3028), page 15 (as printed), line 23, to page 16 (as printed), line 17 and page 29 (as printed), line 11 to page 30 (as printed), line 24; Merck response dated 17 September 2014 to the First Letter of Facts (document 3489), paragraphs 11–20; Merck DPS Written Response (document 4033), paragraphs 2.3–2.4.

¹³⁸¹ Merck Annual Report 2001 (document 2583), pages 2, 18 and 25 (all page numbers as printed); Merck also submitted that, as regards the reference on page 2 of this report, other language on the same page *'underlines that the generics business is NOT part of Merck's "core" business', but simply a generator of revenues that will be used to expand Merck's core business.'* (Merck response dated 17 September 2014 to the First Letter of Facts (document 3489), paragraph 15). The CMA is not persuaded of this interpretation, but notes in any event that Merck's submission does not relate the reference to generics on page 18 or page 25 of the same report.

*new product launches of our subsidiary Generics UK, including the ulcer medicine omeprazole.*¹³⁸²

- 9.26 Merck submitted that its ownership of GUK was purely as a financial investor and that there was no other reporting to Merck on matters such as strategic outlook, operations, business development or future plans. Whilst Merck submitted that it had obtained no or only little information on GUK, this is not the case. The CEO of the Merck Generics Group, [X] confirmed in a witness statement that: *'I reported to [X], the CEO of Merck KGaA'*.¹³⁸³ By way of example, [Merck's Chairman of the Executive Board] was updated as to the GUK Litigation on several occasions by [the Chief Executive of Merck Generics Group].¹³⁸⁴ In addition, Merck had organised all of its generics businesses under the control of one holding company, MGH. [X] was the CEO of the Merck Generics Group and was also a Director of GUK.¹³⁸⁵ [The Chief Executive of Merck Generics Group] was therefore in charge of the worldwide management of the Merck Generics Group and reporting to Merck on the performance on the Merck Generics Group (including GUK).¹³⁸⁶
- 9.27 The evidence indicates that Merck influenced decision-making within the Merck Generics Group (including GUK). [The Chief Executive of Merck Generics Group] reported to [Merck's Chairman of the Executive Board] on key decisions and also provided an opportunity for [Merck's Chairman of the Executive Board] to influence key decisions. For example, in October 2001, [the Chief Executive of Merck Generics Group] asked [Merck's Chairman of the Executive Board] to confirm whether he disagreed with the proposed approach of offering a guarantee from the Merck Generics Group to GSK in the context of the cross-undertaking in damages in the GUK Litigation.¹³⁸⁷ [The Chief Executive of Merck Generics Group] and [Merck's Chairman of the

¹³⁸² Merck Annual Report 2002 (document 2584), pages 4 and 26 (all page numbers as printed).

¹³⁸³ See Annex 2 to GUK SO Written Response - [the Chief Executive of Merck Generics Group] witness statement dated 25 July 2013 (document A 0041), paragraph 1.

¹³⁸⁴ See email from [the Chief Executive of Merck Generics Group] to [Merck's Chairman of the Executive Board] dated 29 May 2001 (document 0850), email from [the Chief Executive of Merck Generics Group] to [Merck's Chairman of the Executive Board] and [another GUK employee] dated 9 October 2001 (document 0895) and email chain between [the Chief Executive of Merck Generics Group] [and another Merck employee] and others dated 14 March 2002 (document 1011).

¹³⁸⁵ See Annex 2 to GUK SO Written Response - [the Chief Executive of Merck Generics Group] witness statement dated 25 July 2013 (document A 0041), paragraph 1.

¹³⁸⁶ See Annex 2 to GUK SO Written Response - [the Chief Executive of Merck Generics Group] witness statement dated 25 July 2013 (document A 0041), paragraphs 1 and 5.

¹³⁸⁷ Email from [the Chief Executive of Merck Generics Group] to [Merck's Chairman of the Executive Board] and [another GUK employee] dated 9 October 2001 (document 0895).

Executive Board] also agreed a common approach on press announcements after the GUK-GSK Agreement was entered into.¹³⁸⁸

- 9.28 Merck submitted that the communications between [the Chief Executive of Merck Generics Group] and [Merck's Chairman of the Executive Board] were only for information and were simply to update Merck on its financial investment and do not demonstrate financial control by Merck.¹³⁸⁹ The CMA does not find these submissions persuasive. The CMA considers that the communications represent a reporting line from [the Chief Executive of Merck Generics Group] to [Merck's Chairman of the Executive Board] on key matters.
- 9.29 There were also other indications of Merck's influence over decision-making within the Merck Generics Group (including GUK):
- (a) GUK's financial accounts were consolidated with Merck's accounts during the Relevant Period.¹³⁹⁰ The GC has ruled that the consolidation of financial accounts '*certainly corroborates*' that a company exercised decisive influence '*even if that consolidation is [...] mandatory under the national law applicable*'.¹³⁹¹ Furthermore, in 2002, as an additional means for Merck to exercise control over the Merck Generics Group, Merck concluded a domination and profit transfer agreement with MGH, of which GUK was an (indirect) 100% subsidiary.¹³⁹²
 - (b) In April 2001, Merck seconded a member of its staff to GUK ([Strategic Sourcing Specialist]) for six years to assist in relation to sourcing API,

¹³⁸⁸ Email from [the Chief Executive of Merck Generics Group] to [and another Merck employee] dated 14 March 2002 entitled 'Settlement' (document 1011), which states that: '[Merck's Chairman of the Executive Board] *and I agree that we should not make any announcements.*'

¹³⁸⁹ Transcript of Merck SO Oral Hearing dated 17 October 2013 (document 3028), page 30, line 20, to page 32, line 18 and at page 36, at lines 9–19; Merck submission dated 25 November 2013 (document C0013R), paragraphs 9–19. Merck response dated 17 September 2014 to the First Letter of Facts (document 3489), paragraph 14.

¹³⁹⁰ Merck KGaA Annual Report 2002 (document 2584).

¹³⁹¹ Judgment of 12 December 2012, *1. garantovaná v Commission*, T-392/09, ECR, EU:T:2012:674, paragraph 57.

¹³⁹² See *Beherrschungsvertrag* (Domination and Profit Transfer Agreement) dated 15 Jan 2002, between Merck KGaA and MGH (documents 3206 (English translation) and 3207 (original German version)). For example: MGH agrees to: (a) put '*its management under control of Merck KGaA so the latter 'has the right to give instructions to [MGH] regarding the management of [MGH]; and (b) give its profit to Merck KGaA, but the latter will absorb any losses by the former (document 3206, page 1, clause 2.1). Merck submitted that the *Beherrschungsvertrag* 'only established a link to Merck Generics Holding GmbH and not to GUK itself' and 'did not give Merck any additional rights vis-a-vis Merck Generics Holding GmbH'; Merck also submitted that the agreement was 'to establish fiscal unity with Merck and to facilitate the preparation of profit and loss accounts' and 'does not demonstrate that Merck actually exercised decisive influence' (Merck response dated 17 September 2014 to the First Letter of Facts (document 3489), paragraphs 16–18). The CMA notes that, as stated at the start of the paragraph, the consolidation of financial accounts may corroborate a finding that a company exercised decisive influence.*

including for GUK's paroxetine product.¹³⁹³ This demonstrates that Merck was involved in the conduct of GUK, and not merely a financial investor. The identification of a business need for a secondment for such a long period within GUK by Merck demonstrates that Merck was well informed about, and involved in, GUK's overall conduct. Merck submitted that the secondment was not successful because [Merck's Strategic Sourcing Specialist] remained at Merck's offices in Germany, was not integrated within GUK and GUK '*perceived him as an "intruder"*'.¹³⁹⁴ Merck also submitted that a secondment arrangement is not relevant to the issue of parental liability because it is not an effective way to control a business.¹³⁹⁵ The CMA considers that the fact that the secondment lasted for six years indicates that the secondment was successful and that the ability to introduce secondees may be one way that a parent company may decide to influence the affairs of its subsidiaries. On the facts, [Merck's Strategic Sourcing Specialist] was also clearly involved in decision making and providing advice in relation to the sourcing of paroxetine API and in relation to order quantities from Sumika.¹³⁹⁶

- (c) Further, at any time Merck had the power to appoint, and remove, executives of the Merck Generics Group (including GUK).¹³⁹⁷ Merck was involved in removing, in the Relevant Period, [X] from his position as

¹³⁹³ Merck submitted that: '*The reason for the secondment was to make [Merck's Strategic Sourcing Specialist's] special expertise in raw material procurement available to GUK, with a view to improving GUK's financial performance through reducing cost.*' (Merck submission dated 25 November 2013 (document C0013R), paragraph 32). [Merck's Strategic Sourcing Specialist] assisted in negotiations to source paroxetine API from Sumika and had special expertise in raw material procurement; Merck also submitted that the secondment of [Merck's Strategic Sourcing Specialist] was '*limited to procurement questions*' and did '*not prove any decisional link between GUK and Merck*': Merck response dated 17 September 2014 to the First Letter of Facts (document 3489), paragraph 19. See also GUK supplementary submission to the CMA dated 1 August 2014 (document 3214), page 5 and associated footnotes referring to document 0848.

¹³⁹⁴ Merck submission dated 25 November 2013 (document C0013R), paragraph 33; Merck response dated 17 September 2014 to the First Letter of Facts (document 3489), paragraph 11.

¹³⁹⁵ Merck submission dated 25 November 2013 (document C0013R), paragraph 34.

¹³⁹⁶ Email chain between [Merck's Head of Patents and Raw Material Support Group], [GUK's Managing Director], [the Chief Executive of Merck Generics Group], [GUK's General Manager], [GUK's Head of Research and Development], [GUK's Senior Patents Manager] dated 31 October 2001 (document 0926) stating that [Merck's Strategic Sourcing Specialist] '*needs to be kept informed on 2001 deoliveries [sic] and orders for 2002.*' See also the email from [Merck's Strategic Sourcing Specialist] to [Sumitomo employee] dated 23 May 2001 enclosing paroxetine forecasts for the Merck Generics Group, including for the UK (documents 0848 and 0847).

¹³⁹⁷ Merck conceded that '*theoretically at least, [Merck] did have the power to remove [the Chief Executive of Merck Generics Group] by virtue of its shareholding*' (Merck submission dated 25 November 2013 (document C0013R), paragraph 36); '*Of course Merck, as the ultimate parent company, could, withdraw or remove the directors of ...[MGH], which itself could withdraw the directors of the Dutch holding company, which again, could take influence on the directors of GUK*' (Transcript of Merck SO Oral Hearing dated 17 October 2013 (document 3028), page 37 (as printed), lines 2–5). The German law agreement referred to at footnote 1392 provided an additional means for Merck to exercise total control over MGH and the generics businesses beneath MGH (including GUK).

CEO of the Merck Generics Group, and therefore his role as a Director of GUK.¹³⁹⁸

- 9.30 The CMA finds that the fact of Merck's sale of its generics business to Mylan Inc. in 2007 does not make Merck a mere financial investor in the period before 2007. The GC has held that '*... a "pure financial investor" [...] refer[s] to the case of an investor who holds shares in a company in order to make a profit, but who refrains from any involvement in its management and in its control.*'¹³⁹⁹ As evidenced above, this is not the case in relation to Merck's shareholding in GUK.

Conclusion on attribution of liability to Merck

- 9.31 In light of the above, the CMA has concluded that Merck has not adduced sufficient evidence to rebut the presumption that Merck exercised decisive influence over the conduct of GUK during the Relevant Period. The CMA therefore finds Merck jointly and severally liable, with GUK, for the infringement in respect of the GUK-GSK Agreement.

c) Conclusion on attribution of liability to the GUK-Merck entities

- 9.32 In light of the above, the Decision is addressed to GUK and Merck.

iii) Alharma

- 9.33 In respect of Alharma, the CMA attributes liability to the following legal entities:

¹³⁹⁸ Merck submitted in November 2013 that: [Merck's Chairman of the Executive Board] and [the Chief Executive of Merck Generics Group] *mutually agreed to terminate* [the Chief Executive of Merck Generics Group's] *activity within the Merck group in exchange for an indemnification* – see Merck submission dated 25 November 2013 (document C0013R), paragraph 36. GUK noted that this was after Merck was approached by a whistle-blower, and GUK stated that it '*would have made no sense for a whistle-blower to approach Merck if - as claimed by Merck - it had no power to take action in relation to these allegations and dismiss* [the Chief Executive of Merck Generics Group]' (GUK supplementary submission to the CMA dated 1 August 2014 (document 3214), page 4, paragraph 4.1(b)). Merck submitted that the fact that '*Merck is approached by a whistle-blower in relation to conduct of* [the Chief Executive of Merck Generics Group] *is no proof of control*'; Merck also submitted that '*[the Chief Executive of Merck Generics Group] was not dismissed unilaterally; rather the termination of the working relationship between him and the Merck Generics Group was "mutually agreed" - he effectively resigned*' (Merck response dated 17 September 2014 to the First Letter of Facts (document 3489, paragraph 14)). The appointment of board members is amongst the prerogatives of a parent company which enable that parent company to exercise, except in exceptional circumstances, decisive influence over its subsidiary (Judgment in *Eni v Commission*, C-508/11P, EU:C:2013:289, paragraphs 55, 67 and 72).

¹³⁹⁹ Judgment of 12 December 2012, *1. garantovaná v Commission*, T-392/09, ECR, EU:T:2012:674, paragraph 52.

- Actavis UK Limited¹⁴⁰⁰ (formerly Alparma Limited) ('Actavis');
- Xellia Pharmaceuticals ApS¹⁴⁰¹ (formerly Alparma ApS) ('Xellia'); and
- Alparma LLC (formerly Zoetis Products LLC, Alparma LLC and Alparma Inc) ('Zoetis').¹⁴⁰²

a) Actavis

9.34 Alparma Limited was directly involved in the Infringement in respect of the Alparma-GSK Agreement.

(a) The Alparma-GSK Settlement Agreement and Alparma-IVAX Agreement were entered into by Alparma Limited.¹⁴⁰³

(b) Individuals involved in the negotiation and implementation of the Alparma-GSK Agreement were employees of Alparma Limited.¹⁴⁰⁴

9.35 On 19 December 2005, the Actavis group acquired the underlying assets of the worldwide human generics business of Alparma Inc including Alparma Limited.¹⁴⁰⁵ Subsequently, Alparma Limited changed its name to Actavis UK Limited on 18 May 2006.¹⁴⁰⁶ However, at the time of this change, there were no consequent changes in the company number or the identities of its directors who continued to serve on the board of Actavis UK Limited.¹⁴⁰⁷

¹⁴⁰⁰ Company number 00079585, Registered address: Whiddon Valley, Whiddon Valley Industrial Estate, Barnstaple, Devon, EX32 8NS.

¹⁴⁰¹ Incorporated in Denmark.

¹⁴⁰² On 28 April 2010, Alparma Inc changed from a United States corporation into a United States limited liability company, Alparma LLC (see Certificate of Conversion dated 28 April 2010 (document 2788)). Alparma LLC was then re-named Zoetis Products LLC on 15 April 2013 (see Certificate of Amendment filed with, and delivered to, the Delaware Department of State on 15 April 2013 (document 2789)). In a letter from the OFT to Xellia and Zoetis dated 28 June 2013 (document 2796), the OFT confirmed to Zoetis that the SO applied to it and that references in the SO to Alparma LLC should be understood as referring to Zoetis. Subsequently, Zoetis Products LLC was re-named Alparma LLC on 6 July 2015: see Xellia-Zoetis DPS Written Response (document 4055), Footnote 1, and Annex 1 to Xellia-Zoetis DPS Written Response (document 4055) – Certificate of Amendment filed with, and delivered to, the Delaware Department of State on 6 July 2015 (document 4057).

¹⁴⁰³ Alparma-GSK Settlement Agreement (document 0356); Alparma-IVAX Agreement (document 1806). For an analysis of the Alparma-GSK Agreement, see paragraphs 3.319–3.379.

¹⁴⁰⁴ For example [Alparma Ltd's Director of Sales and Marketing] signed the Alparma-GSK Settlement Agreement (document 0356) on behalf of Alparma Limited (see paragraphs 3.355–3.362).

¹⁴⁰⁵ As described in paragraphs 9.43 and 9.52, this acquisition did not include the shares in Alparma Inc or Alparma ApS which continued to operate as separate legal entities.

¹⁴⁰⁶ The company number (79585) remained the same following the change of name. See also Actavis UK Limited (formerly Alparma Limited) Annual Report for the year ended 31 December 2005 (document 2588), for example at page 1 (as printed) confirming the change of name.

¹⁴⁰⁷ All company directors, with one exception, continued to serve on the board of Alparma Limited following the acquisition by the Actavis group. See Actavis UK Limited (formerly Alparma Limited) Annual Report for the year ended 31 December 2005 (document 2588). See also Actavis UK Limited (formerly Alparma Limited) Annual Report for the year ending 31 December 2006 (document 2586).

Actavis UK Limited remains active at the time of this Decision as a pharmaceutical supplier.¹⁴⁰⁸

- 9.36 Actavis submitted that no Alharma Limited employee was involved in any meetings with GSK in relation to, or in negotiating the actual terms, of the Alharma-GSK Agreement, and that to the extent that Alharma Limited had any involvement regarding the Alharma-GSK Agreement, Alharma Limited acted under the instructions – and subject to the approval – of Alharma ApS and/or Alharma Inc.¹⁴⁰⁹ The CMA finds that Alharma Limited participated directly in the Alharma-GSK Agreement, as described at paragraph 9.34, and also notes that in some instances certain employees of Alharma Limited provided advice to Alharma ApS and/or Alharma Inc in relation to the negotiation and implementation of the Alharma-GSK Agreement.¹⁴¹⁰ In any event, the CMA does not consider that the fact that Alharma ApS and/or Alharma Inc were directly involved in leading the negotiation of the terms of the Alharma-GSK Agreement should mean that the CMA should not find Actavis liable for its direct participation in the Alharma-GSK Agreement. The CMA also notes that Actavis made no submissions as regards the role of Alharma Limited employees in the implementation of the Alharma-GSK Agreement.
- 9.37 In light of the functional and economic continuity between Alharma Limited and Actavis, the CMA finds that Actavis is liable for its participation in the Infringement in respect of the Alharma-GSK Agreement.

¹⁴⁰⁸ Actavis UK Limited (formerly Alharma Limited) Annual Report for the year ended 31 December 2014 (document 4071).

¹⁴⁰⁹ Actavis submitted, for example, that *'the people who were actually involved in the negotiations of the Settlement Agreement were employed by Alharma ApS and Alharma Inc'*. Actavis also submitted that [Alharma Ltd's Director of Sales and Marketing] *'did not play a significant role in the negotiations. The evidence on file shows that although [Alharma Ltd's Director of Sales and Marketing] was copied into various correspondence that discussed the negotiations, the actual negotiating was carried out by [Alharma Inc's Vice President of Intellectual Property] and [Alharma ApS's Sales and Marketing Director] who worked at Alharma Inc and Alharma ApS respectively.'* Actavis SO Written Response, (document 2754) Section 13, and paragraphs 14.8, 14.11–14.12, 14.14 and 14.17; Transcript of Actavis SO Oral Hearing dated 23 October 2013 (document 3088), page 71, line 24, to page 72, line 13, and page 102, lines 2–25; Slides for Actavis SO Oral Hearing dated 23 October 2013 (document 2936), slides 41–42; transcript of Actavis SSO Oral Hearing dated 11 December 2014 (document 3752), page 34, lines 16–18 and page 35, line 21, to page 36, line 6.

¹⁴¹⁰ For example, see footnote 1404; in addition, [Alharma Ltd's Director of Sales and Marketing] – as noted at paragraph 3.360 of this Decision – sent an email on 14 October 2002 to [Alharma ApS's Sales and Marketing Director] outlining [Alharma Ltd's Director of Sales and Marketing's] *'[i]nitial thoughts regarding this proposal from GSK'*, and discussing, for example, pack prices, stock levels and packing arrangements (document 1361, page 1).

b) Xellia

9.38 For the reasons set out in paragraphs 9.39 to 9.45, the CMA finds that Xellia (formerly Alparma ApS, during the Relevant Period) is liable for the Infringement in respect of the Alparma-GSK Agreement.

Direct involvement

9.39 Alparma ApS was directly involved in the Infringement in respect of the Alparma-GSK Agreement due to the fact that one of its employees, [✂] [Alparma ApS's Sales and Marketing Director], was involved in the negotiation and implementation of the Alparma-GSK Agreement. [Alparma ApS's Sales and Marketing Director] was directly involved in the negotiations with GSK and met [GSK's Finance Director A] to negotiate the Alparma-GSK Agreement on a number of occasions.¹⁴¹¹

9.40 Xellia-Zoetis stated that Alparma ApS was not directly involved in the Infringement in respect of the Alparma-GSK Agreement, and that to the extent that Alparma ApS employees became involved in negotiations or communications regarding the Alparma-GSK Agreement, these were under the direction and instructions of AL Industrier.¹⁴¹² The CMA does not consider that these submissions have been substantiated, on the basis of paragraph 9.39 and given that there is no evidence to indicate that the employee referred to in paragraph 9.39 was acting under instructions from AL Industrier, rather than in his capacity as an employee of Alparma ApS.

9.41 In light of the functional and economic continuity between Alparma ApS and Xellia explained at paragraphs 9.43 and 9.44, the CMA finds that Xellia is liable for its participation in the Infringement in respect of the Alparma-GSK Agreement.

¹⁴¹¹ See further paragraphs 3.355–3.362.

¹⁴¹² Xellia-Zoetis submitted that AL Industrier was the 'top company' and ultimate owner which exercised decisive influence over, Xellia and Zoetis during the Relevant Period: Xellia-Zoetis SO Written Response (document 2767), Sections 8.1–8.2, 8.3(a) and 9.2; Slides for Xellia-Zoetis SO Oral Hearing (Session 1) dated 22 October 2013 (document 2994A), Slide 3; Transcript of Xellia-Zoetis SO Oral Hearing dated 22 October 2013 (document 3126), page 21, line 25 – page 22, line 9 and page 46, lines 11–29; Xellia-Zoetis Summary Submission dated 21 May 2014 (document 3136A), pages 5-6; Xellia-Zoetis Written First Letter of Facts Response (document 3496), Sections 4–7; slides for Xellia-Zoetis SSO Oral Hearing dated 10 December 2014 (document 3708), Slides 39–40 and 42; transcript of Xellia-Zoetis SSO Oral Hearing dated 10 December 2014 (document 3878), page 21, line 25, to page 23, line 9; Xellia-Zoetis DPS Written Response (document 4055), paragraph 11.

Decisive influence

9.42 As described at paragraph 3.7, Alpharma Limited was, during the Relevant Period, an indirect 100% owned subsidiary of Alpharma ApS.¹⁴¹³ Applying the presumption referred to in paragraph 9.6, the CMA finds that Alpharma ApS exercised decisive influence over the conduct of Alpharma Limited, in light of the 100% ownership by Alpharma ApS of Alpharma Limited. The CMA has not been provided with any evidence to rebut the presumption that Alpharma ApS exercised decisive influence over the conduct of Alpharma Limited during the Relevant Period.

Corporate changes - functional and economic continuity

- 9.43 As described at paragraph 3.8, on 19 December 2005, the Actavis group acquired the underlying assets of the worldwide human generics business of Alpharma Inc, including some assets – but not the whole – of Alpharma ApS. Alpharma ApS was sold by Alpharma Inc in March 2008 to an international investment group, after which Alpharma ApS was first re-named Axellia Pharmaceuticals ApS and then, as of 2010, Xellia Pharmaceuticals ApS. In 2013, Xellia was sold to Novo A/S, a holding company of the Novo Group.
- 9.44 The CMA finds that Xellia (currently named Xellia Pharmaceuticals ApS) is the functional and economic successor to Alpharma ApS.¹⁴¹⁴ The CMA therefore finds Xellia jointly and severally liable in this case for the Infringement in respect of the Alpharma-GSK Agreement.
- 9.45 Xellia-Zoetis submitted that Xellia no longer carries out any activities on the UK paroxetine market.¹⁴¹⁵ However, withdrawal from the relevant market does not relieve Xellia of any liability for the Infringement in respect of the Alpharma-GSK Agreement.

¹⁴¹³ See Alpharma ApS Annual Report for 2003 dated 31 December 2003 (document 2587). Alpharma ApS owned 100% of Alpharma Limited indirectly via a company named Cox Investments Limited. During the Relevant Period, Alpharma ApS also owned several other subsidiaries in the Alpharma group, notably in Belgium, Finland, France, Germany, the Netherlands, Norway and Sweden.

¹⁴¹⁴ The company number (CVR-Nr. 61 09 46 28) has remained the same following the changes of name. See Alpharma ApS Annual Report for the year ending 31 December 2003 (document 2587), page 1, and Xellia Pharmaceuticals ApS (formerly Alpharma ApS) Annual Report for the year ending 31 December 2011 (document 2593), page 1.

¹⁴¹⁵ Xellia-Zoetis SO Written Response (document 2767), paragraphs 337–338, 379 and 393, and Section 9.2: Xellia-Zoetis submitted that to the extent there existed a discretion to include companies, the OFT should have used its discretion to not to address the SO ‘to any entity not currently forming part of the human generics business that allegedly committed the infringement’. Certain other Xellia-Zoetis submissions to the effect that the CMA should not attribute liability to Xellia, albeit based on different reasoning are considered in paragraphs 9.55–9.62.

c) Zoetis

9.46 For the reasons set out in paragraphs 9.47 to 9.54, the CMA finds that Zoetis (formerly Alparma Inc, during the Relevant Period) is liable for the Infringement in respect of the Alparma-GSK Agreement.

Direct involvement

9.47 Alparma Inc was directly involved in the Infringement in respect of the Alparma-GSK Agreement on the basis that certain employees of Alparma Inc were involved in the negotiation and implementation of the Alparma-GSK Agreement. In particular, [X], Vice President, Intellectual Property, Alparma Inc, played a significant, direct role in negotiations with GSK leading to the Alparma-GSK Agreement.¹⁴¹⁶ In addition, [X], Chief Legal Officer, Alparma Inc, provided advice relating to the Alparma-GSK Agreement.¹⁴¹⁷ The decision to enter into the Alparma-GSK Agreement also required approval from Alparma Inc.¹⁴¹⁸ In his witness statement, [X], Sales and Marketing Director (Western Europe) / Vice President, New Products, Alparma ApS (Denmark), referred to the requirement to seek approval from Alparma Inc:¹⁴¹⁹

'...[T]he direct involvement for the actual settlement agreement with GSK came from senior management – [Alparma Inc's President (Human Generics)], [Alparma Inc's Chief Legal Officer] and [Alparma Inc's Chief Financial Officer]. This contract had to go to the Board of Alparma Inc. for approval.'

¹⁴¹⁶ Email from [Alparma ApS's Sales and Marketing Director] to [Alparma Ltd's Director of Sales and Marketing] and others dated 24 October 2002 (document 1364). See also paragraphs 3.355–3.362. In addition, [Alparma Inc's Vice President of Intellectual Property] received various emails from Alparma employees reporting on discussions which had taken place between representatives of Alparma and GSK, including considerations regarding GSK's proposals and circulating drafts of both the Alparma-GSK Settlement Agreement and the Alparma-IVAX Agreement. Furthermore, on 11 November 2002, [Alparma Inc's Vice President of Intellectual Property] was the Alparma representative who sent an email to [GSK's Associate General Counsel for Europe] suggesting final amendments to the Alparma-GSK Settlement Agreement (see email from [Alparma Inc's Vice President of Intellectual Property] to [GSK's Associate General Counsel for Europe] and others dated 11 November 2002 (document 1396)).

¹⁴¹⁷ See paragraph 3.355.

¹⁴¹⁸ See Alparma Contract Policy dated 6 June 2002 (document A0026), pages 1–3: 'Contract Approval Requirements [...] (d) Board of Directors. Prior to approval, the CEO shall obtain authorization from the Board of Directors if the contract involves: [...] (iv) any other contract...for US\$ 5 Million or more [...] Procedure for Legal Review [...] (d) The legal approval...must be obtained from the Chief Legal Officer for any contract which...must be approved by the CEO or the Board of Directors.'

¹⁴¹⁹ [X]WS (document 3172), paragraph 3.6. See also email from [Alparma Inc's Vice President of Intellectual Property] to [Alparma ApS's Sales and Marketing Director] and [Alparma Ltd's Director of Sales and Marketing] dated 18 November 2002 (document A0055) stating: 'Please do not sign the Ivax document until I let you know that we have board approval. This contract is greater than US\$5 million so we need board approval. We have an executive committee meeting this afternoon and [Alparma Inc's Chief Legal Advisor] will be seeking approval, which we expect to be granted'.

- 9.48 Furthermore, minutes of a meeting of the Executive and Finance Committee of the Board of Directors of Alpharma Inc held on 18 November 2002, signed by [Alpharma Inc's Chief Legal Officer], specifically approve the Alpharma-GSK Agreement.¹⁴²⁰

[Alpharma Inc's Chief Legal Officer] next explained the settlement negotiated with Glaxo-Smith-Kline relating to paroxetine in the United Kingdom. After a full discussion upon motion made, seconded and unanimously carried, the Committee approved the settlement.'

- 9.49 Xellia-Zoetis stated that Alpharma Inc was not directly involved in the Infringement in respect of the Alpharma-GSK Agreement, and that to the extent that Alpharma Inc employees became involved in negotiations or communications regarding the Alpharma-GSK Agreement, these were under the direction and instructions of AL Industrier.¹⁴²¹ The CMA does not consider that these submissions have been substantiated, on the basis of paragraphs 9.47 and 9.48 and that there is no evidence to indicate that the employees referred to in those paragraphs were acting under instructions from AL Industrier rather than in their capacity as employees of Alpharma Inc.
- 9.50 In light of the functional and economic continuity between Alpharma Inc and Zoetis (currently named Alpharma LLC), explained at paragraphs 9.52 and 9.53, the CMA finds that Zoetis is liable for its participation in the Infringement in respect of the Alpharma-GSK Agreement.

Decisive influence

- 9.51 As described at paragraphs 3.7 to 3.9, during the Relevant Period, Alpharma Limited was an indirect 100% owned subsidiary of Alpharma ApS, and Alpharma ApS was owned 100% by Alpharma Inc. Applying the presumption referred to in paragraph 9.6, the CMA finds that Alpharma Inc exercised decisive influence over the conduct of Alpharma ApS and Alpharma Limited. The CMA has not been provided with any evidence to rebut the presumption that Alpharma Inc exercised decisive influence over the conduct of Alpharma ApS and/or Alpharma Limited during the Relevant Period.

¹⁴²⁰ Minutes of a Meeting held on 18 November 2002 of the Executive and Finance Committee of the Board of Directors of Alpharma Inc. (documents D 211, D 212).

¹⁴²¹ See footnote 1412.

Corporate changes - functional and economic continuity

- 9.52 As described at paragraph 3.8, on 19 December 2005, the Actavis group acquired the underlying assets of the worldwide human generics business of Alparma Inc, including some assets – but not the whole of – Alparma ApS. Alparma Inc was acquired in December 2008 by King Pharmaceuticals Inc. King Pharmaceuticals Inc was, in turn, acquired by Pfizer Inc in February 2011. Alparma Inc became a limited liability company, Alparma LLC, in April 2010. In April 2013, Alparma LLC changed its name to Zoetis Products LLC. In July 2015, Zoetis Products LLC changed its name to Alparma LLC. It continues to exist as a separate legal entity within the Zoetis group of companies.
- 9.53 The CMA finds that Zoetis (currently named Alparma LLC) is the functional and economic successor to Alparma Inc, which changed its name to Alparma LLC, then to Zoetis Products LLC and then to Alparma LLC. The CMA therefore finds Zoetis jointly and severally liable in this case for the Infringement in respect of the Alparma-GSK Agreement.¹⁴²²
- 9.54 Xellia-Zoetis submitted that Zoetis no longer carries out any activities on the UK paroxetine market.¹⁴²³ However, withdrawal from the relevant market does not relieve Zoetis of any liability for the Infringement in respect of the Alparma-GSK Agreement.

Representations of Xellia-Zoetis regarding the inclusion of Xellia and Zoetis in the Investigation

- 9.55 Xellia-Zoetis submitted that the CMA should attribute liability for the Infringement in respect of the Alparma-GSK Agreement, not to Xellia or Zoetis, but instead to Alparma Limited only and/or to AL Industrier (which, Xellia-Zoetis submitted, exercised decisive influence over Alparma Inc during the Relevant Period).¹⁴²⁴

¹⁴²² The CMA has also considered the potential attribution of parental liability to AL Industrier, which is based in Norway, on the grounds that it exercised decisive influence over the conduct of Alparma Inc during the Relevant Period. However, the CMA considers that further work to establish such liability on the part of AL Industrier does not constitute an administrative priority for the CMA. See further paragraphs 9.57–9.59.

¹⁴²³ See footnote 1415.

¹⁴²⁴ Xellia-Zoetis SO Written Response (document 2767), Section 8.2; Xellia and Zoetis - Written Representations on additional evidence dated 9 October 2013 (document 2985), Section 3; Slides for Xellia-Zoetis SO Oral Hearing (Session 1) dated 22 October 2013 (document 2994A), Slides 26–33; Transcript of Xellia-Zoetis SO Oral Hearing dated 22 October 2013 (document 3126), page 19, line 21 to page 23, line 9 and page 46, lines 11–29; Xellia-Zoetis Summary Submission dated 21 May 2014 (document 3136A), pages 5–6; Xellia-Zoetis Written First Letter of Facts Response (document 3496), Sections 4–7; slides for Xellia-Zoetis SSO Oral Hearing dated 10 December 2014 (document 3708), Slides 39–40 and 42; transcript of Xellia-Zoetis SSO Oral Hearing dated 10 December 2014 (document 3878), page 21, line 25 to page 23, line 9; Xellia-Zoetis DPS Written Response (document 4055), paragraphs 9–11.

Representations of Xellia-Zoetis on the non-inclusion of AL Industrier in the Investigation

- 9.56 Xellia-Zoetis submitted that AL Industrier should have been included within the scope of the Investigation, as AL Industrier was the parent company of Alpharma ApS and Alpharma Inc during the Relevant Period and exercised decisive influence over the conduct of Alpharma ApS and Alpharma Inc.
- 9.57 Before the issue of the SO, the OFT considered whether to include AL Industrier as a party to the Investigation on the basis that AL Industrier was a significant shareholder in Alpharma Inc during the Relevant Period. However, the OFT considered that further investigation and information gathering would have been necessary to establish any such potential liability on the part of AL Industrier which was not justified by the negligible beneficial direct or indirect impact of doing so. The OFT therefore concluded in February 2013, following an assessment undertaken by reference to its prioritisation principles,¹⁴²⁵ that extending the scope of the Investigation to include AL Industrier did not constitute an administrative priority for the OFT.¹⁴²⁶
- 9.58 Following consideration of representations from Xellia-Zoetis on the SO, the CMA re-considered whether extending the scope of the Investigation to include AL Industrier was an administrative priority for the CMA by reference to its prioritisation principles.¹⁴²⁷ In October 2014, the Case Decision Group concluded that it was not an administrative priority for the CMA to include AL Industrier within the scope of the Investigation, on the basis that AL Industrier had at that point been dissolved¹⁴²⁸ and the inclusion of AL Industrier would require further investigation and information gathering while leading to a negligible beneficial direct or indirect impact on consumers.
- 9.59 The CMA has therefore decided not to proceed further in respect of potentially attributing liability for the Infringement in respect of the Alpharma-GSK Agreement to AL Industrier, as a matter of its administrative priorities. The CMA does not therefore make any finding as to whether AL Industrier

¹⁴²⁵ OFT Prioritisation Principles (OFT953, October 2008).

¹⁴²⁶ See footnote 17.

¹⁴²⁷ Prioritisation principles for the CMA (CMA16, April 2014).

¹⁴²⁸ See email dated 28 August 2014 from the CMA to [external lawyers for A.L. Industrier] (document 3241), page 1: 'A.L. Industrier was notified to the Norwegian Company Registration Office as being dissolved as of 14 June 2014.'

exercised decisive influence over the conduct of Alpharma Limited, Alpharma ApS or Alpharma Inc during the Relevant Period.¹⁴²⁹

Representations of Xellia-Zoetis on alleged discriminatory treatment

- 9.60 Xellia-Zoetis also submitted that Xellia and Zoetis are the subject of discrimination, since the OFT/CMA has included them, but not other parent companies such as MGH, within the scope of the Investigation.¹⁴³⁰
- 9.61 Each of Xellia and Zoetis was directly involved in the Infringement in respect of the Alpharma-GSK Agreement and is therefore in a different position to MGH, which the CMA does not consider to be directly involved in the Infringement in respect of the GUK-GSK Agreement.
- 9.62 On this basis, there is no discrimination in attributing liability (and addressing the Decision) to Xellia and Zoetis (currently named Alpharma LLC) but not attributing liability to MGH.

d) Conclusion on attribution of liability to the Alpharma entities

- 9.63 In light of the above, the Decision is addressed to Actavis UK Limited, Xellia Pharmaceuticals ApS and Alpharma LLC.

¹⁴²⁹ The CMA notes that the European Commission found in its *Lundbeck* Decision that AL Industrier did exercise decisive influence over Alpharma ApS and Alpharma Inc (see Commission Decision of 19 June 2013, COMP/AT. 39226 – *Lundbeck*).

¹⁴³⁰ See for instance, Xellia-Zoetis SO Written Response (document 2767), Sections 8.3 and 9.2; Xellia and Zoetis - Written Representations on additional evidence dated 9 October 2013 (document 2985), Section 3; Slides for Xellia-Zoetis SO Oral Hearing (Session 2) dated 22 October 2013 (document 2994B), Slide 35; Transcript of Xellia-Zoetis SO Oral Hearing dated 22 October 2013 (document 3126), page 57, lines 20–27; Xellia-Zoetis Summary Submission dated 21 May 2014 (document 3136A), page 6; Xellia-Zoetis Submission on additional evidence dated 7 July 2014 (document 3223), pages 2–3; Note of Xellia-Zoetis State of Play Meeting on 19 June 2014 (document 3476), page 7, paragraph 21; Xellia-Zoetis DPS Written Response (document 4055), paragraphs 9 and 12.

10. OTHER ASPECTS OF THE LEGAL ASSESSMENT

A. Introduction

10.1 This Part states the conclusions that the CMA has drawn from the evidence set out and analysed by the CMA in the preceding Parts of this Decision in relation to the remaining aspects of the legal framework.

B. Appreciability

10.2 An agreement will fall within the Chapter I prohibition or Article 101(1) TFEU only if it has as its object or effect an appreciable prevention, restriction or distortion of competition.¹⁴³¹ Set out below is the CMA's reasoning for concluding that each of the GUK-GSK Agreement and Alpharma-GSK Agreement had as its object and/or effect an appreciable prevention, restriction, or distortion of competition.

10.3 First, the aggregate market shares of the Parties to the GUK-GSK and Alpharma-GSK Agreements were high, and each Party was a substantial undertaking. At the time of the GUK-GSK and Alpharma-GSK Agreements, GSK was one of the world's leading research-based pharmaceutical and healthcare companies, and GUK and Alpharma were among the largest providers of generic medicines in the UK.

10.4 As described in Part 4 Section 4D, the relevant market is no wider than the supply of paroxetine in the UK. The CMA has set out market share data for the UK paroxetine market during the term of the Agreements (see paragraphs 3.397 to 3.398, in particular Table 3.4 which sets out market shares by value of paroxetine suppliers for 2001-2005 and Table 3.5 which sets out market shares by volume of paroxetine suppliers for 1998-2005). This data shows that, during the term of the GUK-GSK Agreement and Alpharma-GSK Agreement:

- GSK's individual market share ranged between 53 to 74% (by value) and 37 to 69% (by volume), and that the aggregate market shares of the Parties to each Agreement were greater;

¹⁴³¹ *Agreements and concerted practices* (OFT401, December 2004), adopted by the CMA, at paragraph 2.15. The Act, section 2(7).

- the aggregate market shares of GUK and GSK ranged between 64 to 80% (by value) and 49 to 77% (by volume);¹⁴³² and
- the aggregate market shares of Alpharma and GSK ranged between 72 to 74% (by value) and 52 to 69% (by volume).

10.5 Second, the likely effect of each of the GUK-GSK and Alpharma-GSK Agreements was significant in that it:

- deferred the threat of true generic competition in the UK paroxetine market and the associated price decreases; and
- assisted GSK in preserving the barriers to entry faced by potential entrants and thereby enabled GSK to maintain its market power.

10.6 Moreover, and separately, the CMA has concluded that, in so far as each Agreement had the object of preventing, restricting or distorting competition, it constituted, by its very nature, an appreciable restriction of competition.¹⁴³³

10.7 In view of the foregoing, the CMA has concluded that each of the GUK-GSK Agreement and Alpharma-GSK Agreement had the object and/or effect of preventing, restricting, or distorting competition to an appreciable extent.¹⁴³⁴

C. Duration of the Infringements

10.8 As described in paragraphs 3.249 to 3.379, the GUK-GSK Agreement and Alpharma-GSK Agreement were in effect for the following periods:¹⁴³⁵

¹⁴³² The CMA notes also that the aggregate market shares are significantly in excess of the so-called 'safe harbour' created by the market share thresholds set out in the relevant Commission notice – which, in any event, does not apply to agreements that have as their object the prevention, restriction or distortion of competition (see Commission Communication: Notice on agreements of minor importance which do not appreciably restrict competition under Article 101(1) of the Treaty on the Functioning of the European Union (De Minimis Notice) OJ C 291/01, 30.8.2014, paragraphs 2, 8–11 and 13).

¹⁴³³ Judgment in *Expedia v Autorité de la Concurrence and Others*, C-226/11, EU:C:2012:795, paragraph 37; Commission Communication: Notice on agreements of minor importance which do not appreciably restrict competition under Article 101(1) of the Treaty on the Functioning of the European Union (De Minimis Notice), OJ C 291/01, 30.8.2014, paragraphs 2 and 13.

¹⁴³⁴ The CMA has also concluded, for the same reasons, that each of the Agreements did not have a merely 'insignificant' effect on the relevant market in the sense described in Judgment in *Völk v Vervaecke*, 5/69, EU:C:1969:35, paragraph 7.

¹⁴³⁵ For the purposes of applying the Chapter I prohibition and Article 101 TFEU, the CMA finds that the GUK-GSK and Alpharma-GSK Agreements were 'in effect' from the dates that the GUK-GSK Settlement Agreement and the Alpharma-GSK Settlement Agreement were entered into by the Parties and lasted until these Agreements terminated. However, the CMA considers that the duration of the anti-competitive effects of the GUK-GSK Agreement and the Alpharma-GSK lasted from the date that the GUK-GSK Settlement Agreement and the Alpharma-GSK Settlement Agreements were entered into by the Parties until at least 30 November 2003. See Part 7.

- GUK-GSK Agreement – from 13 March 2002 to 1 July 2004, a period of two years and three months; and
- Alparma-GSK Agreement – from 12 November 2002 to 13 February 2004, a period of one year and three months.

10.9 Following the entry into force of the Modernisation Regulation which was applicable from 1 May 2004, the CMA is required, when applying national competition law to agreements between undertakings which may affect trade between Member States, also to apply Article 101 TFEU.¹⁴³⁶ The CMA has applied Article 101 TFEU to the GUK-GSK Agreement from 1 May 2004 until the termination of the GUK-GSK Agreement. Article 101 TFEU has not been applied to the Alparma-GSK Agreement, since that Agreement terminated before 1 May 2004.

10.10 The CMA has found that GSK infringed the Chapter II prohibition from 3 October 2001 (the date when the IVAX-GSK Agreement was entered into) until 30 November 2003. Article 102 TFEU has not been applied from 1 May 2004, since GSK's dominant position ended prior to 1 May 2004 (see Part 4 Section E).

D. Effect on trade

i) The GUK-GSK and Alparma-GSK Agreements

a) Effect on trade within the UK

10.11 By virtue of section 2(1)(a) of the Act, the Chapter I prohibition applies only to agreements which: '*...may affect trade within the United Kingdom*'.

10.12 For the purposes of the Chapter I prohibition, the UK means any part of the UK in which an agreement operates or is intended to operate.¹⁴³⁷

10.13 According to settled case law, the concept of '*trade*' includes cases where an agreement affects the competitive structure of the market, for example by eliminating or threatening to eliminate a potential or actual competitor. When an undertaking is or risks being eliminated, the competitive structure in the

¹⁴³⁶ Modernisation Regulation, Article 3.

¹⁴³⁷ The Act, section 2(7).

market is affected and so are the economic activities in which the undertaking is engaged.¹⁴³⁸

10.14 An agreement does not actually have to affect trade. It is sufficient to establish that it is '*capable*' of having such an effect.¹⁴³⁹

10.15 The GUK-GSK Agreement and the Alpharma-GSK Agreement were both implemented throughout the UK. As set out at paragraphs 3.305 to 3.310 and 3.363 to 3.369 respectively, the GUK-GSK Agreement and the Alpharma-GSK Agreement included entry restrictions, whereby GUK and Alpharma agreed not to enter the UK paroxetine market independently of GSK (and whereby GUK and Alpharma were prevented from assisting any other company in entering the UK paroxetine market). Therefore, each of the Agreements affected the competitive structure of the UK paroxetine market, in particular by deferring a potential competitor's efforts to enter the market independently of GSK. These Agreements were therefore, at the very least, capable of affecting trade within the UK.

Appreciability

10.16 If the appreciability requirement extends to the effect on trade within the UK,¹⁴⁴⁰ the CMA finds that the effect on trade within the UK of each of the GUK-GSK and Alpharma-GSK Agreements was appreciable for the following reasons (taken individually or collectively):

- (a) First, and primarily, the aggregate market shares of the Parties to each Agreement were high and each Party to the Agreements was a substantial undertaking (see paragraphs 10.3 to 10.4).
- (b) Second, paroxetine was traded throughout the UK (and beyond). The relevant market relates to the supply, nationwide within the UK, of paroxetine, which was a widely prescribed antidepressant medicine and became a 'blockbuster' product for GSK, with UK sales of £91 million in 2001.¹⁴⁴¹

¹⁴³⁸ Commission Notice: Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty (now Articles 101 and 102 of the TFEU), OJ C101/81, 27 April 2004 ('Effect on Trade Guidelines'), paragraph 20 and footnote 12 citing Judgment of 8 October 1996, *Compagnie Maritime Belge and others*, Joined Cases T-24/93, ECR, EU:T:1996:139, paragraph 203.

¹⁴³⁹ Judgment of 12 July 2001, *Tate & Lyle and Others v Commission*, Joined Cases T-202/98, T-204/98 and T-207/98, ECR, EU:T:2001:185, paragraph 78; Judgment of 7 October 1999, *Irish Sugar v Commission*, T-228/97, ECR, EU:T:1999:246, paragraph 170; and Judgment of 21 February, *SPO and Others v Commission*, T-29/92, ECR, EU:T:1995:34, paragraph 235. See also the Effect on Trade Guidelines, paragraph 26.

¹⁴⁴⁰ *Aberdeen Journals Ltd v Office of Fair Trading* [2003] CAT 11, at [459]–[462].

¹⁴⁴¹ CMA's calculations, based on data provided by relevant parties.

- (c) Third, the likely effect of each Agreement was significant in that it: (i) deferred the threat of true generic competition in the UK paroxetine market and the associated price decreases; and (ii) assisted GSK in preserving the barriers to entry faced by potential entrants, and thereby enabled GSK to maintain its market power.

10.17 The CMA also finds that, in light of the reasoning set out in paragraphs 10.3 to 10.5 and 10.16 (a) and (c), there is a close nexus between appreciable effect on competition and appreciable effect on trade within the UK in this case. Where such a close nexus exists, if one is satisfied then the other is likely to be so.¹⁴⁴² In this case, the CMA has found that the GUK-GSK and Alpha-GSK Agreements each constituted an appreciable restriction of competition (see paragraphs 10.2 to 10.7). For the additional reasons set out in this paragraph the CMA finds that, if the appreciability requirement extends to the effect on trade within the UK, then the effect on trade within the UK of each of the GUK-GSK and Alpha-GSK Agreements was appreciable.

Conclusion on the effect on trade within the UK

10.18 The CMA finds that, for the reasons set out at paragraphs 10.15 to 10.17, taken individually or collectively, each of the GUK-GSK and Alpha-GSK Agreements has satisfied the test that it *'may affect trade within the United Kingdom'*.¹⁴⁴³

b) Effect on trade between Member States

10.19 Article 101 TFEU applies only to agreements which: *'...may affect trade between [EU] Member States'*.

10.20 An agreement *'may affect trade'* where it is *'possible to foresee with a sufficient degree of probability on the basis of a set of objective factors of law or of fact that the agreement or practice may have an influence, direct or indirect, actual or potential, on the pattern of trade between Member States'*.¹⁴⁴⁴

¹⁴⁴² *North Midland Construction Plc v OFT* [2011] CAT 14, at [62]. The CAT accepted that, at least in that case, there was a close nexus between appreciable effect on competition and appreciable effect on trade within the UK, in that if one was satisfied then the other was likely to be so. Accordingly, the CAT was of the view that, if the appreciability requirement extends to the effect on trade within the UK, it was satisfied.

¹⁴⁴³ Section 2(1)(a) of the Act.

¹⁴⁴⁴ Effect on Trade Guidelines, paragraphs 23–43.

- 10.21 As set out at 10.13, the concept of '*trade*' includes cases where an agreement affects the competitive structure of the market, for example by eliminating or threatening to eliminate a potential or actual competitor.¹⁴⁴⁵
- 10.22 As set out at 10.14, an agreement does not actually have to affect trade. It is sufficient to establish that it is '*capable*' of having such an effect.¹⁴⁴⁶
- 10.23 The application of the effect on trade criterion is independent of the definition of the relevant geographic markets. Trade between Member States may be affected where the relevant geographic market is national (or sub-national) in scope.¹⁴⁴⁷
- 10.24 As regards the application of Article 101 TFEU to the GUK-GSK Agreement, the CMA finds that the GUK-GSK Agreement has satisfied the requirement that it may affect trade between EU Member States for the following reasons:
- (a) As set out at paragraph 10.15, the GUK-GSK Agreement affected the competitive structure of the UK paroxetine market, in particular by deferring a potential competitor's efforts to enter the market independently of GSK. When an undertaking is or risks being eliminated, the competitive structure within the Community is affected and so are the economic activities in which the undertaking is engaged.¹⁴⁴⁸
 - (b) Further, and separately, the GUK-GSK Agreement had at least a potential influence on the pattern of trade between Member States¹⁴⁴⁹ for the following reasons (taken individually or collectively):
 - (i) First, and primarily, the aggregate market shares of the Parties to each Agreement were high, and each of GSK and GUK were substantial undertakings (see paragraph 10.3 to 10.4).
 - (ii) Second, paroxetine is (and was at the time of the GUK-GSK Agreement) traded throughout the UK and across borders, as

¹⁴⁴⁵ Effect on Trade Guidelines, paragraph 20 and footnote 12 citing judgment of 8 October 1996, *Compagnie Maritime Belge and others*, Joined Cases T-24/93, ECR, EU:T:1996:139, paragraph 203.

¹⁴⁴⁶ Judgment of 12 July 2001, *Tate & Lyle and Others v Commission*, Joined Cases T-202/98, ECR, EU:T:2001:185, paragraph 78; Judgment of 7 October 1999, *Irish Sugar v Commission*, T-228/97, EU:T:1999:246, paragraph 170; and Judgment of 21 February, *SPO and Others v Commission*, T-29/92, EU:T:1995:34, paragraph 235. See also the Effect on Trade Guidelines, paragraph 26.

¹⁴⁴⁷ Effect on Trade Guidelines, paragraph 22. See also Judgment of 14 December 2006, *Raiffeisen Zentralbank Österreich v Commission*, T-259/02, ECR, EU:T:2006:396, paragraph 181. Upheld on appeal in Judgment in *Austrian Banks v Commission*, Joined Cases C-125/07 P, C-133/07 P, C-135/07 P and C-137/07 P, EU:C:2009:576, paragraphs 36–46. See also Judgment in *Asnef-Equifax v Ausbanc*, C-238/05, EU:C:2006:734, paragraph 34. As set out at Part 4 Section 4.D, the CMA has found the relevant market in this case to be no wider than the supply of paroxetine in the UK.

¹⁴⁴⁸ Effect on Trade Guidelines, paragraph 20.

¹⁴⁴⁹ Effect on Trade Guidelines, paragraph 23.

demonstrated by the existence of parallel traders across the sector. As described at paragraph 3.392, after entry by the Generic Companies selling GSK paroxetine (including through the GUK-GSK Agreement), sales of parallel imported paroxetine fell to virtually nothing. Further, paroxetine was a widely prescribed antidepressant medicine and became a 'blockbuster' product for GSK.

(iii) Third, the GUK-GSK Agreement was capable of affecting cross-border economic activities that, in its absence, could have come about. Patent challenges are an important (and at times unavoidable) part of the competitive process. When generic suppliers are able to successfully enter the market, the onset of true generic competition will often result in the originator's market position being eroded rapidly. However, the likely effect of the GUK-GSK Agreement was significant in that it: (i) deferred a potential competitor's efforts to enter the market independently; and (ii) assisted GSK in preserving barriers to entry and, thereby, maintaining its market power (see paragraph 10.16(c)). The GUK-GSK Agreement was therefore capable of rendering any competition (including cross-border activities) more difficult.

(iv) Fourth, GUK gave undertakings that neither GUK nor any member of the Merck Generics Group would '*make, import, supply or offer to supply paroxetine hydrochloride*' (save as purchased from IVAX or otherwise manufactured or marketed by GSK or with GSK's consent), which had a clear potential influence on the pattern of trade between Member States.

Appreciability

10.25 The effect on trade between Member States must be appreciable. The assessment of appreciability depends on the circumstances of each case, in particular the nature of the agreement, the nature of the products and the market position of the undertakings concerned.¹⁴⁵⁰

10.26 The CMA finds that the effect on trade between Member States of the GSK-GUK Agreement was appreciable for the reasons set out at paragraphs 10.24 (i) to (iii).

¹⁴⁵⁰ Effect on Trade Guidelines, paragraphs 44–45.

Conclusion on the effect on trade between Member States

10.27 The CMA finds that, for the reasons set out at paragraphs 10.24 to 10.26, the GUK-GSK Agreement has satisfied the test that it '*may affect trade between [EU] Member States*'.

ii) GSK's abuse of a dominant position

a) Effect on trade within the UK

10.28 By virtue of section 18(1) of the Act, the Chapter II prohibition applies only to conduct which: '*...may affect trade within the United Kingdom*'.

10.29 For the purposes of the Chapter II prohibition, the UK means the UK or any part of it.

10.30 As set out at paragraph 10.13, according to settled case law, the concept of '*trade*' includes cases where conduct affects the competitive structure of the market, for example by eliminating or threatening to eliminate a potential or actual competitor.¹⁴⁵¹

10.31 Conduct which amounts to an abuse of a dominant position does not actually have to affect trade. It is sufficient to establish that it is '*capable*' of doing so.¹⁴⁵²

10.32 As set out in Part 8, the CMA has found that GSK held a dominant position in the UK paroxetine market (at least between January 1998 and November 2003), and that GSK abused that dominant position by making value transfers to induce the Generic Companies to delay their potential entry to the UK paroxetine market. Such conduct is inherently capable of affecting the structure of competition in the market, and thereby of affecting trade within the UK.

Appreciability

10.33 The CAT has previously held in a Chapter II case that the requirement that there should be an effect on trade within the UK does not require that the

¹⁴⁵¹ Effect on Trade Guidelines, paragraph 20 and footnote 12 citing Judgment of 8 October 1996, *Compagnie Maritime Belge and others*, Joined Cases T-24/93, ECR, EU:T:1996:139, paragraph 203.

¹⁴⁵² See, for example Judgment of 7 October 1999, *Irish Sugar v Commission*, T-228/97, ECR, EU:T:1999:246, paragraph 170.

effect should be appreciable.¹⁴⁵³ However, the High Court subsequently expressed misgivings as to whether the CAT was correct on this point.¹⁴⁵⁴

10.34 If the appreciability requirement extends to the effect on trade within the UK, the CMA finds that the effect on trade within the UK of the conduct was appreciable for the following reasons:

- (a) First, and primarily, GSK held a dominant position in the UK paroxetine market, and each of the Generic Companies was a substantial undertaking.¹⁴⁵⁵
- (b) Second, paroxetine was traded throughout the UK (and beyond). The relevant market relates to the supply, nationwide within the UK, of paroxetine, which was a widely prescribed antidepressant medicine and became a 'blockbuster' product for GSK, with UK sales of £91 million in 2001.¹⁴⁵⁶
- (c) Third, at the time of the conduct, the likely effect of the value transfers was significant in that, in each case, it was to induce each of the Generic Companies to delay their efforts to enter the market independently of GSK and the associated price decreases, and to assist GSK in preserving the entry barriers faced by the Generic Companies and other potential entrants (thereby enabling GSK to maintain its market power).

Conclusion on the effect on trade within the UK

10.35 The CMA finds that, for the reasons set out at paragraphs 10.32 and 10.34, taken individually or collectively, GSK's conduct has satisfied the test that it *'may affect trade within the United Kingdom.'*¹⁴⁵⁷

¹⁴⁵³ *Aberdeen Journals Ltd v Office of Fair Trading* [2003] CAT 11, at [459]-[462].

¹⁴⁵⁴ *P&S Amusements Ltd v Valley House Leisure Ltd* [2006] EWHC 1510 (Ch), paragraphs 21–22 and 34. *Pirtek v Joinplace* [2010] EWHC 1641 (Ch), paragraphs 61–67, in particular at paragraph 62.

¹⁴⁵⁵ See Part 4 Section 4.E. and paragraphs 10.3–10.4.

¹⁴⁵⁶ CMA's calculations, based on data provided by relevant parties.

¹⁴⁵⁷ Section 2(1)(a) of the Act.

E. Legal exclusion

- 10.36 Section 3 of the Act provides that the Chapter I prohibition does not apply to any of the cases in which it is excluded by or as a result of Schedules 1-3 of the Act.¹⁴⁵⁸
- 10.37 At the time of the GUK-GSK Agreement and the Alpharma-GSK Agreement, the Vertical Agreements Exclusion Order excluded from the Chapter I prohibition agreements, to the extent they fell within the definition of ‘vertical agreement’ set out in the Vertical Agreements Exclusion Order.¹⁴⁵⁹
- 10.38 The Vertical Agreements Exclusion Order came into force on 1 March 2000 and was revoked with effect from 1 May 2005.¹⁴⁶⁰
- 10.39 The Vertical Agreements Exclusion Order does not prevent the application of the Chapter II prohibition or Article 101 and Article 102 TFEU.
- 10.40 The CMA has concluded that neither the GUK-GSK Agreement nor the Alpharma-GSK Agreement fall within the scope of the Vertical Agreements Exclusion Order. In particular, those Agreements specifically related to the settlement (or deferral) of litigation that concerned a potential competitor’s proposed market entry. GUK and Alpharma (as potential competitors to GSK in the UK paroxetine market) expressly agreed to entry restrictions in return for the value transfers from GSK.¹⁴⁶¹ Therefore for the purposes of each of the GUK-GSK Agreement and the Alpharma-GSK Agreement, GUK and Alpharma respectively were not *‘for the purposes of the agreement, at a different level of the production or distribution chain’* to GSK.¹⁴⁶² The fact that GUK and Alpharma ultimately distributed GSK’s product does not alter that conclusion. The GUK-GSK Agreement and the Alpharma-GSK Agreement were not therefore *‘vertical agreements’* within the scope of the Vertical Agreements Exclusion Order and therefore do not benefit from the disapplication, by virtue of that Order, of the Chapter I prohibition.¹⁴⁶³

¹⁴⁵⁸ See also *Agreements and concerted practices* (OFT401, December 2004), adopted by the CMA, paragraph 6.2, (regarding exclusions from the Chapter I prohibition) and paragraph 6.1 (regarding exclusions from the application of Article 101 TFEU).

¹⁴⁵⁹ Vertical Agreements Exclusion Order, Article 2.

¹⁴⁶⁰ The Vertical Agreements Exclusion Order was repealed, with effect from 1 May 2005, by The Competition Act 1998 (Land Agreements Exclusion and Revocation) Order 2004 SI 2004/1260.

¹⁴⁶¹ See paragraphs 3.305–3.310 for the GUK-GSK Agreement and paragraphs 3.363–3.375 for the Alpharma-GSK Agreement.

¹⁴⁶² See Article 2 of the Vertical Agreements Exclusion Order.

¹⁴⁶³ Therefore, Article 3 of the Vertical Agreements Exclusion Order does not apply to the GUK-GSK Agreement or the Alpharma-GSK Agreement.

- 10.41 In relation to the Parties' representations on the applicability of the Vertical Agreements Exclusion Order to the GUK-GSK Agreement or the Alpharma-GSK Agreements, see Annex M.¹⁴⁶⁴
- 10.42 The CMA has concluded that none of the exclusions provided for by section 3 of the Act apply in respect of the GUK-GSK and Alpharma-GSK Agreements.¹⁴⁶⁵ Similarly, the CMA finds that no EU exclusions apply in respect of the GUK-GSK and Alpharma-GSK Agreements.¹⁴⁶⁶

F. Vertical block exemption

- 10.43 The Commission has adopted a number of Block Exemption Regulations, which define categories of agreements which the Commission considers satisfy the conditions in Article 101(3) TFEU and are not prohibited under Article 101 TFEU. An agreement will be exempt from the Chapter I prohibition if it is covered by a Block Exemption Regulation, or would be covered by a Block Exemption Regulation if the agreement had an effect on trade between Member States.¹⁴⁶⁷
- 10.44 At the time of the GUK-GSK Agreement and Alpharma-GSK Agreement, the Commission block exemption regulation in relation to vertical agreements¹⁴⁶⁸ exempted certain vertical agreements from the application of Article 101 TFEU, with a parallel exemption from the application of the Chapter I prohibition.¹⁴⁶⁹
- 10.45 The 1999 VBER came into force on 1 June 2000 and expired on 31 May 2010, after the adoption of a revised block exemption regulation.¹⁴⁷⁰

¹⁴⁶⁴ The CMA issued a decision on 12 February 2016 that the Vertical Agreements Exclusion Order applied to the IVAX-GSK Agreement (as articulated in the SSO) and consequently the Chapter I prohibition does not apply to it.

¹⁴⁶⁵ *Agreements and Concerted Practices* (OFT401, December 2004), adopted by the CMA, paragraph 6.2. None of the Parties have advanced any submissions that any of the exclusions set out at section 3 of the Act apply.

¹⁴⁶⁶ *Agreements and Concerted Practices* (OFT401, December 2004), adopted by the CMA, paragraph 6.1.

¹⁴⁶⁷ *Agreements and Concerted Practices* (OFT401, December 2004), adopted by the CMA, paragraph 4.1.

¹⁴⁶⁸ Commission Regulation (EC) No 2790/1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices, OJ L 336 of 29.12.1999 ('1999 VBER'), page 21.

¹⁴⁶⁹ Section 10(1) of the Act provides that an agreement is exempt from the Chapter 1 prohibition if it is exempt from the Community prohibition 'by virtue of regulation'.

¹⁴⁷⁰ Commission Regulation (EC) No 330/2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices, OJ L 102 of 23.4.2010 ('2010 VBER'), page 1.

10.46 The CMA finds it appropriate to consider the application of the 1999 VBER to the GUK-GSK and Alpharma-GSK Agreements, as the 1999 VBER was in force at the time of the GUK-GSK and Alpharma-GSK Agreements.¹⁴⁷¹

10.47 GUK submitted in its representations that the limitation on its ability to manufacture or supply a different product under the GUK-GSK Agreement was standard in a vertical supply agreement, and covered by the 2010 VBER (insofar as it did not exceed five years).¹⁴⁷² None of the other Parties made representations in relation to the application of the 1999 or 2010 VBER.¹⁴⁷³

i) Vertical agreement

10.48 The 1999 VBER states that Article 101 TFEU shall not apply to ‘vertical agreements’, which are defined as agreements:

‘...entered into between two or more undertakings each of which operates, for the purposes of the agreement, at a different level of the production or distribution chain, and relating to the conditions under which the parties may purchase, sell or resell certain goods or services.’¹⁴⁷⁴

10.49 The CMA has concluded that the GUK-GSK Agreement and the Alpharma-GSK Agreement were not ‘vertical agreements’ within the scope of the 1999 VBER. In particular, and as set out at paragraph 10.40, those agreements specifically related to the ‘settlement’ (or deferral) of litigation that concerned a potential competitor’s proposed market entry, and each of GUK and Alpharma (as potential competitors to GSK) expressly agreed to entry restrictions in return for the value transfers from GSK. Therefore GUK and Alpharma were not each ‘for the purposes of the agreement, at a different level of the production or distribution chain’ to GSK.¹⁴⁷⁵

10.50 The CMA has therefore concluded that the GUK-GSK Agreement and Alpharma-GSK Agreement are not exempt under the 1999 VBER on the basis that those agreements are not ‘vertical agreements’ for the purposes of the 1999 VBER.

¹⁴⁷¹ 1999 VBER does not exempt or exclude vertical agreements from the application of Chapter II of the Act, paragraph 16 of 1999 VBER.

¹⁴⁷² GUK SO Written Response (document 2752), paragraph 5.8 (c). GUK also submitted that it did not have a market share of over 30%. See also Merck SO Written Response (document 2764), paragraph 4.83.

¹⁴⁷³ The CMA notes that GSK submitted that, in applying the ‘intentionally or negligently’ test, the CMA must have regard to the relevant legal framework at the time, which included the 1999 VBER (see GSK SO Written Response (document 2755), paragraph 10.4).

¹⁴⁷⁴ 1999 VBER, Article 2(1).

¹⁴⁷⁵ See also the CMA’s findings set out at paragraphs 6.92 and 6.155.

ii) Market share

10.51 In any event, it is noted that the 1999 VBER states that the exemption shall apply ‘...on the condition that the market share held by the supplier does not exceed 30% of the relevant market on which it sells the contract goods or services.’¹⁴⁷⁶

10.52 The CMA finds that the 1999 VBER does not apply to the GUK-GSK Agreement or the Alpharma-GSK Agreement on the basis that GSK, as the supplier, held a market share of more than 30% in the relevant market for the supply of paroxetine in the UK. As set out at Tables 3.4 and 3.5, during the term of the GUK-GSK and Alpharma-GSK Agreements, GSK’s individual market share (in the relevant market for the supply of paroxetine in the UK) ranged between 53 and 74% (by value) and 37 and 69% (by volume).

iii) Conclusion

10.53 The CMA has therefore concluded that the GUK-GSK Agreement and Alpharma-GSK Agreement are not exempt under the 1999 VBER on the basis that the Agreements were not ‘*vertical agreements*’ for the purposes of the 1999 VBER and, separately, GSK’s market share at the time of the Agreements exceeded the market share threshold set out in the 1999 VBER.

G. Individual exemption**i) Introduction**

10.54 An agreement which restricts competition is exempt from, and does not therefore infringe, the Chapter I prohibition or Article 101 TFEU where the efficiencies generated by it outweigh the restriction on competition.¹⁴⁷⁷ Article 1(2) of the Modernisation Regulation provides that agreements caught by Article 101(1) TFEU which satisfy the conditions of Article 101(3) TFEU shall not be prohibited, no prior decision to that effect being required.¹⁴⁷⁸ Similarly, those agreements which satisfy the criteria set out in section 9 of the Act benefit from exemption from the Chapter I prohibition.¹⁴⁷⁹

¹⁴⁷⁶ 1999 VBER, Article 3(1).

¹⁴⁷⁷ See section 9 of the Act and Article 101(3) TFEU.

¹⁴⁷⁸ Modernisation Regulation, Article 1(2). See also Article 101(3) Guidelines, paragraph 1 which states that Article 101(3) TFEU ‘*provides a defence to undertakings against a finding of an infringement of [Article 101(1) TFEU]*’.

¹⁴⁷⁹ Section 9 of the Act applies to agreements to which section 2 of the Act applies. Article 101(3) applies to agreements to which Article 101 TFEU applies. The text in section 9(1) of the Act is almost identical to that of Article 101(3), except that the phrase ‘of goods’ is not included in the first condition in section 9(1) of the Act. The

10.55 For the exemption in Article 101(3) TFEU and section 9 of the Act to apply, four cumulative conditions (the 'exemption criteria') must be met. The agreement must:

- contribute to improving production or distribution or to promoting technical or economic progress (referred to as the requirement of 'section 9 / Article 101(3) efficiency gains');
- allow consumers a fair share of the resulting benefits;
- not impose on the undertakings concerned restrictions which are not indispensable to the attainment of the section 9 / Article 101(3) efficiency gains; and
- not afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

10.56 An undertaking that seeks individual exemption under section 9 of the Act or Article 101(3) TFEU must demonstrate, by means of convincing arguments and evidence, that the conditions for obtaining an exemption are satisfied.¹⁴⁸⁰ Given that, for Article 101(3) to apply, the pro-competitive effects flowing from the agreement must outweigh its anti-competitive effects, it is necessary to verify what is the link between the agreement and the claimed section 9 / Article 101(3) efficiency gains and what is the value of those efficiency gains.¹⁴⁸¹

10.57 In the case of claimed cost efficiency gains, a party must as accurately as reasonably possible calculate or estimate the value of the claimed efficiency gain and describe in detail how the amount has been computed. A party must also describe the method(s) by which the efficiency gains have been or will be achieved. The data submitted must be verifiable so that there can be a sufficient degree of certainty that the efficiency gains have materialised or are likely to materialise.¹⁴⁸²

10.58 The Article 101(3) Guidelines apply a two-fold test in relation to the requirement that the agreement must not impose restrictions which are not

omission of these words is intended to make clear that improvements in production or distribution of services may also satisfy the first condition in section 9(1) of the Act (which is consistent with the Commission's application of Article 101(3) TFEU).

¹⁴⁸⁰ Judgment in *GlaxoSmithKline Services v Commission*, Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, EU:C:2009:610, paragraph 82.

¹⁴⁸¹ Article 101(3) Guidelines, paragraph 50.

¹⁴⁸² Article 101(3) Guidelines, paragraph 56.

indispensable to the attainment of the section 9 / Article 101(3) efficiency gains:

- the restrictive agreement as such must be reasonably necessary in order to achieve the section 9 / Article 101(3) efficiency gains; and
- the individual restrictions of competition that flow from the agreement must also be reasonably necessary for the attainment of the section 9 / Article 101(3) efficiency gains.¹⁴⁸³

10.59 The Article 101(3) Guidelines further state that *'[t]he question is not whether in the absence of the restriction the agreement would not have been concluded, but whether more efficiencies are produced with the agreement or restriction than in the absence of the agreement or restriction.'*¹⁴⁸⁴ The section 9 / Article 101(3) efficiency gains must be specific to the agreement in question in the sense that there are *'no other economically practicable and less restrictive means of achieving the efficiencies.'*¹⁴⁸⁵ The parties must explain and demonstrate why the *'seemingly realistic and significantly less restrictive alternatives to the agreement would be significantly less efficient.'*¹⁴⁸⁶

10.60 The possibility that an agreement restricting competition may be exempted under Article 101(3) TFEU and section 9 of the Act applies also to agreements restricting competition by object. However, severe restrictions of competition (such as price fixing or limiting, controlling and sharing markets) rarely meet the conditions for exemption under Article 101(3) TFEU and section 9 of the Act, because, as the Commission states in the Article 101(3) Guidelines, they generally fail (at least) the two first conditions of Article 101(3) TFEU, ie they *'neither create objective economic benefits nor do they benefit consumers.'*¹⁴⁸⁷

10.61 Prior to the entry into force of the Modernisation Regulation, an exemption under Article 101(3) TFEU was only available upon notification of the arrangements to the Commission.¹⁴⁸⁸ Similarly, an exemption under section 9 of the Act was only available upon notification of the arrangements to the then OFT. Without such notification, an undertaking could not benefit from an individual exemption.

¹⁴⁸³ Article 101(3) Guidelines, paragraph 73.

¹⁴⁸⁴ Article 101(3) Guidelines, paragraph 74.

¹⁴⁸⁵ Article 101(3) Guidelines, paragraph 75.

¹⁴⁸⁶ Article 101(3) Guidelines, paragraph 75.

¹⁴⁸⁷ Article 101(3) Guidelines, paragraph 46.

¹⁴⁸⁸ Previously Article 81(3) of the EC Treaty.

ii) Section 9 / Article 101(3) efficiency gains

10.62 With respect to the first condition in the exemption criteria (ie the existence of section 9 / Article 101(3) efficiency gains) a party invoking Article 101(3) TFEU must substantiate each efficiency claim so that the following can be verified:

- the nature of the claimed efficiency;
- the link between the agreement and the claimed efficiency;
- the likelihood and magnitude of the claimed efficiency;
- how and when the claimed efficiency would be achieved.¹⁴⁸⁹

10.63 Only objective benefits can be taken into account: ‘...*efficiencies are not assessed from the subjective point of view of the parties*’, for example, cost savings that arise simply from the exercise of market power.¹⁴⁹⁰

10.64 The Parties’ representations¹⁴⁹¹ identify the following claimed efficiency gains:

- efficiency gains resulting from accelerated market entry, leading to increased competition in the supply of paroxetine, reduced prices and improvements in the distribution network;
- efficiency gains resulting from avoided litigation; and
- efficiency gains resulting from the opportunity to recoup investments which could be channelled into future product development, thus more generally promoting innovation and competition in the industry.

10.65 However, none of the Parties submitted the evidence necessary to demonstrate that all four conditions for the application of section 9 of the Act or Article 101(3) TFEU have been met for any of the claimed section 9 / Article 101(3) efficiency gains with respect to any Infringing Agreement.

10.66 In summary:

¹⁴⁸⁹ Article 101(3) Guidelines, paragraph 51.

¹⁴⁹⁰ Article 101(3) Guidelines, paragraph 49; Judgment in *Consten and Grundig v Commission*, Joined Cases 56/64 and 58/66, EU:C:1966:41, pages 348 and 349; Judgment in *GlaxoSmithKline Services v Commission*, Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, EU:C:2009:610, paragraph 92.

¹⁴⁹¹ Transcript of GSK SO Oral Hearing dated 18 October 2013 (document 3053) page 119; GSK Response dated 18 August 2015 to the GSK DPS and the Proposed NGFA Decision (‘GSK DPS and Proposed NGFA Written Response’) (document 4064), paragraph 2.6; GUK SO Written Response (document 2752), chapter 7; Actavis SO Written Response (document 2754), paragraph 12.19.

- First, none of the Parties have substantiated their claims that the claimed efficiencies referred to in paragraph 10.64 would in fact arise.
- Second, none of the Parties submitted sufficient evidence that consumers would have received a fair share of any claimed efficiency.
- Third, none of the Parties showed that the GUK-GSK or Alparma-GSK Agreements imposed restrictions which were indispensable to the attainment of the claimed efficiency gains. In this regard, as set out at paragraphs 10.90 to 10.94, the CMA finds that the individual restrictions of competition that flowed from those Agreements cannot be regarded as reasonably necessary in order to achieve the claimed efficiency gains.

10.67 With respect to each of the three claimed efficiency gains referred to by the Parties, the CMA makes the following observations.

a) *Alleged efficiency gains resulting from accelerated entry, leading to reduced prices and improved distribution network*

Accelerated entry

10.68 GSK, GUK and Actavis submitted that the Agreements accelerated GUK and Alparma's entry into the UK paroxetine market, which resulted in more choice and reduced prices for consumers,¹⁴⁹² and an improved distribution network.¹⁴⁹³ It was submitted that entry would have been delayed, or would not have occurred at all, in the absence of the Agreements¹⁴⁹⁴ and that their accelerated entry improved competition in the supply of paroxetine.¹⁴⁹⁵

10.69 GUK submitted that when the GUK-GSK Agreement was entered into, it was subject to the GUK Interim Injunction and therefore it was unable to enter the market. GUK submitted that the GUK-GSK Agreement therefore allowed GUK to enter the market earlier than it would have done otherwise.¹⁴⁹⁶ Actavis also stated that it was subject to the Alparma Undertaking and that it could not launch a generic product independently of GSK. Actavis submitted that the

¹⁴⁹² Transcript of GSK SO Oral Hearing dated 18 October 2013 (document 3053), page 119. GSK SO Written Response (document 2755), Chapter 2, and paragraph 4.15.

¹⁴⁹³ GUK SO Written Response (document 2752), chapter 7. Actavis SO Written Response (document 2754), paragraph 12.19.

¹⁴⁹⁴ GUK SO Written Response (document 2752), paragraph 7.5. Actavis SO Written Response (document 2754), paragraph 12.19.

¹⁴⁹⁵ For example, see Transcript of GSK SO Oral Hearing dated 18 October 2013 (document 3053), page 119. GUK SO Written Response (document 2752), paragraph 7.2.

¹⁴⁹⁶ GUK SO Written Response (document 2752), paragraph 1.4.

Alpharma-GSK Agreement therefore achieved entry earlier than independent entry by Alpharma would have occurred.¹⁴⁹⁷

10.70 GSK submitted that the Agreements allowed for ‘*authorised supplied early entry*’ which introduced earlier generic competition than if litigation had proceeded and GSK prevailed: ‘[i]n other words, the Agreements accelerated early entry, they did not restrict it’.¹⁴⁹⁸

10.71 For the reasons set out in Part 7, the CMA finds that the likely effect of each of the GUK-GSK Agreement and Alpharma-GSK Agreement was to restrict competition. The CMA finds that, in the counterfactual, the outcome would have been more competitive in that each of GUK and Alpharma would have continued to be a competitive threat and remained a potential competitor to GSK that was pursuing its efforts to enter the market independently of GSK. GUK and Alpharma’s competitive behaviour would not have been distorted by value transfers made in return for entry restrictions. The realistic and likely outcomes are that GUK and Alpharma would have each pursued its challenge to GSK’s patent claims or, alternatively, that GUK and Alpharma would have entered into a settlement on terms that were not ‘bought’ using the value transfers, and that legitimately reflected the uncertainty regarding GSK’s patent claims. Furthermore, the CMA has found that, under the terms of the GUK-GSK and Alpharma-GSK Agreements, GUK’s and Alpharma’s entry as distributors of GSK product was not likely to materially increase the actual competitive constraints faced by GSK and therefore could not be expected to have any meaningful impact on the actual competitive constraints faced by GSK or on the price competition it was facing in the UK paroxetine market. This is supported by the fact that neither GUK’s nor Alpharma’s entry pursuant to the GUK-GSK and Alpharma-GSK Agreements had a meaningful impact on market prices (see Part 7 and paragraphs 10.72 and 10.73). The GUK-GSK and Alpharma-GSK Agreements deferred the threat of true generic competition and the associated price decreases.

Price reduction

10.72 The Parties also submitted that the claimed accelerated entry resulted in reduced prices for consumers, the CMA notes that:

¹⁴⁹⁷ Actavis SO Written Response (document 2754), paragraph 12.19.

¹⁴⁹⁸ GSK SO Written Response (document 2755), paragraph 6.111.

- Both GSK¹⁴⁹⁹ and GUK¹⁵⁰⁰ submitted that the Agreements resulted in a positive welfare effect and a reduction in the price of paroxetine 20mg for the NHS, in particular due to the category change of paroxetine from C to A following entry of the Generic Companies. GSK submitted that by focussing on the prices at which paroxetine was sold to pharmacies, the CMA's analysis has an incorrect focus and has ignored effects on the NHS.¹⁵⁰¹
- Actavis submitted that the Alparma-GSK Agreement resulted in another distributor in the market and this resulted in lower prices for consumers. Actavis stated that its authorised generic product was sold at a lower price than Alparma's original intended price, below the reported generic selling price in October 2002 and significantly below GSK's price for its branded product.¹⁵⁰²

10.73 As explained at paragraphs 7.42 and 7.45 and 7.95 to 7.98, the actual prices at which paroxetine was sold to pharmacies, either directly or indirectly through wholesalers, did not fall as a consequence of either the GUK-GSK Agreement or the Alparma-GSK Agreement, and the fact that paroxetine reimbursement prices fell is a consequence of the way that the Drug Tariff and PPRS price mechanisms functioned (specifically that a generic product being available caused a reduction in the Drug Tariff reimbursement price).¹⁵⁰³ In fact, any decrease in the Drug Tariff reimbursement price did not reflect efficiencies generated by the Agreements and passed on to consumers, but instead related to the allocation of monies between the NHS and

¹⁴⁹⁹ GSK SO Written Response (document 2755), summary box pages 68 and 257, paragraphs 2.10–2.41, 2.54–2.55 and 8.8 (see also paragraph 9.50). GSK considered that the Agreements led to a 15% reduction in the price paid by the NHS on generic prescriptions of paroxetine 20mg by December 2003 (GSK SO Written Response (document 2755), paragraph 8.8), and estimated that, overall, the Agreements resulted in savings to the NHS of £15.6 million in the period 2002-2003 (GSK SO Written Response (document 2755), summary box on page 68, paragraph 2, paragraph 2.6 and of Annex 3 of GSK SO Written Response (document 2755), paragraph 31).

¹⁵⁰⁰ GUK SO Written Response (document 2752), paragraphs 5.7, 6.9, Annex 1 to GUK SO Written Response (document 2753), page 3. GUK noted that entry by the Generic Companies pursuant to the Agreements had a marked impact on reducing the Drug Tariff by 12% which coincided with a category change of paroxetine from C to A on 1 June 2002 (Annex 1 to GUK SO Written Response (document 2753), pages 32–33).

¹⁵⁰¹ GSK SO Written Response (document 2755), paragraph 8.13. GUK also submitted that entry by authorised generics is likely to have had an important impact on reducing the Drug Tariff which fell more during the period of entry by IVAX, GUK and subsequently Alparma than it did when independent generic entry occurred (GUK SO Written Response (document 2752), paragraph 7.3).

¹⁵⁰² Actavis SO Written Response (document 2754), paragraph 12.19.

¹⁵⁰³ Indeed, GSK acknowledged the latter point in its representations by stating that because of the way the NHS reimbursement system operated, the reduction in the Drug Tariff price in June 2002 would have resulted from the Agreements even if the Agreements had no effect on the prices paid by pharmacies (GSK SO Written Response (document 2755), paragraph 8.13).

pharmacies.¹⁵⁰⁴ Further, as the reimbursement systems designed by DH¹⁵⁰⁵ are intended to ensure that any decrease in the price paid by pharmacies is passed on to the NHS, the CMA observes that a decrease in the Drug Tariff in the absence of a price decrease to pharmacies does not indicate that there was an overall saving for the NHS. Further the CMA notes that it was not the GUK-GSK or Alharma-GSK Agreements that led to the Drug Tariff reclassification described above and that the resulting price decrease had in fact already taken place following IVAX's entry as a supplier of GSK product.

10.74 Finally, for the reasons described in Sections 7C and 7D, the CMA is satisfied that, in the counterfactual, the outcome would have been more competitive and could therefore have been expected to provide for more favourable prices to pharmacies overall.

10.75 For the reasons outlined at paragraphs 10.73 to 10.74, the CMA does not accept GSK and GUK's submissions concerning the impact on prices of the GUK-GSK Agreement, or Actavis' submissions that the Alharma-GSK Agreement led to lower prices for consumers.

Improved distribution network

10.76 GUK¹⁵⁰⁶ and Actavis¹⁵⁰⁷ submitted that the claimed accelerated entry improved the distribution of paroxetine in the UK, by giving customers a greater choice of suppliers.

10.77 The CMA does not consider that the Parties have identified, or substantiated with evidence, any specific efficiencies arising from the GUK-GSK Agreement or the Alharma-GSK Agreement, such as increasing customer access or improving delivery, service or quality.¹⁵⁰⁸

10.78 Further, GSK submitted in the context of its representations on its reasons for settling that '*...the issue is not whether the terms of the Alharma-GSK*

¹⁵⁰⁴ For example, an argument that NHS list prices decreased while prices to pharmacies remained the same implies that any benefits to the NHS would be at the expense of pharmacies, who would be worse off. This is not an efficiency caused by GSK's conduct, but rather a reallocation of monies from pharmacies to the NHS.

¹⁵⁰⁵ In particular, as explained at paragraphs 3.110 and 3.111, DH uses a mechanism referred to as 'clawback' to regulate pharmacy buying profits, which works by providing pharmacies with an initial reimbursement price (set by reference to the Drug Tariff in relation to generic medicines), but then using 'discount inquiries' to determine what pharmacies have spent on medicines, and how much of their buying profits DH should take back through 'clawback'.

¹⁵⁰⁶ GUK SO Written Response (document 2752), paragraph 7.2.

¹⁵⁰⁷ Actavis SO Written Response (document 2754), paragraph 12.19(a).

¹⁵⁰⁸ Article 101(3) Guidelines, paragraph 72 recognise that distribution agreements may give rise to qualitative efficiencies. This may be because of broader outreach or improved business offerings. For example, the Article 101(3) Guidelines note that specialised distributors may be able to provide services that are better tailored to customer needs or to provide quicker delivery or better quality assurance throughout the distribution chain.

*Agreement provided benefit to GSK in terms of distributing paroxetine. That misses the whole point of the legal and economic context. The context was settlement of the Patent Dispute, not establishing a distribution network. GSK has never suggested otherwise.*¹⁵⁰⁹ The CMA notes that GSK's position is at odds with GUK and Actavis' submissions as set out in paragraph 10.76.

10.79 In any case the CMA observes that: (i) the product that GUK and Alpharma supplied was identical to the product supplied by GSK; and (ii) for the reasons described at paragraphs 7.25 to 7.41 and 7.76 to 7.94 the fact that GUK and Alpharma could only source restricted volumes of product ensured that the increased choice of supplier had no meaningful impact on actual competition or on market prices.

10.80 Moreover, the CMA notes that at the time of the GUK-GSK and Alpharma-GSK Agreements, GSK was already able to distribute its products (including Seroxat) throughout the UK, and Seroxat had been supplied throughout the UK for many years prior to the commencement of the GUK-GSK Agreement and Alpharma-GSK Agreement. The additional sub-distribution agreement with the Generic Companies did not provide any opportunities to increase GSK's supply or to lower GSK's distribution costs.¹⁵¹⁰ Any strategy aimed at increasing the supply of paroxetine was reliant on persuading GPs to issue more prescriptions for paroxetine, and could not be achieved by changes to GSK's distribution model.

b) *Alleged efficiency gains resulting from avoided litigation*

10.81 GSK submitted that the Agreements resulted in risky and time-consuming litigation being settled (*'...very real cost savings amounting to an estimated £5.8 million...'*) and were a prudent means of replacing the uncertainty of litigation with compromise in order to facilitate business planning and free up resources.¹⁵¹¹

10.82 GUK made similar representations. It submitted that the GUK-GSK Agreement allowed both Parties to avoid the potential pursuit of costly and lengthy patent litigation and the related uncertainties, costs and dissipation of

¹⁵⁰⁹ GSK SO Written Response (document 2755), paragraph 7.68.

¹⁵¹⁰ GSK documents that discuss entry into sub-distribution agreements make no reference to efficiencies or gains to be made through increased distribution, but rather, focus on the need to protect GSK's price and patent position. See, for example, GSK presentation entitled 'Seroxat Patent Challenge' by [GSK's Finance Director A] and [GSK's Head of Regulatory Affairs] dated 5 February 2001 (document 0123), and [X]WS2 (GUK) (document 0182) / [X]WS2 (Alpharma) (document 0289).

¹⁵¹¹ GSK SO Written Response (document 2755), paragraphs 9.41 onwards. The CMA notes that these representations were made in relation to GSK's representations on objective justification in relation to Chapter II of the Act.

resources. GUK added that: *[i]t also meant that GUK avoided the losses which it would have suffered had it not settled and been prevented from getting access to the market.*¹⁵¹² Actavis observed more generally that *[l]itigation is costly, time-consuming and is always unpredictable. Accordingly, it is widely acknowledged that settlement agreements play an important role in avoiding expensive litigation and in facilitating the fair and efficient resolution of disputes.*¹⁵¹³

10.83 For the reasons set out at paragraphs 6.115 to 6.126 and paragraphs 6.179 to 6.190, the CMA does not accept that the GUK-GSK and Alpharma-GSK Agreements provided for the avoidance of litigation costs or the associated uncertainty. Neither the GUK-GSK Agreement nor the Alpharma-GSK Agreement settled the litigation, as the contested issues (and the associated costs) were merely deferred (see Part 6).

c) *Alleged efficiency gains resulting from investment in future product development, thus promoting innovation and competition in the industry*

10.84 Both GSK and GUK submitted that the Agreements allowed them to invest in future research and product development to the benefit of consumers.

10.85 GSK submitted that *[s]ettling litigation frees up resources to refocus on research and development to the benefit of GSK and future patients alike.*¹⁵¹⁴ GUK stated that the GUK-GSK Agreement *‘...gave GUK an opportunity to recoup its investments by earning revenues on the sale of paroxetine which could be channelled into future product development thus more generally also promoting innovation and competition in the pharmaceutical industry.’*¹⁵¹⁵

10.86 Neither GSK nor GUK have substantiated with evidence that any recoupment or cost and resource savings have been used to invest in future research or product development (see also paragraph 8.68).¹⁵¹⁶

10.87 Further, taking GSK and GUK’s submission to its logical conclusion would amount to allowing pharmaceutical companies to enter into agreements which restrict competition in order to cross-subsidise R&D investment in other drugs

¹⁵¹² GUK SO Written Response (document 2752), paragraph 7.2.

¹⁵¹³ Actavis SO Written Response (document 2754), paragraph 9.7.

¹⁵¹⁴ GSK SO Written Response (document 2755), paragraph 9.45.

¹⁵¹⁵ GUK SO Written Response (document 2752), paragraph 7.2.

¹⁵¹⁶ The CMA also notes that the GUK-GSK and Alpharma-GSK Agreements deferred rather than resolved the litigation disputes, and therefore would have simply deferred any claimed cost and resource savings.

and effectively provide the sector with an exclusion from an aspect of competition law. Legislation does not provide for any such exclusion.

iii) Allowing consumers a fair share of resulting benefits

10.88 As stated above, the Parties have not shown that any efficiency gains arose as a result of the GUK-GSK Agreement or the Alpharma-GSK Agreement (or in the case of price decreases, these were not attributable to the Agreements). In any event, the CMA considers that the Parties were not incentivised to pass any efficiency savings generated by the GUK-GSK and Alpharma-GSK Agreements on to consumers. This is because, as a consequence of the volume restrictions in the GUK-GSK and Alpharma-GSK Agreements, GUK's and Alpharma's entry under the terms of the GUK-GSK and Alpharma-GSK Agreements could not reasonably have been expected to result in any meaningful impact on actual competition or on prevailing price levels, and nor did their entry result in meaningful price decreases in practice.

10.89 Further, GSK and GUK have not established that the claimed investment that could have resulted from the GUK-GSK and Alpharma-GSK Agreements (which has not been substantiated) has produced objective benefits for consumers, for example increased innovation or competition in the pharmaceutical industry.

iv) Indispensability of the restrictions

10.90 GSK and GUK submitted that the entry restrictions contained in the GUK-GSK and Alpharma-GSK Agreements were reasonable and necessary to achieve settlement of the Patent Disputes.¹⁵¹⁷

10.91 Actavis stated that, in the absence of the restriction on independent entry, there would have been no authorised generic product for Alpharma to sell, and independent entry would have been delayed significantly. Alpharma also noted that the restrictions were limited to a maximum of one year with one month's termination notice.¹⁵¹⁸

¹⁵¹⁷ GSK stated that '*...insofar as these agreements included restrictions on entry, terms of entry, we say, for GUK and Alpharma, these were the minimum necessary to achieve the goal...the restrictions on GUK and Alpharma were reasonable and necessary to settle those patent disputes...*'. Transcript of GSK SO Oral Hearing dated 18 October 2013 (document 3053), page 120, line 2. Also see GSK SO Written Response (document 2755), chapters 6(c) and 7(c). GUK made similar representations, in particular that '*...there is no realistic basis to assume that GUK could have negotiated less restrictive settlement terms with GSK...[and] this limitation placed on GUK's conduct was ancillary and dictated by the commercial necessities...without such limitation the Settlement is unlikely to have materialised.*' GUK SO Written Response (document 2752), at paragraph 7.4.

¹⁵¹⁸ Actavis SO Written Response (document 2754), paragraph 12.19.

- 10.92 As set out above, the CMA finds that the Parties have not demonstrated to the requisite standard that the GUK-GSK and Alpharma-GSK Agreements generated efficiency gains. Further, in any event, the CMA finds that the individual restrictions of competition that flowed from these Agreements cannot be regarded as reasonably necessary in order to achieve the claimed efficiency gains (see paragraphs 10.58 to 10.59).
- 10.93 In particular, the CMA notes that any of the claimed efficiency gains could have been achieved through a settlement agreement that that did not include terms (such as entry restrictions) that had been induced as a result of the value transfers made by GSK. For example, absent the value transfers made by GSK, the Parties may, for example, have entered into a less restrictive agreement which allowed more competitive terms of entry (see paragraphs 7.54 to 7.57 and paragraphs 7.107 to 7.110).¹⁵¹⁹ Further, in the case of the claimed efficiency gains resulting from investment in future product development, neither GSK nor GUK have substantiated with evidence that such R&D could not have occurred in the absence of the Agreements.
- 10.94 The CMA notes that it is irrelevant whether the restrictions were ‘necessary’ terms in the GUK-GSK and Alpharma-GSK Agreements in order for the Parties to reach a commercially acceptable resolution to the Patent Dispute.

v) Conclusion

- 10.95 The CMA concludes that none of the Parties submitted the evidence required to demonstrate that the GUK-GSK or Alpharma-GSK Agreements would be exempt under section 9 of the Act or Article 101(3) TFEU. As the Parties have failed to establish that the GUK-GSK or Alpharma-GSK Agreements meet the aforementioned three cumulative conditions of the exemption criteria, it is not necessary to assess the remaining condition of whether those agreements eliminated competition in respect of a substantial part of the products in question.
- 10.96 The CMA also notes that the GUK-GSK and Alpharma-GSK Agreements were entered into prior to the implementation of the Modernisation Regulation. In light of the legal framework in existence at that time, should the Parties have wished to rely on exemption under Article 101(3) TFEU (then Article 81(3)), the GUK-GSK and Alpharma-GSK Agreements should have been pre-notified

¹⁵¹⁹ Article 101(3) Guidelines, paragraph 75.

to the Commission and an individual exemption sought at the time.¹⁵²⁰ Similarly, undertakings that wished to benefit from an individual exemption under section 9 of the Act were required to notify their arrangements to the then-OFT. None of the Agreements which are the subject of this Decision were so notified.¹⁵²¹

H. Conclusion on exclusion and exemption

10.97 The CMA has concluded that none of the exclusions or exemptions from the Chapter I prohibition or Article 101(1) TFEU, provided for by the Act or by the TFEU, are applicable in this case.

¹⁵²⁰ Under the pre-modernisation regime, the Commission had the sole power to grant individual exemptions, and exemption was not available without pre-notification (EEC Council: Regulation No 17: First Regulation implementing Articles 85 and 86 of the Treaty, OJ 013 21.02.1962, Articles 4 and 9).

¹⁵²¹ Actavis submitted that an undertaking is not prevented from claiming benefit of section 9 of the Act and Article 101(3) TFEU where it did not notify the relevant agreement pre- 1 May 2004 (Actavis SO Written Response (document 2754), paragraphs 12.1–12.6). The CMA has not specifically responded to these representations in the Decision on the basis that it has considered the exemption criteria and concluded that GUK-GSK and Alpharma-GSK Agreements do not satisfy the exemption criteria section 9 of the Act and/or Article 101(3) TFEU.

11. THE CMA'S ACTION

11.1 Further to the CMA's findings in respect of the Infringements (as set out at Parts 6, 7 and 8), Part 11 sets out the enforcement action which the CMA is taking and its reasons for that action.

A. Directions

11.2 If the CMA has made a decision that an agreement infringes the Chapter I prohibition or Article 101 TFEU, or that conduct infringes the Chapter II prohibition, it may give to such person or persons such directions as it considers appropriate to bring the infringement to an end.¹⁵²²

11.3 Each of the Infringements has ceased. Therefore, it is unnecessary in the circumstances of this case to give directions to any Party to bring to an end any of the Infringements.

B. Financial penalties – general points

i) *Intention/negligence*

11.4 The CMA may impose a penalty on an undertaking which has infringed the Chapter I prohibition, Article 101 TFEU or the Chapter II prohibition only if the CMA is satisfied that the infringement has been committed intentionally or negligently.¹⁵²³ However, the CMA is not obliged to specify whether it considers the infringement to be intentional or merely negligent.¹⁵²⁴

11.5 The CAT has defined the terms 'intentionally' and 'negligently' as follows:

*'...an infringement is committed intentionally for the purpose of section 36(3) of the Act if the undertaking must have been aware, or could not have been unaware, that its conduct had the object or would have the effect of restricting competition. An infringement is committed negligently for the purposes of section 36(3) if the undertaking ought to have known that its conduct would result in a restriction or distortion of competition. The OFT is not, however, obliged to decide whether an infringement is committed intentionally or negligently...'*¹⁵²⁵

¹⁵²² The Act, sections 32(1) and 33(1).

¹⁵²³ The Act, section 36(3).

¹⁵²⁴ *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1, at [453]–[457]; see also *Argos Limited and Littlewoods Limited v OFT* [2005] CAT 13, at [221].

¹⁵²⁵ *Argos Limited and Littlewoods Limited v OFT* [2005] CAT 13, at [221].

11.6 This is consistent with the approach taken by the CJ which has confirmed:

'the question whether the infringements were committed intentionally or negligently... is satisfied where the undertaking concerned cannot be unaware of the anti-competitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty'.¹⁵²⁶

11.7 The CMA may infer that an infringement has been committed intentionally where consequences giving rise to an infringement are plainly foreseeable from the pursuit of a particular policy by an undertaking.¹⁵²⁷

11.8 The fact that a particular type of agreement has not previously been found to infringe the Act or the TFEU does not mean that the infringement cannot be committed intentionally or negligently.¹⁵²⁸ The CMA also notes that whilst at the time of the Infringements there had been no finding that this specific form of anti-competitive agreements (so-called 'pay for delay' agreements) infringed the Chapter I prohibition, Article 101 TFEU, the Chapter II prohibition or Article 102 TFEU, it was already well established that excluding actual or potential competitors from the market was likely to infringe competition law. The CMA has taken this into account in the round when calculating penalties in this case.

11.9 In light of the evidence set out at Parts 6 and 7, each of the Parties must have been aware, or could not have been unaware, that its conduct had the object or would have the effect of restricting competition.

11.10 The CMA finds that the Infringements of Chapter I/Article 101 set out in this Decision were committed intentionally. In relation to the Infringing Agreements, the CMA has found that the objective aim of the value transfers was to induce each of GUK's and Alpharma's acceptance of entry restrictions, and that the level of value transfers made cannot be explained on the basis of the stated purpose of the value transfers, nor on any basis that was not anti-competitive. Similarly, the CMA finds that it was reasonable to expect that the likely effect of those value transfers would be to restrict competition. As such, the nature of the restrictions themselves meant that the Parties must have been aware, or could not have been unaware, that their conduct had the

¹⁵²⁶ Judgment in *Deutsche Telekom v Commission*, C-280/08 P, EU:C:2010:603, paragraph 124, referring to judgment in *IAZ v Commission*, 96/82, EU:C:1983:310, paragraph 45, and to judgment in *Nederlandsche Banden-Industrie Michelin v Commission*, 322/81, EU:C:1983:313, paragraph 107.

¹⁵²⁷ *Enforcement* (OFT407, December 2004), adopted by the CMA, paragraph 5.11. See also *Napp Pharmaceutical Holdings v Director General of Fair Trading* [2002] CAT 1, at [456].

¹⁵²⁸ *Enforcement* (OFT407, December 2004), adopted by the CMA, paragraph 5.8.

object or would have the effect of preventing, restricting or distorting competition.

- 11.11 Even if the Infringements of Chapter I/Article 101 set out in this Decision were not committed intentionally, the CMA finds that the Parties acted at least negligently in entering into such anti-competitive agreements. It is apparent from the evidence set out and referred to in Parts 6 and 7 that the Parties at the very least ought to have known that each Infringing Agreement would result in a restriction of competition. The CMA therefore finds that the Parties committed the Infringements of Chapter I/Article 101 set out in this Decision at least negligently.
- 11.12 The CMA finds that the Infringement of Chapter II set out in this Decision was committed intentionally. In relation to the Infringing Conduct, the CMA finds that the purpose of GSK committing to make cash payments and other value transfers to the Generic Companies was to induce the Generic Companies to delay their efforts to enter the market independently of GSK. It was reasonable to expect that the likely effect of the Infringing Conduct would be to assist GSK in protecting its dominant position and delaying the threat of true generic competition. GSK must have been aware, or could not have been unaware, that the Infringing Conduct was restrictive of competition.
- 11.13 Even if the Infringement of Chapter II set out in this Decision was not committed intentionally, the CMA finds that GSK acted at least negligently in engaging in such anti-competitive conduct. It is apparent from the evidence set out and referred to in Part 8 that GSK at the very least ought to have known that the Infringing Conduct would reduce competition in the UK paroxetine market and that, therefore, GSK committed the Infringement of Chapter II set out in this Decision at least negligently.
- 11.14 In conclusion, the CMA has found that each Party committed the relevant Infringement(s) intentionally, or at the very least negligently.

ii) Small agreements and conduct of minor significance

11.15 Given the applicable turnover of each Party, the CMA finds that no Party benefits from the ‘small agreement’ immunity,¹⁵²⁹ and that GSK does not benefit from the ‘conduct of minor significance’ immunity.¹⁵³⁰

iii) The CMA’s discretion to impose penalties

11.16 If the CMA has made a decision that an agreement has infringed the Chapter I prohibition or Article 101 TFEU, or that certain conduct has infringed the Chapter II prohibition, the CMA may require the undertaking(s) concerned to pay a penalty in respect of the relevant infringement(s).¹⁵³¹ When setting the amount of any penalty, the CMA must have regard to the guidance on penalties being in force at the time.¹⁵³²

11.17 The CMA considers that it is appropriate in the circumstances of this case to exercise its discretion under section 36 of the Act to impose financial penalties in respect of the Infringements. This is based, in particular, on the CMA’s view that the Infringements are serious. At the time the Agreements were entered into, it was well established that restricting the entry of actual or potential competitors onto a market was likely to infringe competition law (particularly where such a restriction was induced through a payment from one party to another).

11.18 Penalties in respect of the Infringements are therefore imposed on the addressees of this Decision (as set out in paragraph 1.2).

iv) The CMA’s margin of appreciation in determining penalties

11.19 The CMA has a margin of appreciation when determining the appropriate amount of a penalty under the Act.¹⁵³³

¹⁵²⁹ The Act, section 39 and the Competition Act 1998 (Small Agreements and Conduct of Minor Significance) Regulations 2000, SI 2000/262. In addition, the CMA has found in this Decision that the GUK-GSK Agreement infringed Article 101(1) TFEU; the ‘small agreement’ immunity does not apply in respect of any infringement of Article 101(1) TFEU.

¹⁵³⁰ The Act, section 40 and the Competition Act 1998 (Small Agreements and Conduct of Minor Significance) Regulations 2000, SI 2000/262.

¹⁵³¹ The Act, sections 36(1) and 36(2).

¹⁵³² The Act, section 38(8). The guidance currently in force is the OFT’s *Guidance as to the appropriate amount of a penalty* (OFT423, September 2012) (the ‘Penalty Guidance’), adopted by the CMA, available at www.gov.uk/government/publications/appropriate-ca98-penalty-calculation. In accordance with paragraph 1.11 of the Penalty Guidance, the CMA has had regard to the calculation mechanism contained in this version of the penalty guidance as it was in force at the time the SO in this Investigation was issued on 19 April 2013.

¹⁵³³ Provided that any penalty that the CMA imposes under the Act is within the range of penalties permitted by section 36(8) of the Act, calculated in accordance with The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000, and calculated having regard to the Penalty Guidance in accordance with section 38(8) of

11.20 The CMA is not bound by its decisions in relation to the calculation of financial penalties in previous cases under the Act.¹⁵³⁴ Rather, the CMA makes its assessment on a case-by-case basis,¹⁵³⁵ having regard to all relevant circumstances and the objectives of its policy on financial penalties. In line with statutory requirements, and the twin objectives of the CMA's policy on financial penalties as reflected in the guidance on penalties in force at this time (currently, the Penalty Guidance), the CMA will also have regard to the seriousness of the infringement and the desirability of deterring the undertaking on which the penalty is imposed and others from engaging in behaviour that infringes any prohibition under the Act or the TFEU, as the case may be.¹⁵³⁶

v) Single penalty for GSK

11.21 The CMA has discretion whether to impose a single penalty or multiple penalties for infringing behaviour that can be characterised as more than one infringement.¹⁵³⁷

11.22 In this case, the CMA finds that GSK entered into the Infringing Agreements, each of which individually constitutes an infringement of the Chapter I prohibition (and, in the case of the GUK-GSK Agreement, Article 101 TFEU), and that GSK's Infringing Conduct amounted to an infringement of the Chapter II prohibition. In the present case, the CMA considers it appropriate to calculate, and impose, a separate penalty for each Infringement by GSK, subject to the adjustments further detailed at paragraphs 11.62 and 11.67.

C. Calculation of penalties

11.23 When setting the amount of a penalty, the CMA has had regard to the six-step approach for calculating a penalty set out in the Penalty Guidance.

the Act. *Argos Limited and Littlewoods Limited v OFT* [2005] CAT 13, at [168] and *Umbro Holdings Limited and others v OFT* [2005] CAT 22, at [102].

¹⁵³⁴ See, for example, *Eden Brown and Others v OFT* [2011] CAT 8, at [78].

¹⁵³⁵ See, for example, *Kier Group and Others v OFT* [2011] CAT 3, at [116] where the CAT noted that '*other than in matters of legal principle there is limited precedent value in other decisions relating to penalties, where the maxim that each case stands on its own facts is particularly pertinent*'. See also *Eden Brown and Others v OFT* [2011] CAT 8, at [97], where the CAT observed that '*[d]ecisions by this Tribunal on penalty appeals are very closely related to the particular facts of the case*'.

¹⁵³⁶ The Act, section 36(7A); Penalty Guidance, paragraph 1.4.

¹⁵³⁷ See, for example, *Kier Group and Others v OFT* [2011] CAT 3, at [179].

i) Step 1 – Starting point

11.24 The starting point for determining a penalty is calculated having regard to the seriousness of the infringement and the undertaking's relevant turnover.¹⁵³⁸

a) Seriousness

11.25 In order to reflect adequately the seriousness of an infringement, the CMA will apply a rate of up to 30% to an undertaking's relevant turnover. The actual percentage which is applied to the relevant turnover depends, in particular, upon the nature of the infringement: the more serious and widespread the infringement, the higher the starting point is likely to be. When making its assessment of the seriousness of the infringement, the CMA will consider a number of factors, including the nature of the product or service, the structure of the market, the market shares of the undertakings involved in the infringement, entry conditions and the effect on competitors and third parties. The CMA will also take into account the need to deter other undertakings from engaging in such infringements in the future. The damage caused to consumers whether directly or indirectly will also be an important consideration. The assessment will be made on a case-by-case basis for all types of infringement, taking account of all the circumstances of the case.¹⁵³⁹

11.26 In this case, each Infringing Agreement involved GSK making value transfers in return for each of GUK's and Alpharma's acceptance of entry restrictions. Each Infringing Agreement had the object and/or effect of restricting competition in the supply of paroxetine in the UK. Such 'horizontal' restrictions, involving payments from an incumbent to potential competitors with the purpose of delaying their potential market entry, constitute serious infringements. Further, GSK's Infringing Conduct (in making value transfers in order to induce the Generic Companies to delay their potential entry) also constitutes an abuse of dominance and a serious infringement.

11.27 The factors set out below are also relevant to determining the appropriate starting point for financial penalties in respect of the Infringements.

(a) Nature of the product/services: the relevant market relates to the supply, nationwide within the UK, of paroxetine, which was a widely prescribed antidepressant medicine and became a 'blockbuster' product for GSK, with UK sales of £91 million in 2001.¹⁵⁴⁰

¹⁵³⁸ Penalty Guidance, paragraphs 2.3–2.11.

¹⁵³⁹ Penalty Guidance, paragraph 2.6.

¹⁵⁴⁰ CMA's calculations, based on data provided by relevant parties.

- (b) Market shares and market structure: each Infringement was aimed at preserving GSK's market power and/or dominant position on the relevant market. Moreover, each of GUK and Alparma was prepared to accept the restrictions in question to defer its efforts to launch a generic paroxetine product independently of GSK only on the basis that GUK and Alparma respectively was adequately compensated using value transfers.¹⁵⁴¹
- (c) Entry conditions: for as long as they remained unchallenged, GSK's paroxetine patents represented a barrier to entry, and enabled GSK to litigate, and seek injunctions, in response to the proposed market entry of potential competitors.¹⁵⁴²
- (d) Effect on competitors and third parties/damage caused to consumers: the likely effect of the Infringements was to defer the threat of true generic competition and the associated price declines. True generic competition typically results in significant decreases in the prices paid by pharmacies (and, ultimately, by the NHS). Shortly before the Agreements were entered into, GSK's own expert had forecasted that, if successful, generic entry in relation to paroxetine would have resulted in price decreases of around 60% within two years.¹⁵⁴³

11.28 The CMA has concluded that each Infringement was serious in nature. Each Infringement involved a Generic Company accepting entry restrictions and/or deferring its efforts to enter the market independently of GSK on the basis that it would receive the value transfers from GSK. The CMA therefore considers that there is no basis for differentiating, in the context of assessing seriousness, between either the various Infringements or, more generally, between the respective roles of GSK, GUK and Alparma in the Infringements.

11.29 For the above reasons, a starting point of 21% is appropriate in relation to each of:

- (a) the Infringing Agreements, and should be applied to each of GSK, and GUK or Alparma (as appropriate), in that context; and

¹⁵⁴¹ As set out, for example, in Part 6.

¹⁵⁴² As set out, for example, in Part 4.

¹⁵⁴³ In particular, [GSK's independent expert's] expectation, based on four case studies, was that '*generics will probably undercut the pre-generic price of Seroxat by around 30% within 6 months of launch, by 45 to 50% after 12 months and by 60% after 24 months.*' [GSK's independent expert's]WS (document 0143), paragraph 20. See also paragraphs 3.63 and 3.161–3.162.

(b) the Infringing Conduct, and should be applied to GSK in that context.

b) Relevant turnover

11.30 'Relevant turnover' is the turnover of an undertaking in the relevant product market and geographic market affected by the infringement in the undertaking's last business year, which for the purposes of determining the penalty starting point is the financial year preceding the date when the infringement ended.¹⁵⁴⁴

11.31 As set out at paragraph 11.39, each Infringing Agreement ended in 2004, and the abuse by GSK of a dominant position ended in 2003. Accordingly, the CMA has calculated the relevant turnover as follows:

(a) for the purposes of calculating penalties in relation to the Infringing Agreements ('GSK's Chapter I/Article 101 penalties'), GSK's, GUK-Merck's and Alpharma's relevant turnover is that recorded in the financial year ended 31 December 2003;¹⁵⁴⁵ and

(b) for the purposes of calculating GSK's penalty for the Infringing Conduct, GSK's relevant turnover is that recorded in the financial year ended 31 December 2002 ('GSK's Chapter II penalty');

11.32 Relevant turnover is calculated after the deduction of sales rebates, value added tax and other taxes directly related to turnover.¹⁵⁴⁶

11.33 Generally, the CMA will base relevant turnover on figures from an undertaking's audited accounts, but in exceptional circumstances it may be appropriate to use a different figure as reflecting the true scale of an undertaking's activities in the relevant market.¹⁵⁴⁷ Relevant turnover is a measure of the scale and impact of infringing activity for the purpose of calculating the appropriate penalty.¹⁵⁴⁸

11.34 As set out in Part 4, the CMA finds that the relevant product and geographic market affected by the Infringements is no wider than the supply of paroxetine in the UK. Accordingly, in calculating relevant turnover, the CMA has included

¹⁵⁴⁴ Penalty Guidance, paragraph 2.7.

¹⁵⁴⁵ As set out in this Decision, the GUK-GSK Agreement and the Alpharma-GSK Agreement comprise two distinct infringements, by GSK, of the Chapter I prohibition and/or, in the case of the GUK-GSK Agreement, Article 101 TFEU. The CMA considers it appropriate to calculate, and impose on GSK, a separate penalty for each of these Infringements by GSK, subject to the adjustment further detailed at paragraph 11.62.

¹⁵⁴⁶ Penalty Guidance, footnote 19.

¹⁵⁴⁷ Penalty Guidance, paragraph 2.8.

¹⁵⁴⁸ *Eden Brown and Others v OFT* [2011] CAT 8, at [55].

each of the amounts set out below, which the Parties reported to the CMA as being their respective net sales of paroxetine to customers in the UK in the years stated in paragraph 11.31:

- (a) £67,122,000, in respect of GSK's Chapter I/Article 101 penalties;¹⁵⁴⁹
- (b) £75,800,000, in respect of GSK's Chapter II penalty;¹⁵⁵⁰
- (c) £8,132,276, in respect of GUK-Merck;¹⁵⁵¹ and
- (d) £4,328,620, in respect of Alparma.¹⁵⁵²

11.35 The CMA considers that the net sales set out at paragraphs 11.34(c) and 11.34(d) do not, on their own, reflect the true scale of income that GUK and Alparma derived from supplying paroxetine in the UK. This is because in the financial year ended 31 December 2003 GUK and Alparma each received, under the Infringing Agreements, other income – namely, certain cash payments from GSK¹⁵⁵³ (whether directly or indirectly via IVAX).¹⁵⁵⁴ This additional income was directly linked to, and was a significant part of the revenue received by, GUK and Alparma in relation to their activities on the relevant market. The CMA considers that any calculation of relevant turnover which did not include this other income would not reflect the true scale of each

¹⁵⁴⁹ This reflects GSK's total sales of paroxetine in its financial year ended 31 December 2003, after the deduction of the items mentioned in paragraph 11.32: response dated 14 November 2014 to the Section 26 Notice dated 21 October 2014 sent to GSK (document 3610), paragraphs 3.2 and 5.2.

¹⁵⁵⁰ This reflects GSK's total sales of paroxetine in its financial year ended 31 December 2002, on the same basis as set out in footnote 1549.

¹⁵⁵¹ This reflects GUK's total sales of paroxetine in its financial year ended 31 December 2003, after the deduction of the items mentioned in paragraph 11.32: response dated 4 November 2014 to the Section 26 Notice dated 21 October 2014 sent to GUK, Annex 2 (document 3571); response dated 30 January 2015 to the Section 26 Notice dated 16 January 2015 sent to GUK (document 3784R), question 2.

¹⁵⁵² This reflects Alparma's total sales of paroxetine in its financial year ended 31 December 2003, after the deduction of the items mentioned in paragraph 11.32: response dated 30 January 2015 to the Section 26 Notice dated 16 January 2015 sent to Actavis (document 3786), and accompanying spreadsheet entitled 'Paroxetine Net Rev calculation' (document 3787); response dated 4 November 2014 to the Section 26 Notice dated 21 October 2014 sent to Actavis (document 3576), and accompanying statement (document 3574).

¹⁵⁵³ GSK made various value transfers to GUK (see paragraphs 6.91–6.133) and Alparma (see paragraphs 6.155–6.196), including the transfer of a distribution margin to be achieved through GSK transferring a restricted volume of product, ultimately, to GUK and Alparma. For the purposes of calculating relevant turnover the CMA has not taken into account as an additional value transfer the margin earned by GUK (or, respectively, Alparma) on the difference between its selling price to wholesalers and pharmacies and the supply price defined in the GUK-GSK Agreement (or, respectively, the Alparma-GSK Agreement). Since this transfer will form part of the net paroxetine sales of GUK (or Alparma) set out at paragraph 11.341.1(c) (or paragraph 11.341.1(d)), the CMA has not taken this into account for penalty calculation purposes as an additional value transfer.

¹⁵⁵⁴ While certain additional value transfers were provided for under the GUK-IVAX Agreement and the Alparma-IVAX Agreement, the CMA has assessed those value transfers by reference to GSK rather than IVAX. This is because the GUK-IVAX Agreement was entered into pursuant to the GUK-GSK Settlement Agreement, and likewise the Alparma-IVAX Agreement was entered into pursuant to the Alparma-GSK Settlement Agreement. In addition, if the GUK-IVAX Agreement was terminated or if IVAX was unable to fulfil its obligations, GSK agreed to perform certain of IVAX's obligations – one of which was 'to maintain GUK's minimum level of profit' – as if those were imposed directly on GSK (GUK-GSK Settlement Agreement (document 0995), clauses 5.1 and 5.2).

of those undertaking's activities in the relevant market, and would not be an appropriate measure of the scale and impact of the infringing activity in which each of GUK and Alpharma was engaged.

11.36 Accordingly, in calculating the relevant turnover of GUK-Merck and Alpharma, the CMA has also included as appropriate the amounts set out below:

- (a) the marketing allowance payments paid to GUK in connection with its distribution of GSK paroxetine product,¹⁵⁵⁵ which amounted to £1,650,000 in the financial year ended 31 December 2003;¹⁵⁵⁶
- (b) the stock purchase payments paid to GUK in connection with the sale by GUK of its paroxetine product (to GSK),¹⁵⁵⁷ which amounted to £2,408,535 in the financial year ended 31 December 2003;¹⁵⁵⁸
- (c) the profit guarantee payments paid to GUK in connection with its distribution of GSK paroxetine product,¹⁵⁵⁹ which amounted to £822,358 in the financial year ended 31 December 2003;¹⁵⁶⁰

¹⁵⁵⁵ Under the GUK-GSK Settlement Agreement (document 0995), clause 2, GSK agreed to pay GUK a marketing allowance of £1,650,000 per annum, in equal instalments on the quarter days during a three-year period commencing on 31 March 2002.

¹⁵⁵⁶ Receipt, by GUK, of such payments was confirmed by the response dated 17 October 2011 to the Section 26 Notice dated 12 August 2011 sent to GUK (document 1195), page 2 and a spreadsheet accompanying that response (document 1196).

¹⁵⁵⁷ Under the GUK-GSK Settlement Agreement (document 0995), clause 1.3, GSK agreed to purchase GUK's stock of paroxetine hydrochloride anhydrate for US\$12.5 million, payable on a quarterly basis over three years, with a first payment of US\$1.5 million payable on 31 March 2002, and subsequent payments of US\$1.5 million payable for the remainder of the term (commencing 30 June 2002). The relevant payments during 2003 were US\$1 million, due on each of 31 March 2003, 30 June 2003, 30 September 2003 and 31 December 2003.

¹⁵⁵⁸ Receipt, by GUK, of certain stock purchase payments – namely, US\$999,940.45 on 25 March 2003, US\$999,989.89 on 26 June 2003, US\$999,990.02 on 24 September 2003 and US\$999,989.31 on 22 December 2003 – was confirmed by the response dated 17 October 2011 to the Section 26 Notice dated 12 August 2011 sent to GUK (document 1195), page 2, and a spreadsheet accompanying that response (document 1196). The CMA has taken into account the stock purchase payment figures actually received by GUK, and used the Bank of England's daily spot rates for the relevant dates (£1 = US\$1.5721, £1 = US\$1.6633, £1 = US\$1.6565 and £1 = US\$1.7618 respectively) in order to express in pounds sterling the total of stock purchase payments made to GUK within GUK's financial year ended 31 December 2003.

¹⁵⁵⁹ The GUK-IVAX Agreement dated 14 March 2002 (document 1003), clause 4.3 provided for a minimum profit guarantee. As noted at footnote 495, GUK invoked this in relation to GUK's UK paroxetine sales in the first (2002–03) and second (2003–04) contract years.

¹⁵⁶⁰ The CMA has calculated that this total of profit guarantee payments was invoked by GUK in relation to its 2003 financial year, based on certain data contained in spreadsheets of reconciliation for (a) the first contract year (spreadsheet entitled 'Norton/GUK Paroxetine Deal 2002/3' dated 5 March 2003 (document 1108), originally attached to an email from [a GUK Sales and Marketing employee] to [IVAX's Sales and Marketing Manager] dated 6 March 2003 (document 1112)), and (b) the second contract year (spreadsheet entitled 'Norton/GUK Paroxetine Deal 2003/4' dated 15 March 2004 (document 1129), originally attached to an email dated 16 March 2004 (document 1130)). Whilst another document on file (spreadsheet entitled 'Norton/GUK Paroxetine Deal 2002/03' (document 1136)) sets out several revisions to the spreadsheet entitled 'Norton/GUK Paroxetine Deal 2003/4' dated 15 March 2004 (document 1129), no such revision relates to payments in GUK's financial year ended 31 December 2003.

- (d) the marketing allowance payments paid to Alparma in connection with its distribution of GSK paroxetine product,¹⁵⁶¹ which amounted to £1,200,000 in the financial year ended 31 December 2003;¹⁵⁶² and
- (e) the 'Supply of Product' compensation payments paid to Alparma in connection with delays to its distribution of GSK paroxetine product,¹⁵⁶³ which amounted to £200,000 in the financial year ended 31 December 2003.¹⁵⁶⁴

11.37 Taking into account the relevant amounts set out at paragraphs 11.34(c), 11.34(d) and 11.36, the CMA calculates GUK-Merck's total relevant turnover to be £13,013,169, and Alparma's total relevant turnover to be £5,728,620.

ii) Step 2 – Adjustment for duration

11.38 The CMA may adjust the starting point under step 1 to take into account the duration of the infringement. Where the total duration of an infringement is more than one year, the CMA will round up part years to the nearest quarter year, although the CMA may in exceptional cases decide to round up the part year to a full year.¹⁵⁶⁵

¹⁵⁶¹ Under the Alparma-GSK Settlement Agreement (document 0356), clause 5, GSK agreed to pay a marketing allowance to Alparma of £100,000 per month (for a maximum of 12 months) during the term of the Alparma-IVAX Agreement.

¹⁵⁶² Receipt, by Alparma, of these marketing allowance payments was confirmed by the response dated 27 September 2011 to the Section 26 Notice dated 12 August 2011 sent to Actavis (document 1496), pages 2–3.

¹⁵⁶³ Clause 5.1 in the Alparma-IVAX Agreement (document 1806) provided for Alparma to receive £200,000 per month in the event that IVAX was unable to deliver product. Alparma appears to have interpreted this as a 'profit compensation for any delays' after 1 December 2002 (see email from [Alparma ApS's Sales and Marketing Director] to [Alparma Ltd's Director of Sales and Marketing] and others dated 24 October 2002 (document 1364), entitled 'Quick note on UK settlement for Paroxetine – meeting October 23 2002'). Alparma made no sales until 19 February 2003 (see 'Parox Sales' data in a document entitled 'Report on company day sales' (document 1411), as attached to an email from [Alparma employee] to [Alparma Ltd's Director of Sales and Marketing] and others dated 10 March 2003 (document 1419)).

¹⁵⁶⁴ Two payments of £235,000 inclusive of VAT (£200,000 exclusive of VAT) were made to Alparma on 24 February 2003 by IVAX, who had received two payments of the same amount from GSK on 12 February 2003; these were 'Supply of Product' compensation payments paid in connection with the supply of GSK paroxetine product to Alparma in the months of December 2002 and January 2003 (see Teva Response dated 15 October 2015 to the Section 26 Notice dated 1 October 2015 (document 4081) and the accompanying Annexes (documents 4082, 4083 and 4084), and part one of the response (dated 10 October 2011) to the Section 26 Notice dated 12 August 2011 sent to Teva, consolidated in the Section 27 Notice dated 6 October 2011 sent to Teva (document 1983), Annex 3, page 10). As at March 2003, Alparma's 'YTD numbers' for paroxetine in its financial year ended 31 December 2003 included 'payments for delayed launch (£328K)' (email from [Alparma's Finance Director] to [Financial Controller of Alparma Inc's Human Pharmaceuticals International Division] and others dated 7 March 2003 (document 1414), page 1); the CMA considers that these comprised the 'Supply of Product' compensation payments of (a) £200,000 in respect of all of January 2003, and (b) approximately £128,000 in respect of February 2003 (resulting from pro-rating £200,000 by the 18 days in that month before Alparma's first paroxetine sales against the total of 28 days in that month). On a conservative basis, the CMA has included in Alparma's relevant turnover for penalty calculation purposes only the aforementioned payment of £200,000 in respect of delay during the month of January 2003.

¹⁵⁶⁵ Penalty Guidance, paragraph 2.12.

11.39 Accordingly, the CMA has applied the following multipliers to the figures reached at the end of step 1 to take into account the duration of the Infringements. Each of the duration multipliers above has been rounded up to the respective nearest quarter year in accordance with the relevant principles of the Penalty Guidance (summarised in paragraph 11.38).

Infringement	Infringement start and end dates ¹⁵⁶⁶	Infringement duration	Multiplier to step 1 figure
GUK-GSK Agreement	13 March 2002–1 July 2004	2 years, 3 months and 18 days	2.5
Alpharma-GSK Agreement	12 November 2002–13 February 2004	1 year, 3 months and 1 day	1.5
GSK's Infringing Conduct	3 October 2001–30 November 2003	2 years, 1 month and 27 days	2.25

iii) Step 3 – Adjustment for aggravating and mitigating factors

11.40 At step 3, the CMA may increase a penalty where there are aggravating factors, or decrease it where there are mitigating factors. A non-exhaustive list of aggravating and mitigating factors is set out in the Penalty Guidance.¹⁵⁶⁷

11.41 When assessing possible aggravating and mitigating factors in this case, the CMA has taken into consideration factors applicable to the Relevant Period or, as appropriate, the period thereafter. In the circumstances of this case, the CMA has considered at step 3 the factors set out below.

a) Aggravating factors

11.42 In the circumstances of this case, the CMA considers there to be no evidence to support the application of any aggravating factor(s).

¹⁵⁶⁶ The CMA has reached the conclusion that the likely effects of each Infringing Agreement would have extended no further than 30 November 2003. This is explained further in the NGFA Decision.

¹⁵⁶⁷ Penalty Guidance, paragraphs 2.14 and 2.15.

b) Mitigating factors**Cooperation**

- 11.43 The CMA may decrease a penalty at step 3 for cooperation which enables the enforcement process to be concluded more effectively and/or speedily. For these purposes, respecting time limits specified by the CMA is a necessary but not sufficient criterion at this step, and cooperation over and above this will be expected in order to merit a reduction.¹⁵⁶⁸
- 11.44 In this case, the CMA considers that it is appropriate to decrease at step 3 a Party's penalty where that Party provided voluntary cooperation during the course of the Investigation over and above that Party's legal obligations, which has enabled the Investigation to be concluded more effectively and/or speedily. In particular, the CMA has taken into account whether any specific Party promptly made relevant members of its staff available for voluntary interviews, and/or by having responded comprehensively and voluntarily to requests for information.¹⁵⁶⁹
- 11.45 The CMA does not consider that GSK has provided voluntary cooperation which has enabled the Investigation to be concluded more effectively and/or speedily, or that any other mitigating factor applies to GSK's Chapter I/Article 101 penalties or GSK's Chapter II penalty.
- 11.46 The CMA does not consider that GUK has provided voluntary cooperation which has enabled the Investigation to be concluded more effectively and/or speedily, or that any other mitigating factor applies to GUK's penalty.¹⁵⁷⁰
- 11.47 The CMA considers that Merck has provided voluntary cooperation which has enabled the Investigation to be concluded more effectively and/or speedily.¹⁵⁷¹ Specifically, following its initial contact with the OFT in relation to the Investigation, Merck voluntarily made available, and provided, to the OFT a substantial volume of relevant documents and information in relation to the

¹⁵⁶⁸ Penalty Guidance, paragraph 2.15 and footnote 28.

¹⁵⁶⁹ Where entities comprised an undertaking during the Relevant Period, but no longer formed part of the same undertaking during this Investigation, at step 3 the CMA has assessed separately whether each of those entities provided cooperation of the type described at paragraph 11.44.

¹⁵⁷⁰ As set out at paragraphs 3.5–3.6, during the Relevant Period GUK and Merck comprised the undertaking referred to in this Decision as GUK-Merck, but Merck sold GUK before the Investigation commenced in August 2011. The CMA has therefore assessed separately at step 3 whether each of those entities provided cooperation of the type described at paragraph 11.44.

¹⁵⁷¹ See footnote 1570.

Investigation.¹⁵⁷² The CMA considers that a 5% reduction for cooperation is appropriate for Merck in the circumstances of this case.

11.48 The CMA considers that Actavis has provided voluntary cooperation which has enabled the Investigation to be concluded more effectively and/or speedily.¹⁵⁷³ Specifically, during the Investigation, Actavis made staff available for interview and assisted in the production of a witness statement post-interview.¹⁵⁷⁴ The CMA considers that a 5% reduction for cooperation is appropriate for Actavis in the circumstances of this case.

11.49 The CMA considers that each of Xellia and Zoetis has provided voluntary cooperation which has enabled the Investigation to be concluded more effectively and/or speedily.¹⁵⁷⁵ Specifically, following their initial contacts with the OFT in relation to the Investigation, Xellia and Zoetis voluntarily provided a substantial volume of key documents and information.¹⁵⁷⁶ The CMA considers that a 5% reduction for cooperation is appropriate for each of Xellia and Zoetis in the circumstances of this case.

iv) Step 4 – Adjustment for specific deterrence and proportionality

11.50 The CMA may adjust any penalty at step 4 to achieve the objective of specific deterrence (namely, ensuring that the penalty imposed on the infringing undertaking will deter it from engaging in anti-competitive practices in the future) or to ensure that a penalty is proportionate, having regard to the appropriate indicators of the size and financial position of the relevant undertaking(s), as well as any other relevant circumstances of the case.¹⁵⁷⁷

¹⁵⁷² For example, the OFT carried out a review of Merck's documents at its solicitors' offices on 6 March 2014 by mutual agreement, following which Merck provided additional documents on 17 March 2014 (documents 3036, D 158R, D 159, D 160, D 161R, D 162R, D 163, D 164, D 165R and D 166R).

¹⁵⁷³ As set out at paragraphs 3.7–3.9, Actavis, Xellia and Zoetis comprised the undertaking referred to as Alpharma during the Relevant Period, but Zoetis (then named Alpharma Inc, currently named Alpharma LLC) sold assets including Actavis and also sold Alpharma ApS (that is, Xellia) before the Investigation commenced in August 2011. The CMA has therefore assessed separately at step 3 separately whether each of those entities provided cooperation of the type described at paragraph 11.44.

¹⁵⁷⁴ See, for example, [X]WS (document 1587) and transcript of interview with [Alpharma Ltd's Marketing Manager] on 21 June 2012, dated 28 September 2012 (document 1588).

¹⁵⁷⁵ See footnote 1573.

¹⁵⁷⁶ See, for example, documents annexed to Xellia-Zoetis SO Written Response (documents 2767 and A 0001–A 0038 inclusive) and the joint additional submissions of Xellia and Zoetis dated 18 October 2013 following further document searches (documents 2990A and B0001, B0002R–B0004R inclusive, B0005–B0009, B0010R, B0011–B0013 inclusive). The OFT also carried out a review of Xellia and Zoetis documents at their solicitors' offices on 24 and 25 March 2014 by mutual agreement, following which Xellia and Zoetis provided additional documents on 28 April 2014 (documents D169A, D169B, D169–D212 inclusive).

¹⁵⁷⁷ Penalty Guidance, paragraphs 2.16 and 2.20. The CMA has taken into account a range of financial indicators in this regard, set out in this Part of this Decision, based on financial information available publicly and/or provided by the Parties to the CMA.

- 11.51 A penalty figure reached after steps 1 to 3 may be increased to ensure that the penalty to be imposed on the undertaking will deter it from infringing competition law in the future, given the specific size and financial position and any other relevant circumstances of the case. The assessment of the need to adjust the penalty will be made on a case-by-case basis for each individual infringing undertaking. Where the CMA is considering the appropriate level of any uplift for specific deterrence, it will ensure that the uplift does not result in a penalty that is disproportionate or excessive having regard to the undertaking's size and financial position and the nature of the infringement.¹⁵⁷⁸
- 11.52 At this step, the CMA will also assess whether, in its view, the overall penalty is appropriate in the round. Where necessary, the CMA may decrease the penalty reached at the end of steps 1 to 3 to ensure that the level of penalty is not disproportionate or excessive. In carrying out this assessment of whether a penalty is proportionate, the CMA will have regard to the undertaking's size and financial position, the nature of the infringement, the role of the undertaking in the infringement and the impact of the undertaking's infringing activity on competition.¹⁵⁷⁹
- 11.53 In this case, the CMA has considered whether any adjustment(s) should be made at step 4 to (a) all Parties' penalties (see paragraphs 11.54 to 11.60), and – separately – (b) any specific Party's penalty (see paragraphs 11.62 to 11.85).¹⁵⁸⁰
- a) *Adjustments to all Parties' penalties***
- 11.54 When assessing whether any penalty in this case would be appropriate in the round, the CMA has had regard to its view that the Infringements were serious in nature, and that there is no basis for differentiating between the respective roles of GSK, GUK and Alpharma in the Infringements, as noted under 'Seriousness' at Step 1 above. The CMA has also had regard to the considerations set out at paragraphs 11.55 to 11.60.
- 11.55 The CMA finds that the purpose of the Infringements was to defer the threat of true generic competition. Substantial gains can be made from deferring the

¹⁵⁷⁸ Penalty Guidance, paragraphs 2.17 and 2.19. Such increases will generally be limited to situations in which an undertaking has a significant proportion of its turnover outside the relevant market or where the CMA has evidence that the infringing undertaking has made or is likely to make an economic or financial benefit from the infringement exceeding the penalty reached at the end of step 3.

¹⁵⁷⁹ Penalty Guidance, paragraph 2.20.

¹⁵⁸⁰ Where entities comprised an undertaking during the Relevant Period, but as at the date of this Decision no longer form part of the same undertaking, at step 4 the CMA has assessed these entities separately.

full development of true generic competition in the pharmaceutical sector, since such competition can, in general, result in significant price decreases.¹⁵⁸¹ This is demonstrated by the examples set out at paragraphs 3.62 and 6.36. In addition, in this case, Seroxat prices fell by around 60% within two years of the emergence of true generic competition (following Apotex's entry)¹⁵⁸²; moreover, such a fall was consistent with the Parties' expectations of the likely impact of true generic competition in the UK paroxetine market.¹⁵⁸³

- 11.56 As such, sustaining substantially higher pharmaceutical prices, via so-called 'pay for delay' arrangements, enables both the participating originators and generic suppliers to realise significant financial gains through sharing the relevant originator's monopoly profits (which are at levels far higher than would exist after the emergence of true generic competition), at the expense of the NHS. In this case, for example, GSK made profits on its sales of Seroxat of £46.3 million in 2001 (that is, prior to the Infringements) and these had fallen to £5.8 million by 2005 (after the emergence of true generic competition).
- 11.57 Given the relevant circumstances of this case set out at paragraphs 11.55 to 11.56, the CMA has reflected on whether the penalty figures reached after steps 1 to 3 should be increased, in order to ensure that the penalties imposed in this case would deter the Parties from infringing competition law in the future.
- 11.58 However, the CMA notes that at the time of the Infringements there had been no finding that this specific form of anti-competitive agreements (so-called 'pay for delay' agreements) infringed the Chapter I prohibition, Article 101 TFEU, the Chapter II prohibition or Article 102 TFEU, although it was already well established that excluding actual or potential competitors from the market was likely to infringe competition law. The CMA has taken this into account in the round when calculating penalties in this case.
- 11.59 In addition, the CMA is mindful of the passage of time between the Relevant Period and the launch of this Investigation. While each Party has been able to identify and provide a substantial volume of contemporaneous evidence relevant to the Investigation (and in many instances, relevant witnesses have given evidence to the OFT/CMA), the CMA recognises that, given the passage of time, searching for contemporaneous evidence and/or data

¹⁵⁸¹ As set out, for example, in paragraphs 3.62–3.63.

¹⁵⁸² Fall in average Seroxat prices (20mg and 30mg combined) between December 2003 and December 2005. CMA calculations based on data submitted by relevant parties.

¹⁵⁸³ See, for example, the forecasts referred to at paragraphs 3.63 and 3.161–3.162.

relevant to this Investigation may have involved an increased administrative burden for the Parties.

- 11.60 Having assessed the relevant circumstances set out at paragraphs 11.55 to 11.59, in the specific circumstances of this case the CMA considers that:
- (a) no further uplift should be made, to the penalty for any Party, in order to achieve specific deterrence on the basis of the relevant circumstances set out at paragraphs 11.55 to 11.56; and
 - (b) it is appropriate, considering the factors in the round, to apply a 10% reduction of the penalty for each Party reached at the end of steps 1 to 3, in order to reach an appropriate penalty for each Party.

11.61 It is entirely possible that in future similar cases where parties have significant turnover outside the relevant market and/or substantial gains would likely be made given the relevant circumstances set out at paragraphs 11.55 to 11.56, the CMA may consider that penalties should be increased at this step of a penalty calculation in order to achieve specific deterrence.

b) Adjustments to each Party's penalty

Adjustments to GSK's overall penalty

11.62 The CMA may, as a matter of law, impose separate penalties in respect of the Infringements by GSK in relation to each of the Infringing Agreements and the Infringing Conduct. However, the CMA has assessed whether it would be appropriate, taken in the round, to impose separate penalties on GSK. The CMA notes that the Infringing Agreements and the Infringing Conduct arise from materially the same facts, relate to the same product and geographic market and have substantially overlapping time periods. Accordingly, the CMA considers in the circumstances of this case that it is appropriate to impose only a single penalty on GSK in respect of infringements of Chapter I/Article 101 and Chapter II arising from the same set of facts, to ensure that the GSK's overall penalty is not disproportionate or excessive. The CMA has therefore reduced to zero, after step 6, the lower of GSK's Chapter I/Article 101 penalties combined or GSK's Chapter II penalty.

11.63 The CMA has set out below its assessment of whether any specific deterrence or proportionality adjustment(s) should be made at step 4 to each of GSK's Chapter I/Article 101 penalties or to GSK's Chapter II penalty, taken individually, and whether each of those penalties is appropriate in the round.

Adjustments to GSK's Chapter I/Article 101 penalties

11.64 After steps 1 to 3 and the 10% reduction outlined at paragraph 11.60, the figures reached in respect of GSK's Chapter I/Article 101 penalties are:

- (a) £31,715,145 in respect of the GUK-GSK Agreement; and
- (b) £19,029,087 in respect of the Alparma-GSK Agreement.

11.65 The CMA observes that GSK's resulting aggregate penalty in respect of the two Infringing Agreements (£50,744,232) would represent, for example:¹⁵⁸⁴

- 0.20% of GSK's average annual worldwide turnover in its last three financial years (0.13% and 0.08% in respect of the GUK-GSK Agreement and the Alparma-GSK Agreement respectively), and 0.22% of GSK's worldwide turnover in its 2014 financial year (0.14% and 0.08% in respect of the GUK-GSK Agreement and the Alparma-GSK Agreement respectively);
- 1.2% of GSK's average annual profit after tax in its last three financial years (0.72% and 0.43% in respect of the GUK-GSK Agreement and the Alparma-GSK Agreement respectively), and 1.8% of GSK's profit after tax in its 2014 financial year (1.1% and 0.67% in respect of the GUK-GSK Agreement and the Alparma-GSK Agreement respectively);
- 1.3% of GSK's dividends in its 2014 financial year (0.83% and 0.50% in respect of the GUK-GSK Agreement and the Alparma-GSK Agreement respectively);
- 1.0% of GSK's net assets in its 2014 financial year (0.64% and 0.39% in respect of the GUK-GSK Agreement and the Alparma-GSK Agreement respectively);
- 0.31% of the sum of GSK's net assets in its 2014 financial year, and GSK's total annual dividends in its last three financial years (0.19% and 0.12% in respect of the GUK-GSK Agreement and the Alparma-GSK Agreement respectively); and
- 75.6% of GSK's relevant turnover (47.3% and 28.4% in respect of the GUK-GSK Agreement and the Alparma-GSK Agreement respectively).

¹⁵⁸⁴ GSK's latest accounts cover the financial years ended 31 December 2014, 31 December 2013 and 31 December 2012: see GlaxoSmithKline Plc Annual Report 2014 (document 3671) and GlaxoSmithKline Plc Annual Report 2013 (document 3670).

- 11.66 The CMA considers that, if it were to impose a penalty on GSK in respect of only the GUK-GSK Agreement or the Alpharma-GSK Agreement, either of those penalties would, assessed in isolation, be appropriate to deter GSK from future infringements, and at a level which would not be disproportionate or excessive.
- 11.67 However, the CMA considers it appropriate to calculate, and impose on GSK, a separate penalty for each Infringing Agreement. The CMA has therefore considered whether to make any adjustments in order to ensure that the level of GSK's Chapter I/Article 101 Penalties is not disproportionate or excessive. Having had regard to the financial indicators in paragraph 11.65, and the overlaps in the product market, geographic area and time periods as between the two Infringing Agreements, the CMA considers that it is appropriate to reduce GSK's penalty in respect of the Alpharma-GSK Agreement (which was entered into later in time than the GUK-GSK Agreement) at the end of step 3 by 85%, so that this penalty is £1,057,172 at the end of step 4.
- 11.68 Having assessed the resulting level of GSK's Chapter I/Article 101 Penalties (£32,772,317) in the round, the CMA considers this to be at an appropriate level to deter GSK from infringing competition law in the future, without being disproportionate or excessive.

Adjustments to GSK's Chapter II penalty

- 11.69 After steps 1 to 3 and the 10% reduction outlined at paragraph 11.60, the figure reached in respect of GSK's Chapter II penalty is £32,233,950. This would represent, for example:¹⁵⁸⁵
- 0.13% of GSK's average annual worldwide turnover in its last three financial years, and 0.14% of GSK's worldwide turnover in its 2014 financial year;
 - 0.74% of GSK's average annual profit after tax in its last three financial years, and 1.1% of GSK's profit after tax in its 2014 financial year;
 - 0.84% of GSK's dividends in its 2014 financial year;
 - 0.65% of GSK's net assets in its 2014 financial year;
 - 0.20% of the sum of GSK's net assets in its 2014 financial year, and GSK's total annual dividends in its last three financial years; and

¹⁵⁸⁵ See footnote 1584.

- 42.5% of GSK's relevant turnover.
- 11.70 The CMA has considered whether GSK's Chapter II penalty at the end of step 3 should be increased to deter GSK from infringing competition law in the future. The CMA has had regard, as a relevant circumstance of the case, to the fact that the Infringing Conduct involved repeated instances of a certain course of conduct, since GSK's Infringing Conduct involved value transfers made to three potential competitors. The CMA considers that, in principle, GSK's Chapter II penalty should reflect the repeated instances of the course of conduct giving rise to GSK's Infringing Conduct. However, the CMA is also mindful that the repeated instances of the course of conduct relate to the same product and geographic market as well as substantially overlapping time periods. In the specific circumstances of this case, the CMA therefore considers it appropriate to include within GSK's Chapter II penalty a modest increase at step 4 to reflect the repeated instances of the course of conduct giving rise to GSK's Infringing Conduct.
- 11.71 Having had regard to the financial indicators in paragraph 11.69, and the overlaps described in the preceding paragraph between the repeated instances of the course of conduct, the CMA considers that it is appropriate to increase GSK's Chapter II penalty by 15%. In determining the level of this uplift for specific deterrence, the CMA has had regard to the need to ensure that the uplift to GSK's Chapter II penalty would not lead to a disproportionate or excessive overall penalty.
- 11.72 Assessing the resulting penalty (£37,606,275) in the round, the CMA considers this to be at an appropriate level to deter GSK from infringing competition law in the future, without being disproportionate or excessive.

Adjustments to the penalties of GUK-Merck

- 11.73 As set out at paragraphs 3.5 to 3.6, during the Relevant Period GUK and Merck comprised the undertaking referred to in this Decision as GUK-Merck, but as at the date of this Decision no longer form part of the same undertaking. The CMA has therefore assessed the penalty for each of these entities separately at step 4, addressing GUK first (at paragraphs 11.74 to 11.75) and then Merck (at paragraphs 11.76 to 11.77).

11.74 After steps 1 to 3 and the 10% reduction outlined at paragraph 11.60, the penalty for which GUK would be liable is £6,148,722. This would represent:¹⁵⁸⁶

- 8.8% of GUK's average annual worldwide turnover in its last three financial years, and 8.5% of GUK's worldwide turnover in its 2014 financial year;
- 149.3% of GUK's average annual profit after tax in its last three financial years, and 264.1% of GUK's profit after tax in its 2014 financial year;
- 68.3% of GUK's total annual dividends in its 2014 financial year;
- 20.0% of GUK's net assets in its 2014 financial year;
- 11.1% of the sum of GUK's net assets in its 2014 financial year, and GUK's total annual dividends in its last three financial years;¹⁵⁸⁷ and
- 47.3% of GUK's relevant turnover.

11.75 The CMA considers that, in the circumstances of this case, an unadjusted penalty would represent a disproportionate share of GUK's profits and total turnover in its last three financial years. Having had regard to GUK's size and financial position, the CMA considers that it is appropriate to reduce by 50% the penalty for GUK at the end of step 3, to £2,732,765. Assessing the resulting penalty in the round, the CMA considers the adjusted penalty to be at an appropriate level to deter GUK from infringing competition law in the future, without being disproportionate or excessive.

11.76 After steps 1 to 3 and the 10% reduction outlined at paragraph 11.60, the penalty for which Merck would be liable is £5,841,286. This would represent:¹⁵⁸⁸

¹⁵⁸⁶ GUK's latest accounts cover the financial years ended 31 December 2014, 31 December 2013 and 31 December 2012: see Generics (UK) Limited Directors' report and financial statements dated 31 December 2014 (document 4072), and Generics (UK) Limited Directors' report and financial statements dated 31 December 2013 (document 3559).

¹⁵⁸⁷ GUK paid dividends in each of its last three financial years.

¹⁵⁸⁸ Merck's latest accounts cover the financial years ended 31 December 2014, 31 December 2013 and 31 December 2012: see Merck Annual Report 2014 (document 3939) and Merck 2013 Annual Report (document 3920). In respect of gross profits in each of the financial years ended 31 December 2014 and 31 December 2013, the CMA has taken into account the figures stated in the Merck Annual Report 2014 (following the change of accounting principles explained at page 88 of that report); in respect of gross profits in the financial year ended 31 December 2012, the CMA has taken into account the figure stated at page 180 of the Merck Annual Report 2013. To express in pounds sterling Merck's financial results, the CMA has used the Bank of England's annual average exchange rate for 2014, 2013 and 2012 (£1 = €1.2411, £1 = €1.1776 and £1 = €1.2337 respectively).

- 0.06% of Merck's average annual worldwide turnover in its last three financial years, and also 0.06% of Merck's worldwide turnover in its 2014 financial year;
- 0.72% of Merck's average annual profit after tax in its last three financial years, and 0.62% of Merck's profit after tax in its 2014 financial year;
- 1.4% of Merck's dividends in its 2014 financial year;
- 0.06% of Merck's net assets in its 2014 financial year;
- 0.06% of the sum of Merck's net assets in its 2014 financial year, and Merck's total annual dividends in its last three financial years;¹⁵⁸⁹ and
- 44.9% of Merck's relevant turnover.

11.77 Having had regard to Merck's size and financial position, and having assessed this penalty in the round, the CMA considers it to be at an appropriate level to deter Merck from infringing competition law in the future, without being disproportionate or excessive.

Adjustments to the penalties of Alpharma

11.78 As set out at paragraphs 3.7 to 3.9, Actavis, Xellia and Zoetis comprised the undertaking referred to as Alpharma during the Relevant Period, but as at the date of this Decision no longer form part of the same undertaking. The CMA has therefore assessed the penalty for each of these entities separately at step 4, addressing Actavis first (at paragraphs 11.79 to 11.80), then Xellia (at paragraphs 11.81 to 11.83) and then Zoetis (at paragraphs 11.84 to 11.85).

11.79 After steps 1 to 3 and the 10% reduction outlined at paragraph 11.60, the penalty for which Actavis would be liable is £1,542,860. This would represent:¹⁵⁹⁰

- 0.74% of Actavis' average annual worldwide turnover in its last three financial years, and 0.71% of Actavis' worldwide turnover in its 2014 financial year;

¹⁵⁸⁹ Merck paid dividends in each of its last three financial years.

¹⁵⁹⁰ Actavis' latest accounts cover the financial years ended 31 December 2014, 31 December 2013 and 31 December 2012: see Actavis' Annual report and financial statements dated 31 December 2014 (document 4071), and Actavis' Directors' report and financial statements dated 31 December 2013 (document 3575).

- 5.6% of Actavis' average annual profit after tax in its last three financial years, and 4.5% of Actavis' profit after tax in its 2014 financial year;
- 1.6% of Actavis' net assets in its 2014 financial year;
- 1.6% of the sum of Actavis' net assets in its 2014 financial year, and Actavis' total annual dividends in its last three financial years;¹⁵⁹¹ and
- 26.9% of Actavis' relevant turnover.

11.80 Having had regard to Actavis' size and financial position, and having assessed this penalty in the round, the CMA considers it to be at an appropriate level to deter Actavis from infringing competition law in the future, without being disproportionate or excessive.

11.81 After steps 1 to 3 and the 10% reduction outlined at paragraph 11.60, the penalty for which Xellia would be liable is £1,542,860. This would represent:¹⁵⁹²

- 1.5% of Xellia's average annual worldwide turnover in its last three financial years, and 1.6% of Xellia's worldwide turnover in its 2014 financial year;
- 1.8% of Xellia's net assets in its 2014 financial year;
- 1.6% of the sum of Xellia's net assets in its 2014 financial year, and Xellia's total annual dividends in its last three financial years;¹⁵⁹³ and
- 26.9% of Xellia's relevant turnover.

11.82 The CMA has not expressed Xellia's penalty as a proportion of profits, since Xellia made a loss in its 2014 financial year, and consequently had a negative average annual profit after tax in its last three financial years.¹⁵⁹⁴

11.83 Having had regard to Xellia's size and financial position, and having assessed this penalty in the round, the CMA considers it to be appropriate to deter

¹⁵⁹¹ Actavis paid no dividends in any of its last three financial years.

¹⁵⁹² Xellia's latest accounts cover the financial years ended 31 December 2014, 31 December 2013 and 31 December 2012: Xellia Annual Report 2014 (document 4058). To express in pounds sterling Xellia's financial results, the CMA has used the Bank of England's annual average exchange rate for 2014, 2013 and 2012 (£1 = DKK 9.2515, £1 = DKK 8.7827 and £1 = DKK 9.1832 respectively).

¹⁵⁹³ Xellia paid dividends in its 2012 financial year, but paid none in its 2013 and 2014 financial years.

¹⁵⁹⁴ Xellia made a loss of approximately £41,581,798 in its 2014 financial year, a profit of approximately £12,960,365 in its 2013 financial year and a profit of approximately £17,702,762 in its 2012 financial year. Consequently, Xellia had a negative average annual profit after tax in its last three financial years.

Xellia from infringing competition law in the future, without being disproportionate or excessive.

11.84 After steps 1 to 3 and the 10% reduction outlined at paragraph 11.60, the penalty for which Zoetis would be liable is £1,542,860. This would represent:¹⁵⁹⁵

- 0.99% of Zoetis's average annual worldwide turnover, based on its last three financial years, and 1.01% of Zoetis's worldwide turnover in its 2014 financial year;
- 5.7% of Zoetis's average annual profit after tax, based on the latest two years for which accounts have been provided, and 4.7% of Zoetis's profit after tax in its 2014 financial year;¹⁵⁹⁶
- 0.8% of Zoetis's net assets in its 2014 financial year;
- 0.8% of the sum of Zoetis's net assets in its 2014 financial year, and Zoetis's total annual dividends in its last two financial years;¹⁵⁹⁷ and
- 26.9% of Zoetis's relevant turnover.

11.85 Having had regard to Zoetis's size and financial position, and having assessed this penalty in the round, the CMA considers it to be appropriate to deter Zoetis from infringing competition law in the future, without being disproportionate or excessive.

v) *Step 5 – Adjustment to prevent maximum penalty from being exceeded and to avoid double jeopardy*

11.86 The final amount of the penalty calculated according to the method set out above may not in any event exceed 10% of the worldwide turnover of the undertaking in its last business year.¹⁵⁹⁸ The relevant business year for these

¹⁵⁹⁵ The latest accounts available to the CMA for Zoetis are unaudited, and cover the financial years ended 31 December 2014 and 31 December 2013: Zoetis unaudited financials for the financial year ended 31 December 2014 (document 4059) and Zoetis unaudited financials for the financial year ended 31 December 2013 (document 3552). Regarding unaudited total turnover in the financial year ended 31 December 2012, see Zoetis response dated 10 May 2013 to the CMA information request dated 19 April 2013 (document 2730). To express in pounds sterling Zoetis financial results, the CMA has used the Bank of England's annual average exchange rate for 2014, 2013 and 2012 (£1 = US\$1.6477, £1 = US\$1.5644 and £1 = US\$1.5851 respectively).

¹⁵⁹⁶ The CMA has no data detailing Zoetis profit after tax in its 2012 financial year, so was not able to compare the penalty to annual profit after tax over a three-year average.

¹⁵⁹⁷ The CMA has no data detailing Zoetis dividends in its 2012 financial year.

¹⁵⁹⁸ Calculated in accordance with The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000, as amended by The Competition Act 1998 (Determination of Turnover for Penalties) (Amendment) Order 2004, SI 2004/1259; see Penalty Guidance, paragraphs 1.12 and 2.21.

purposes will be the one preceding the date on which the decision of the CMA is taken or, if figures are not available for that business year, the one immediately preceding it. The penalty will be adjusted if necessary to ensure that it does not exceed this maximum.¹⁵⁹⁹

- 11.87 In addition, where an infringement ended prior to 1 May 2004, any penalty imposed in respect of an infringement of the Chapter I prohibition or the Chapter II prohibition will, if necessary, be adjusted further to ensure that it does not exceed 10% of turnover in the UK of the undertaking in the financial year preceding the date when the infringement ended (as adjusted, where the length of the infringement was in excess of one year, up to a maximum of three years).¹⁶⁰⁰
- 11.88 The CMA has assessed each Party's penalty against the threshold set out in paragraph 11.86. Where entities comprised an undertaking during the Relevant Period, but as at the date of this Decision no longer form part of the same undertaking, the CMA has calculated and applied the statutory maximum separately to each such entity at step 5. This assessment has not necessitated a reduction to any Party's penalty.
- 11.89 Each of the Infringements in relation to the Alphantra-GSK Agreement and the Infringing Conduct ended prior to 1 May 2004. In respect of the penalties arising from those Infringements, the CMA has therefore also assessed each relevant Party's penalty against the threshold set out in paragraph 11.87. This assessment has not necessitated any reduction to the relevant penalties of GSK¹⁶⁰¹ or Alphantra.¹⁶⁰²
- 11.90 In addition, the CMA must, when setting the amount of a penalty for a particular agreement or conduct, take into account any penalty that has been imposed by the Commission, or by a court or other body in another Member

¹⁵⁹⁹ Penalty Guidance, paragraph 2.21.

¹⁶⁰⁰ Calculated in accordance with The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000, immediately prior to its amendment by The Competition Act 1998 (Determination of Turnover for Penalties) (Amendment) Order 2004 (SI 2004/1259); see Penalty Guidance, paragraph 2.22.

¹⁶⁰¹ Regarding GSK's total UK turnover in its 2003, 2002, 2001 and 2000 financial years, see GlaxoSmithKline Plc Annual Report for the year ended 31 December 2003 (document 2576), page 100, GlaxoSmithKline Plc Annual Report 2002 (document 2591), page 88, and part two of the response dated 19 November 2014 to the Section 26 Notice dated 21 October 2014 sent to GSK (document 3607).

¹⁶⁰² Regarding Alphantra's total UK turnover in its 2003 and 2002 financial years – during which Actavis, Xellia and Zoetis still comprised part of the Alphantra undertaking – see Alphantra Inc's 10-K filing for the financial year ended 31 December 2003 (available at <http://www.secinfo.com/dM9Ba.11w.htm>), under 'Geographic Information', and response dated 27 February 2015 to the information request dated 16 January 2015 sent to Xellia-Zoetis (document 3884).

State in respect of the same agreement or conduct.¹⁶⁰³ No such penalty has been imposed in respect of the Infringements.

11.91 In light of the above, the CMA has made no adjustment at step 5.

vi) Step 6 – Application of reductions for leniency and settlement

11.92 The CMA will reduce an undertaking's penalty at step 6 where the undertaking has a leniency agreement, and/or agrees to settle with, the OFT/CMA.¹⁶⁰⁴

11.93 No Party entered into a leniency or settlement agreement with the OFT (before 1 April 2014) or the CMA (on or after 1 April 2014). The CMA has therefore made no adjustment at step 6.

D. Payment of the financial penalty

11.94 The CMA requires each Party to pay the penalty applicable to it:

- (a) the total penalty for GSK is £37,606,275,¹⁶⁰⁵ for which each entity comprising GSK (as listed in paragraph 1.2) is jointly and severally liable;
- (b) the total penalty for GUK-Merck is £5,841,286:
 - (i) Merck KGaA is liable for £5,841,286 (of which, Generics (UK) Limited is jointly and severally liable for £2,732,765); and
 - (ii) Generics (UK) Limited is jointly and severally liable for £2,732,765;
- (c) the total penalty for Alparma is £1,542,860, of which:
 - (i) Actavis UK Limited is jointly and severally liable for £1,542,860;
 - (ii) Xellia Pharmaceuticals ApS is jointly and severally liable for £1,542,860; and
 - (iii) Alparma LLC is jointly and severally liable for £1,542,860.

¹⁶⁰³ Penalty Guidance, paragraph 2.24.

¹⁶⁰⁴ Penalty Guidance, paragraphs 2.25–2.26.

¹⁶⁰⁵ At the end of step 6, GSK's penalty in respect of the GUK-GSK Agreement was £31,715,145, GSK's penalty in respect of the Alparma-GSK Agreement was £1,057,172. For the reasons explained at paragraph 11.62, since GSK's Chapter I/Article 101 penalties combined (£32,772,317) after step 6 are lower than GSK's Chapter II penalty (£37,606,275), the overall penalty which the CMA imposes on GSK is £37,606,275, for which each entity comprising GSK will be held jointly and severally liable.

11.95 Each of the above penalty figures has been rounded to the nearest pound. More detailed penalty calculation tables are set out at Annex P.

11.96 Each of the above penalties will become due to the CMA in its entirety, and must be paid to the CMA by the close of banking business, on 14 April 2016.¹⁶⁰⁶ If that date has passed and (a) the period during which an appeal against the imposition, or amount, of that financial penalty may be made has expired without an appeal having been made, or (b) such an appeal has been made and determined, the CMA may commence proceedings to recover from the undertaking in question, as a civil debt due to the CMA, any amount payable which remains outstanding.¹⁶⁰⁷

SIGNED:

[✂]

Simon Polito, Inquiry Chair, for and on behalf of the Competition and Markets Authority;

[✂]

Professor Robin Mason, Panel Member, for and on behalf of the Competition and Markets Authority; and

[✂]

Sheldon Mills, Senior Director of Mergers, for and on behalf of the Competition and Markets Authority;

All of whom are the members of, and who together constitute, the Case Decision Group.

12 February 2016

¹⁶⁰⁶ The next working day two calendar months from the expected date of receipt of the Decision. Details of how to pay are notified in the letter accompanying this Decision.

¹⁶⁰⁷ The Act, section 37.

ANNEX A: DEFINED TERMS AND KEY PERSONS**A. Defined Terms specific to the Investigation**

Term	Definition
Actavis	Actavis UK Limited (formerly Alparma Limited).
Actavis DPS Written Response	Actavis Response dated 21 August 2015 to the Alparma DPS.
Actavis Proposed NGFA Response	Actavis response dated 21 August 2015 to the Proposed NGFA Decision.
Actavis SO Written Response	Actavis Response dated 2 August 2013 to the SO.
[X]WS1 (draft)	Draft witness statement of [Alparma Ltd's Director of Sales and Marketing] in the Alparma Litigation, dated July 2002.
[X]WS2	Second witness statement of [Alparma Ltd's Director of Sales and Marketing] in the Alparma Litigation, dated 24 July 2002.
Addenda	Refers to the First Addendum, Second Addendum, Third Addendum and Fourth Addendum collectively.
Agreements	The agreements consisting of the Alparma-GSK Agreement, GUK-GSK Agreement and IVAX-GSK Agreement (each as defined below). This term is used in relation to all of the agreements or any combination of the agreements as specified. The term Agreement is used in relation to any one of these agreements as specified.
Alparma	Actavis, Xellia and Zoetis.
Alparma-GSK Agreement	The Alparma-GSK Agreement means the agreement between Alparma and GSK described in paragraphs 5.10 to 5.11.
Alparma-GSK Settlement Agreement	The settlement agreement between GSK and Alparma Limited dated 12 November 2002 (and subsequently amended on 14 November 2003).
Alparma-IVAX Agreement	The sub-distribution agreement between Alparma and IVAX dated 20 November 2002, reflected in the Third Addendum.

Term	Definition
Alpharma DPS	Draft Penalty Statement issued on 30 June 2015 by the CMA to Actavis, Xellia and Zoetis.
Alpharma Litigation	GSK's action against Alpharma for infringement of the Anhydrate Patent and Alpharma's counterclaim.
Alpharma Product	The Alpharma paroxetine product sourced from Delta Pharmaceuticals and distributed by Medis.
Alpharma Undertaking	The interim undertaking provided by Alpharma on 1 August 2002 to refrain from launching its generic paroxetine in the UK.
Anhydrate Patent	Patent GB 2297550, relating to polymorphs of paroxetine anhydrate and the process used to displace bound organic solvate to produce paroxetine anhydrate (known as the 'displacement step'). It was granted in 1997 and amended in 2001 and 2003. The Anhydrate Patent was granted on 11 March 1997 and, to the extent it remained valid after the BASF Litigation, was due to expire in 2016 but following the non-payment of renewal fees expired in January 2013.
Apotex	Apotex Europe Limited
Apotex Litigation	The Apotex Parties' action against GSK to revoke the Anhydrate Patent, and GSK's action against the Apotex Parties for infringement of the Anhydrate Patent.
Apotex Parties	Apotex, Neolab and Waymade
BASF	BASF AG
BASF Litigation	BASF's revocation action against certain claims in the Anhydrate Patent.
CIMS	Customer Information Management System
[✂]WS	Witness statement of [IVAX's Managing Director], dated 18 January 2013.
Decision	This decision issued by the CMA on 12 February 2016.
Delta	Delta Ltd.

Term	Definition
Draft Penalty Statements	The Alparma DPS, the GSK DPS and the GUK DPS.
Dry Tableting Patent	Patent EP 0 734 260, relating to a process for formulating tablets containing paroxetine in the absence of water.
First Addendum	The first addendum to amend the IVAX-GSK Agreement dated 15 February 2002.
First Letter of Facts	Letter of facts issued by the CMA on 27 August 2014.
Fourth Addendum	The fourth addendum to amend the IVAX-GSK Agreement dated 28 February 2003.
[X]WS	Witness statement of [IVAX's Head of New Business Development], dated 13 February 2013.
GEA	A/S GEA Farmaceutisk Fabrik.
Generic Companies	IVAX, GUK and Alparma, each a 'Generic Company'.
GSK	GlaxoSmithKline plc, GlaxoSmithKline UK Limited, SmithKline Beecham Limited (formerly SmithKline Beecham plc) and Beecham Group plc.
GSK's Chapter I/Article 101 penalties	GSK's penalties in relation to the Infringing Agreements.
GSK DPS	Draft Penalty Statement issued on 30 June 2015 by the CMA to GSK.
GSK DPS and Proposed NGFA Written Response	GSK Response dated 18 August 2015 to the GSK DPS and the Proposed NGFA Decision.
GSK Second Response, Part Two	Part two of the response dated 4 May 2012 to the Section 26 Notice dated 23 March 2012 sent to GSK by the OFT.
GSK Section 27 Notice	Section 27 Notice dated 2 December 2011 sent to GSK by the OFT.
GSK SO Written Response	GSK Response dated 7 August 2013 to the SO.

Term	Definition
GSK Third Response	The response dated 16 July 2012 to the Section 26 Notice dated 18 June 2012 sent to GSK by the OFT.
GUK	Generics (UK) Limited.
GUK-GSK Agreement	GUK-GSK Agreement means the agreement between GUK and GSK described in paragraphs 5.8 to 5.9.
GUK-GSK Settlement Agreement	The settlement agreement between SmithKline Beecham plc, Beecham Group plc and GUK dated 13 March 2002.
GUK-IVAX Agreement	The sub-distribution agreement between GUK and IVAX dated 14 March 2002, reflected in the Second Addendum.
GUK-Merck	GUK and Merck.
GUK DPS	Draft Penalty Statement issued on 30 June 2015 by the CMA to GUK and Merck.
GUK DPS Written Response	GUK Response dated 25 August 2015 to the GUK DPS.
GUK Interim Injunction	The interim injunction granted by Mr Justice Jacob on 23 October 2001 to restrain GUK from selling its generic paroxetine in the UK.
GUK Litigation	GSK's action against GUK for infringement of the Anhydrate Patent and the Hemihydrate Patent and GUK's counterclaim.
GUK Proposed NGFA Response	GUK response dated 25 August 2015 to the Proposed NGFA Decision.
GUK SO Written Response	GUK Response dated 31 July 2013 to the SO.
Hemihydrate Patent	European Patent EP 0 223 403, relating to a particular crystalline form of paroxetine. It was granted in 1986 and expired on 14 October 2006.
Hexal	Hexal AG.

Term	Definition
[X]1	Transcript of interview with [Merck's Head of Patents and Raw Material Support Group] on 25 May 2012, dated 13 November 2012.
[X]WS	Witness statement of [GSK's independent expert] in the GUK Litigation, dated 13 September 2001.
[X]WS	Witness statement of [Alpharma Ltd's Marketing Manager], dated 28 September 2012.
[X]WS	Witness statement of [GSK's Marketing Manager A for Seroxat] in the GUK Litigation, dated 19 September 2001.
Infringements	The infringements comprising the Infringing Agreements and the Infringing Conduct, as defined at paragraphs 1.3 to 1.20 of the Decision. This term is used in relation to all of the infringements or any combination of the infringements as specified. The term Infringement is used in relation to any one of these infringements as specified.
Infringing Agreement	The GUK-GSK Agreement or the Alpharma-GSK Agreement, as applicable. The term Infringing Agreements is used in relation to both of these agreements.
Infringing Conduct	The conduct of GSK defined as the Infringing Conduct in Part 1, as further described in Part 8.
Initial Patent	Patent GB 1 422 263, relating to the original paroxetine hydrochloride molecule. It was granted in 1973 and expired in 2000.
Investigation	The investigation by the OFT and the CMA, as further described in Part 2 of the Decision.
IVAX	Norton and IVAX LLC (formerly IVAX Corporation).
IVAX-GSK Agreement	The supply agreement between IVAX and GSK dated 3 October 2001 (together with Side Letter and Addenda, where appropriate).
IVAX-Tillomed Heads of Agreement	The heads of agreement between IVAX and Tillomed dated 4 October 2001.

Term	Definition
IVAX-Tillomed Supply Agreement	The supply agreement between IVAX and Tillomed dated 11 December 2001 (and supplemental letter, where appropriate).
Medis	Medis Danmark A/S.
Merck	Merck KGaA.
Merck DPS Written Response	Merck Response dated 29 July 2015 to the GUK DPS.
Merck Generics Group	Merck's generics businesses under the control of MGH.
Merck SO Written Response	Merck Response dated 7 August 2013 to the SO.
MGH	Merck Generics Holding GmbH.
[REDACTED]1	Signed transcript of post-SSO interview with [GSK's Finance Director A].
[REDACTED]WS1 (Alpharma)	Witness statement of [GSK's Finance Director A] in the Alpharma Litigation, dated 10 June 2002.
[REDACTED]WS1 (Apotex)	Witness statement of [GSK's Finance Director A] in the litigation between GSK and the Apotex Parties, dated 22 October 2002.
[REDACTED]WS1 (GUK)	Witness statement of [GSK's Finance Director A] in the GUK Litigation, dated 25 September 2001.
[REDACTED]WS2 (Alpharma)	Second witness statement of [GSK's Finance Director A] in the Alpharma Litigation, dated 30 July 2002.
[REDACTED]WS2 (Apotex)	Witness statement of [GSK's Finance Director A] in the litigation between GSK and the Apotex Parties, dated 11 November 2002.
[REDACTED]WS2 (GUK)	Second witness statement of [GSK's Finance Director A] in the GUK Litigation, dated 20 October 2001.
[REDACTED]1	Transcript of interview with [the Chief Executive of Merck Generics Group] on 25 May 2012, dated 17 December 2012.

Term	Definition
Neolab	Neolab Limited.
NGFA Decision	The no grounds for action decision issued by the CMA on 12 February 2016.
Norton	Norton Healthcare Limited (which previously traded as IVAX Pharmaceuticals UK).
Parties	The undertakings listed at paragraph 1.2 of this Decision, each a 'Party'. This term may be used in relation to all Parties and/or one or more of the Parties as specified.
Patent Dispute	A disagreement concerning GSK's paroxetine patents either prior to litigation being initiated (in the case of IVAX, and in the event that IVAX entered the market independently of GSK) or which was the subject of litigation (in the case of Alpharma and GUK). The term Patent Disputes is used in relation to more than one of these disagreements, as specified.
Project Dyke	An internal, global project team at GSK that existed from 1999 to 2004.
Proposed NGFA Decision	The proposed no grounds for action decision issued by the CMA on 30 June 2015.
Relevant Period	The period encompassing the various durations of the Infringements, together being the period from 3 October 2001 to 1 July 2004.
[X]WS2	Witness statement of [GSK's Finance Director B], signed 23 July 2014.
[X]WS	Witness statement of [GUK's General Manager] in the GUK Litigation, dated 15 October 2001.
SB	SmithKline Beecham.
[X]WS	Witness statement of [IVAX's Commercial Director], dated 2 December 2012.
Second Addendum	The second addendum to amend the IVAX-GSK Agreement dated 12 September 2002.

Term	Definition
Second Letter of Facts	Letter of facts issued by the CMA on 1 September 2015.
Seroxat	GSK's branded paroxetine product.
Side Letter	The supplemental letter to the IVAX-GSK Agreement dated 3 October 2001.
SO	Statement of Objections issued by the OFT on 19 April 2013.
SO Addressees	The Parties and IVAX.
SSO	Supplementary Statement of Objections issued by the CMA on 21 October 2014.
Teva	Teva Pharmaceutical Industries Limited.
Teva Second Section 26 Notice	Section 26 Notice dated 23 March 2012 sent to Teva, added to on 26 March 2012 and 5 April 2012.
Teva SO Written Response	Teva Response dated 3 July 2013 to the SO.
Third Addendum	The third addendum to amend the IVAX-GSK Agreement dated 20 November 2002.
Third Letter of Facts	Letter of facts issued by the CMA on 12 January 2016.
[X]WS	Witness statement of [Alpharma ApS's Sales and Marketing Director], signed 21 July 2014.
[X]WS	Witness statement of [Alpharma ApS's Director of Intellectual Property and Technology Affairs] in the Alpharma Litigation, dated 21 June 2002.
Waymade	Waymade Healthcare Plc.
Xellia	Xellia Pharmaceuticals ApS (formerly Alpharma ApS).
Xellia-Zoetis	Xellia and Zoetis. ¹⁶⁰⁸

¹⁶⁰⁸ Xellia and Zoetis submitted joint representations in this Investigation.

Term	Definition
Xellia-Zoetis DPS Written Response	Xellia-Zoetis Response dated 14 August 2015 to the Alharma DPS.
Xellia-Zoetis SO Written Response	Xellia-Zoetis Response dated 7 August 2013 to the SO.
Zoetis	Alharma LLC (formerly Zoetis Products LLC, Alharma LLC and Alharma Inc).

B. Defined Terms specific to the pharmaceutical industry

Term	Definition
API	Active Pharmaceutical Ingredient (of a pharmaceutical product).
ATC	Anatomical Therapeutical Chemical, a classification system for medicines used by the World Health Organisation.
BNF	The British National Formulary.
DDD	Defined Daily Dose. A DDD is the assumed average maintenance dose per day for a drug used for its main indication in adult patients, as defined by the World Health Organization.
DH	The Department of Health.
EPhMRA	European Pharmaceutical Market Research Association, who produce a classification system for medicines.
EPO	The European Patent Office.
IMS	Intercontinental Medical Statistics, a company producing marketing research statistics for the pharmaceutical industry.
IPO	The Intellectual Property Office in the UK.
MA	A Marketing Authorisation for a medicinal product (also referred to as a 'product licence').
MAOI	A monoamine oxidase inhibitor, a type of antidepressant.

Term	Definition
Maudsley Guidelines	The South London and Maudsley NHS Trust Prescribing Guidelines 2001.
MCA	The Medicines Control Agency in the UK, now the MHRA.
MHRA	The Medicines and Healthcare Products Regulatory Agency.
NICE	National Institute for Health and Clinical Excellence.
PPRS	The Pharmaceutical Price Regulation Scheme.
R&D	Research and development.
SNRI	A serotonin norepinephrine re-uptake inhibitor, a type of antidepressant.
SPC	Supplementary Protection Certificate.
SSRI	A selective serotonin re-uptake inhibitor, a type of antidepressant (which includes paroxetine).
TCA	A tricyclic antidepressant.
WFSBP	World Federation of Societies of Biological Psychiatry.
WHO	World Health Organization.

C. Relevant legal terms, guidance and documents

Term	Definition
1999 VBER	The block exemption regulation relating to categories of vertical agreements (Commission Regulation (EC) No 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices, OJ L 336/21, 29.12.1999).
2004 TTBE Guidelines	Commission Notice: Guidelines on the application of Article 81 of the EC Treaty (now Article 101 TFEU) to technology transfer agreements, OJ C 101/2, 27 April 2004.
2010 VBER	The block exemption regulation relating to categories of vertical agreements (Commission Regulation (EC) No 330/2010 on the

Term	Definition
	application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices, OJ L 102 of 23.4.2010).
Act	Competition Act 1998.
Article 101(3) Guidelines	The Commission's Guidelines on the Application of Article 81(3) of the Treaty (now Article 101(3) of the TFEU), OJ C101/97, 27 April 2004.
Article 101 TFEU	Article 101 of the TFEU.
Article 102 TFEU	Article 102 of the TFEU.
CAT	The Competition Appeal Tribunal.
Chapter I prohibition	The prohibition imposed by section 2(1) of the Competition Act 1998.
Chapter II prohibition	The prohibition imposed by section 18(1) of the Competition Act 1998.
CJ	The Court of Justice.
CMA	Competition and Markets Authority.
CMA8	Competition Act 1998: Guidance on the CMA's investigation procedures in Competition Act 1998 cases (CMA8, March 2014).
Commission	The European Commission.
EEA	The European Economic Area.
Effect on Trade Guidelines	The Commission's Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty (now Articles 101 and 102 of the TFEU), OJ C101/81, 27 April 2004.
EU	The European Union.
GC	The General Court.

Term	Definition
Horizontal Guidelines	The Commission's Guidelines on the applicability of Article 101 TFEU to horizontal cooperation agreements, OJ C 11/1, 14 January 2011.
Market Definition Notice	The Commission's Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372/5, 9 December 1997.
Modernisation Regulation	Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ L 1/1, 4 January 2003.
OFT	Office of Fair Trading.
OFT403	<i>Market Definition</i> (OFT403, December 2004), adopted by the CMA.
Penalty Guidance	<i>Guidance as to the appropriate amount of a penalty</i> (OFT423, 10 September 2012), adopted by the CMA.
Section 26 Notice	A notice sent by the OFT/CMA under section 26 of the Act.
Section 27 Notice	A notice sent by the OFT/CMA under section 27 of the Act.
Sector Inquiry	The Pharmaceutical Sector Inquiry was launched by the Commission on 15 January 2008. The Sector Inquiry dealt with the alleged obstacles to market entry for prescription medicines for human use.
Sector Inquiry Final Report	The Commission's final report, <i>Pharmaceutical Sector Inquiry Final Report</i> , published 8 July 2009.
TFEU	Treaty on the Functioning of the European Union.
UK	United Kingdom.
Vertical Agreements Exclusion Order	The Competition Act 1998 (Land and Vertical Agreements Exclusion) Order 2000, SI 2000/310.

D. Key persons in the Investigation

The table below provides the names and roles of the key persons who were involved, in some way, in the consideration, negotiation and execution of the Agreements, or the events surrounding those Agreements, during the Relevant Period and who are frequently referred to in the Decision.

Agreements, or the events surrounding those Agreements, during the Relevant Period and who are frequently referred to in the Decision.

Name	Role in the Relevant Period
GSK	
[✂]	Marketing Director for Seroxat, GSK (UK)
[✂]	Marketing Manager for Seroxat [A], GSK (UK), until January 2002
[✂]	Marketing Manager for Seroxat [B], GSK (UK), from January 2002
Name	Role in the Relevant Period
[✂]	Finance Director [B], GSK (UK), from 2003
[✂]	Finance Director [A], GSK (UK) until 2003
[✂]	Associate General Counsel, Legal Operations Europe, GSK
[✂]	Pricing Manager, GSK (Europe)
[✂]	Patent attorney, GSK
IVAX	
[✂]	Managing Director, IVAX
[✂]	Head of New Business Development and later Director of New Business Development, IVAX
[✂]	Commercial Director, IVAX from June 2001
[✂]	Sales and Marketing Manager, IVAX
[✂]	Head of Intellectual Property, IVAX
Alpharma	
[✂]	Director of Sales and Marketing, Alpharma Limited
[✂]	Managing Director, Alpharma Limited

[✂]	Sales and Marketing Director (Western Europe) / Vice President, New Products, Alharma ApS (Denmark)
[✂]	Vice President, Intellectual Property, Alharma Inc
[✂]	Director of Intellectual Property and Technology Affairs, Alharma ApS (Denmark)
[✂]	Patent Attorney, Alharma ApS (Denmark)
[✂]	Marketing Manager, Alharma Limited
[✂]	Chief Legal Officer, Alharma Inc
Name	Role in the Relevant Period
GUK	
[✂]	Head of Marketing, GUK
[✂]	Strategic Sourcing Specialist, Merck
[✂]	Commercial Director – Europe, Merck Generics
[✂]	Managing Director of GUK, Regional European Director of Merck Generics Group
[✂]	Sales and Marketing, GUK
[✂]	Head Corporate Business Development, Merck Generics (until August 2001). Head Pharmaceutical Division, Merck Japan (from September 2001).
[✂]	Senior Patents Manager, GUK
[✂]	Head of Merck Operation in Canada
[✂]	Head of Merck Operation in Australia (Alphapharm)
[✂]	Head of Patents and Raw Material Support Group, Merck
[✂]	General Manager/ Sales and Marketing Director, GUK
[✂]	Chairman of the Executive Board, Merck, 2000-05

[✂]	Head of Research and Development, GUK
[✂]	Commercial Director, GUK
[✂]	Chief Executive, GUK and Merck Generics Group
Other	
[✂]	Managing Director, Tillomed
[✂]	Independent industry consultant who provided evidence on the likely impact of generic competition for GSK in paroxetine patent litigation.

ANNEX B: IVAX-GSK AGREEMENT

A. Introduction

- B.1 This Annex sets out the CMA's findings on IVAX's position as a potential competitor to GSK at the time the IVAX-GSK Agreement was entered into, the purpose of the cash payment and other value transfers within the IVAX-GSK Agreement, and their likely effects on competition in the relevant market. Those findings are relied on in Part 8 as regards GSK's abuse of a dominant position. Other findings regarding the content of the IVAX-GSK Agreement are referred to in relation to the context of the GUK-GSK Agreement (under the Chapter I prohibition and Article 101 TFEU) and the Alpha-GSK Agreement (under the Chapter I prohibition).
- B.2 As described at paragraphs 3.219 to 3.227, GSK and IVAX entered into the IVAX-GSK Agreement on 3 October 2001, and it was subsequently amended and/or renewed on four occasions, before its termination took effect on 29 June 2004. In addition, GSK and IVAX entered into the Side Letter dated 3 October 2001. A summary of the terms of the IVAX-GSK Agreement and Side Letter is set out at paragraphs 3.220 to 3.222.

B. IVAX's position as a potential competitor to GSK

- B.3 At the time the IVAX-GSK Agreement was entered into, there were real concrete possibilities for IVAX to supply paroxetine in the UK independently of GSK (through each of the options set out below, taken individually or collectively). Thus, IVAX was a potential competitor. The CMA refers to the elements listed below, which are addressed in turn in the following paragraphs:
- IVAX had the capability to supply into the UK generic paroxetine sourced independently of GSK. IVAX had committed significant time and resources in taking steps to enable it to supply generic paroxetine in the UK through each of the following options:
 - Their own product supply (see paragraphs B.6 to B.9);
 - Third party supply from GUK (see paragraphs B.21 to B.25);
 - Third party supply from Tillomed (see paragraphs B.33 to B.36).
 - The prospect of future litigation being brought by GSK against IVAX did not constitute an insurmountable barrier to entry.

- The fact that GSK was willing to make substantial values transfers to IVAX is a strong indication that GSK perceived it as a credible threat, and that it exerted competitive pressure on GSK. GSK was aware that if generic suppliers were successful in their efforts to enter the market prior to the expiry of its Anhydrate Patent (due in 2016), the prices and profits that GSK could have sustained in the UK paroxetine market would have decreased substantially. GSK's expected returns,¹⁶⁰⁹ taking account of the potential that its returns would be substantially lower if generic suppliers were successful in their efforts to enter the market, were therefore lower as a result of the constraint from the threat of IVAX's generic entry.

i) IVAX's capability

B.4 During the Relevant Period, Norton traded as IVAX Pharmaceuticals UK and was a subsidiary of the IVAX Corporation (now 'IVAX LLC'), a major multinational developer of pharmaceutical products. In 2001, IVAX was one of the largest UK providers of generic medicines in the UK (by volume).¹⁶¹⁰ It therefore had experience in developing and bringing generic medicines to market in the UK (and in other countries worldwide), and the general capability to develop and bring medicines such as paroxetine to market.¹⁶¹¹

B.5 At the time the IVAX-GSK Agreement was entered into, IVAX had taken a number of steps towards enabling it to supply generic paroxetine sourced independently of GSK in the UK. As set out at paragraphs 3.166 to 3.209, IVAX had, in particular, explored the following options:

- IVAX launching its own product (by sourcing API from BASF);¹⁶¹² and
- sourcing a product from a third party (GUK or Tillomed).

a) Own product supply

B.6 As set out at paragraphs 3.166 to 3.187, IVAX had:

¹⁶⁰⁹ That is, the average of its possible profits going forward, taking account of the potential revenue and costs associated with each possible outcome (for example, the success or otherwise of independent generic entry), and the likelihood associated with each.

¹⁶¹⁰ [REDACTED]WS2 (document 1325), paragraph 12 (note: the body text refers to 2001, but the source document relates to 2002.)

¹⁶¹¹ See [REDACTED]WS (document 2333), paragraph 2.3 stating that IVAX typically developed around 50% of new products through its in-house development pipeline and around 50% from third parties through 'in-licensing'.

¹⁶¹² Or, at the time of the First Addendum, using the MA that IVAX sourced from Tillomed.

- actively made preparations to enter the UK paroxetine market, with IVAX having first started in 1999 to investigate supplying its own paroxetine product;
- identified and obtained a source of paroxetine API, in this case BASF;
- received an MA in Ireland, IVAX having submitting the relevant application in June 2000, and the Irish Medicines Board having finally accepted it in September 2001. This MA could then be used as a basis for IVAX to obtain an MA in the UK through the mutual recognition procedure; and
- in response to concerns within IVAX that its product might potentially infringe GSK's Hemihydrate Patent, IVAX considered introducing a low humidity manufacturing suite, which would reduce the risk of conversion. There is no indication that IVAX understood that such an upgrade would not be feasible, although it appears that IVAX never fully investigated the feasibility of the upgrade.

B.7 It is evident from paragraph B.6 that IVAX invested significant time and resources in preparation for supplying its own paroxetine product. IVAX pursued this with the awareness that GSK held a number of patents regarding paroxetine and so would have been aware that it may have faced patent infringement claims from GSK in the future.¹⁶¹³ Such knowledge did not, however, stop IVAX from continuing its preparations to enter the UK paroxetine market before entering into the IVAX-GSK Agreement.

B.8 Although the process of developing its own product raised potential conversion risks (and possible delays to entry with its own product), the contemporaneous evidence demonstrates that, at the time of entering into the IVAX-GSK Agreement, IVAX was continuing with its efforts to develop its own product,¹⁶¹⁴ and that the investment necessary to implement the potential solution which IVAX had identified would not have been significant for a business of IVAX's size and resources. Indeed, even after the IVAX-GSK Agreement was entered into, IVAX intended to '*continue to develop it's* [sic]

¹⁶¹³ See, for example [§]WS dated 18 January 2013 (Document 2334), paragraphs 3.2–3.7, "Seroxat (Paroxetine): 14 March 2001 dated 14 March 2001" (Document 1699) and [§]WS dated 13 February 2013 (Document 2333), paragraph 4.14.

¹⁶¹⁴ Document entitled 'New Product Delivery (In House Development & Licensed In) Monthly Report – September 2001' (document 1711); Minutes from the paroxetine team meeting on 11 September 2001 (document 1714).

own [paroxetine] formulation', indicating that further development of its own product remained feasible.¹⁶¹⁵

- B.9 In addition, at the time IVAX entered into the First Addendum (whereby the period of the IVAX-GSK Agreement was extended for a further two years),¹⁶¹⁶ IVAX had a further route to market by developing its own product using the Tillomed MA.¹⁶¹⁷ The CMA notes that possession of the Tillomed MA would have enabled IVAX to take steps to manufacture a product by reference to that MA.¹⁶¹⁸ As set out at paragraph 3.207, in consideration, IVAX agreed to pay Tillomed a royalty of 50% of the net profit it made from the sale of paroxetine in the UK (including from the sale of GSK's paroxetine). Witness evidence from [IVAX's Commercial Director] states that:

[a]n MA is an MA. You can vary it ... an MA ... a dossier is very valuable, ... if you're able to manufacture against that dossier'.¹⁶¹⁹

Representations in relation to own product supply

- B.10 In summary, GSK and/or Teva contended that:
- IVAX did not have a commercially viable product available at the time of entering the IVAX-GSK Agreement that it could have used to enter the market within a short period of time.¹⁶²⁰
 - IVAX encountered insurmountable difficulties in the production of paroxetine anhydrate,¹⁶²¹ in particular as regards conversion of paroxetine from anhydrate to hemihydrate during the production process (thus infringing GSK's Hemihydrate Patent).¹⁶²²

¹⁶¹⁵ Document entitled 'New Product Delivery (In House Development & Licensed In) Monthly Report – October 2001' (document 1719).

¹⁶¹⁶ First Addendum (document 0205). IVAX and GSK entered into this, on 15 February 2002, to amend the IVAX-GSK Agreement so as to extend the IVAX-GSK Agreement for a period of 24 months from 1 December 2002.

¹⁶¹⁷ IVAX-Tillomed Supply Agreement (document 1751). IVAX-Tillomed Heads of Agreement (document 1725).

¹⁶¹⁸ This is consistent with [X]WS (document 2332), paragraph 5.3 in which [IVAX's Commercial Director] mentioned that: 'Having the MA from Tillomed provided IVAX with an additional option if the agreement with GSK did not work out as planned'.

¹⁶¹⁹ Transcript of interview with [IVAX's Commercial Director] on 18 May 2012, dated 9 August 2012 (document 2143), page 35.

¹⁶²⁰ Teva SO Written Response (document 2750), paragraph 76.

¹⁶²¹ Teva SO Written Response (document 2750), paragraphs 79–89. See also GSK SO Written Response (document 2755), paragraph 5.11.

¹⁶²² Teva SO Written Response (document 2750), paragraphs 80–82.

- There is no evidence that investment in a low-humidity packaging suite was an actual solution; a ‘mere “potential” solution’ is not sufficient.¹⁶²³
- The CMA’s analysis relies on a single comment in one document suggesting that the investment would cost in the order of £50,000, whereas Teva engineers consider that it would have cost several times that amount.¹⁶²⁴
- According to GSK, the fact IVAX was considering third party sources of supply demonstrates that it had little faith in the viability of its own product.¹⁶²⁵

B.11 The CMA does not accept these contentions. At the time of the IVAX-GSK Agreement, IVAX had real concrete possibilities to enter the market and supply paroxetine independently of GSK:

- IVAX was continuing with its efforts to develop its own product, and the investment necessary to the potential solution it had identified would not have been significant for a business of IVAX’s size and resources.¹⁶²⁶ IVAX did not face insurmountable barriers to produce a paroxetine anhydrate product.
- IVAX was actively seeking potential solutions to reduce the possible risk of conversion, and it intended to ‘*continue to develop it’s [sic] own [paroxetine] formulation*’.¹⁶²⁷
- The low-humidity manufacturing suite was one way that IVAX was considering to address concerns that it potentially infringed GSK’s Hemihydrate Patent.
- The fact that IVAX was also considering routes to market other than self-supply does not undermine the CMA’s findings. GSK understood that, in the absence of the IVAX-GSK Agreement, IVAX would have launched a

¹⁶²³ Teva SO Written Response (document 2750), paragraphs 87–88. See also GSK SO Written Response (document 2755), paragraph 5.19.

¹⁶²⁴ Teva SO Written Response (document 2755), paragraph 88. IVAX internal document entitled ‘Seroxat: paroxetine, 14 March 2001’, dated 14 March 2001 (document 1699).

¹⁶²⁵ GSK SO Written Response (document 2755), paragraph 5.11.

¹⁶²⁶ See paragraph B.8 and *SmithKline Beecham Plc v Generics (UK) Limited*, transcript of hearing before Jacob J, dated 23 October 2001 (document 0911), page 8, where Jacob J held: ‘*I must also consider the effect on Norton. They are free to enter the generic market with product other than that bought from the patentees. The evidence indicates that they were close to doing it, one way or another, with a product within the patent or without – I am not quite sure.*’

¹⁶²⁷ Document entitled ‘New Product Delivery (In House Development & Licensed In) Monthly Report – October 2001’ (document 1719).

paroxetine product independently of GSK (see paragraph 3.234) or that entry 'at risk' was a real possibility.¹⁶²⁸

- B.12 GSK and Teva also submitted that IVAX's MA in Ireland did not provide a commercially viable route to market, that having an MA does not equate to having a product, and that the grant of an MA results from an approval process which takes no account of potential patent issues.¹⁶²⁹ Furthermore, IVAX stated that the mutual recognition process would have led to a significant delay of at least 15 months in any launch strategy for an IVAX in-house product.¹⁶³⁰ GSK also submitted that the basis for IVAX's application of the MA in Ireland was to give '*strong grounds for discussions*' with third parties in the UK.¹⁶³¹
- B.13 The CMA does not agree with IVAX's estimate of the duration of the mutual recognition process which is governed by time limits (see paragraphs 3.88 and 3.89).¹⁶³² In his witness statement, [GSK's Finance Director A] stated that the granting of MAs for essentially similar products could take as little as seven months¹⁶³³ from the date of application (which was also the average length of time found by the Sector Inquiry).¹⁶³⁴ In this regard it is relevant that GUK was granted a UK MA (following the mutual recognition process) approximately five months from the date it submitted its mutual recognition application (see paragraphs 3.252 to 3.254). Further, IVAX's estimate is also inconsistent with the Commission's findings in *Lundbeck* that mutual recognition would normally take around seven months if all went well and no objections were made to the application.¹⁶³⁵ In relation to the use of the Irish MA as grounds for discussions with third parties, the CMA notes that this does not prevent the Irish MA from also forming part of a route to market for IVAX's own product. Indeed, the document referred to by GSK also refers to the launch of the IVAX product '*when the patent issues are resolved by reasonable testing or if the existing patent is overturned by a 3rd party*'.¹⁶³⁶

¹⁶²⁸ GSK SO Written Response (document 2755), paragraph 4.41.

¹⁶²⁹ Teva SO Written Response (document 2750), paragraph 91. GSK SO Written Response (document 2755), paragraphs 5.11 and 5.22–5.29.

¹⁶³⁰ Teva SO Written Response (document 2750), paragraph 92.

¹⁶³¹ GSK SO Written Response (document 2755), paragraph 5.26–5.28.

¹⁶³² The CMA notes that the exact timescale would depend on the validity of the application.

¹⁶³³ [X]WS1 (GUK) (document 0885), paragraph 7.7.

¹⁶³⁴ Sector Inquiry Final Report, Executive Summary, section 2.1.2.

¹⁶³⁵ Commission Decision of 19 June 2013, *Lundbeck*, Case AT.39226, recitals 85 to 87. The Commission notes that to the extent that an application is incomplete or incorrect, delays could be incurred. Moreover, if one or more of the other Member States considered that granting a marketing authorisation entailed a risk to public health, Directive 2001/83 foresaw if necessary a procedure leading to a binding decision at EC level.

¹⁶³⁶ GSK SO Written Response (document 2755), paragraph 5.26. Document entitled 'New Product Delivery (In House Development & Licensed In) Monthly Report – September 2001' (document 1711), page 10.

- B.14 Teva and GSK submitted that, had IVAX launched its own product, GSK would have commenced litigation.¹⁶³⁷ According to Teva, any such litigation would have been protracted and likely to last for as long as the action against Apotex.¹⁶³⁸ If IVAX had lost, GSK would have claimed damages which Teva said would not have been a reasonable outcome for IVAX.¹⁶³⁹
- B.15 In relation to the relevant litigation, the CMA notes that, at the time the IVAX-GSK Agreement was entered into, the grant of injunctions was rare (see paragraph 3.279 and footnote 434).¹⁶⁴⁰ On that basis, it would have been reasonable for IVAX to expect that, had it pursued the development of its own product, it would have been possible for it to enter the market as soon as its product was finalised and a UK MA had been granted.
- B.16 The CMA accepts that any litigation with GSK had the potential to delay the date of IVAX's entry. However, the potential for delays did not prevent IVAX from being a potential competitor with real concrete possibilities to enter the market independently of GSK, and IVAX's presence as a potential competitor exerted competitive pressure on GSK.¹⁶⁴¹
- B.17 The CMA accepts that had IVAX lost any patent litigation with GSK (resulting from IVAX's entry into the UK paroxetine market), and had its entry not been enjoined prior to such litigation, IVAX would have likely faced a claim for damages from GSK. Even so, that risk did not stop or discourage IVAX from continuing to develop its own product (and exploring the option of sourcing a product from a third party) until it entered into the IVAX-GSK Agreement. IVAX's preference for the terms of the IVAX-GSK Agreement does not undermine the conclusion that it had real concrete possibilities for entering the UK paroxetine market with its own product.
- B.18 GSK submitted that the fact IVAX was considering sourcing API from Knoll/BASF does not demonstrate an ability to enter the market (GSK refers to the court's findings in BASF¹⁶⁴² regarding validity).¹⁶⁴³ GSK further noted

¹⁶³⁷ GSK SO Written Response (document 2755), paragraph 5.24.

¹⁶³⁸ Teva SO Written Response (document 2750), paragraph 92.

¹⁶³⁹ Teva SO Written Response (document 2750), paragraph 73 and 94.

¹⁶⁴⁰ See also Witness statement of [GSK's Finance Director A] dated 1 August 2013 (document A 0059), paragraph 3.6.

¹⁶⁴¹ In the Judgment of 3 April 2003 in *BaByliss SA v Commission*, T-114/02, ECR,EU:T:2003:100, paragraph 102, the GC noted that: *'[t]he mere fact it takes longer than planned to enter the market does not mean that such entry will not take place, particularly since ... the cost and time necessary for entering a new product market may be considerable.'*

¹⁶⁴² *BASF AG v SmithKline Beecham Plc* [2003] EWCA Civ 872.

¹⁶⁴³ GSK SO Written Response (document 2755), paragraphs 5.20–5.21. See also Teva SO Written Response (document 2750), paragraph 74.

that the supply agreement between IVAX and BASF was unsigned, and referred to stability and patent issues with the BASF product.¹⁶⁴⁴

- B.19 Although the BASF supply agreement was unsigned, IVAX and BASF invested time and resources in negotiating the terms of an agreement. This supports the fact that IVAX was pursuing the launch of its own product at the time the IVAX-GSK Agreement was entered into, and the CMA's overall conclusion (based on the reasoning set out at paragraphs B.6 to B.9) that IVAX had real concrete possibilities to enter the UK paroxetine market independently of GSK (with its own product supply).
- B.20 The CMA notes [IVAX's Commercial Director's] witness evidence that IVAX had no commercially viable option other than to obtain paroxetine supplied from GSK.¹⁶⁴⁵ However, [IVAX's Commercial Director] also indicated in his witness statement¹⁶⁴⁶ that at the time IVAX entered into the IVAX-GSK Agreement, the key consideration for IVAX was that it had no product of its own to launch in 2001 and that other third party suppliers would have carried greater infringement or product risks compared to taking supply of paroxetine from the originator, GSK. The potential difficulties and delays in entry referred to by [IVAX's Commercial Director] in relation to IVAX's own product did not constitute insurmountable barriers to entry and IVAX constituted a potential competitor at the time the IVAX-GSK Agreement was entered into.

b) Source a paroxetine product from a third party

- B.21 As set out at paragraph 3.188, during (and before) the Relevant Period, it was not uncommon for generic suppliers to source (or 'in-license') different medicines from one another as a way to expand their respective product portfolios. For example, the CMA understands that IVAX obtained supply of Omeprazole from GUK from January 2002 onwards, demonstrating that such

¹⁶⁴⁴ GSK SO Written Response (document 2755), paragraphs 5.20–5.21.

¹⁶⁴⁵ Teva SO Written Response (document 2750), paragraphs 84–85 and [X]WS (document 2332), paragraph 5.11.

¹⁶⁴⁶ [X]WS (document 2332), paragraph 5.11. [IVAX's Commercial Director] has used different language to refer to IVAX's options at the time of the IVAX-GSK Agreement. In the OFT's meeting with Teva on 24 April 2012, [IVAX's Commercial Director] variously stated that IVAX had 'no other options', had no 'secure' or 'solid' options, and that there had been no discussion 'of substance' with other suppliers. [IVAX's Commercial Director] later indicated that when referring to having no option that he meant that there was 'no other product that, (whether manufactured in house or sourced from a third party): (i) did not carry risk of infringement of patents; (ii) had a marketing authorisation; (iii) was capable of manufacture in accordance with the required specification' (Minutes of meeting between Teva and the OFT dated 24 April 2012 (document 2035), footnote 1). In [IVAX's Commercial Director's] witness statement to the OFT he stated that 'there was no commercially viable option open to IVAX apart from GSK', but also that 'Having the MA from Tillomed provided IVAX with an additional option if the agreement with GSK did not work out as planned' and that he was 'comparing GSK to other options', suggesting that he considered there were other options open to IVAX at the time of the IVAX-GSK Agreement. See [X]WS (document 2332), paragraphs 4.4, 5.3 and 6.8.

arrangements were in principle realistic and viable at the time the IVAX-GSK Agreement was entered into.

Supply from GUK

- B.22 As set out at paragraphs 3.189 to 3.197, IVAX had actively made preparations to enter the UK paroxetine market, with IVAX having first entered into negotiations with GUK around August 2001 regarding the supply of paroxetine from GUK to IVAX.
- B.23 These negotiations involved various senior IVAX employees, including [IVAX's Managing Director] and [IVAX's Commercial Director],¹⁶⁴⁷ and included discussions regarding anticipated potential volumes.¹⁶⁴⁸ Each of the witnesses formerly employed by IVAX recalled that discussions had taken place between IVAX and GUK before the IVAX-GSK Agreement was entered into.¹⁶⁴⁹
- B.24 Indeed, these discussions (characterised by [GSK's Finance Director A] as '*active negotiations*', based on information he obtained from [IVAX's Managing Director] and [IVAX's Commercial Director])¹⁶⁵⁰ had developed such that [GUK's Managing Director] considered that IVAX and GUK had a '*gentleman's agreement*' (albeit that it does not appear that IVAX saw things in the same way) (see paragraphs 3.196 to 3.197).¹⁶⁵¹ Although [IVAX's Managing Director] stated in his witness statement that he did not regard GUK as a '*serious option*' at the time, he also stated that IVAX had not rejected GUK's offer of supply (in [IVAX's Managing Director's] words, it was '*left [...] on the table*').¹⁶⁵²
- B.25 IVAX pursued the negotiations with GUK with the awareness that GSK held a number of patents regarding paroxetine and so would have been aware that it

¹⁶⁴⁷ See [REDACTED]WS (document 2332), paragraphs 5.4 and 5.6, for [IVAX's Commercial Director's] comment that '*I did have discussions with GUK about sourcing paroxetine from them at that time [2001]*'. In particular he noted that he had '*a couple or so telephone discussions*' with GUK regarding that issue.

¹⁶⁴⁸ See email from [GUK's Managing Director] to [the Chief Executive of Merck Generics Group] dated 8 August 2001 (document 0863), which stated: "*Furthermore, I'm negotiating with Norton & Hexal to supply them in the UK. I know Norton is keen with anticipated volume of +/-10mio tablets a year, but I'll firm up on that later.*" The e-mail reports that Norton was '*keen*' to obtain supply from GUK.

¹⁶⁴⁹ See, for example, [REDACTED]WS (document 2332), paragraphs 5.4–5.10.

¹⁶⁵⁰ [REDACTED]WS2 (GUK) Exhibit [REDACTED]5 (document 0888).

¹⁶⁵¹ Email from [IVAX's Head of New Business Development] to [IVAX's Commercial Director] dated 10 October 2001 (document 1795).

¹⁶⁵² See also [REDACTED]WS (document 2334) at paragraphs 4.4 and 4.2. Further, on entering into the IVAX-GSK Agreement, IVAX was sufficiently concerned that GUK would be able to supply generic paroxetine that GSK and IVAX entered into the Side Letter, which provided IVAX with certain assurances in relation to GSK's conduct of the GUK Litigation (document 0167).

may have faced patent infringement claims from GSK in the future, and that certain patent concerns may arise in relation to product sourced from GUK.

Representations in relation to product sourced from GUK

- B.26 Teva submitted that IVAX should not be regarded as a potential competitor insofar as it relied upon the possibility of obtaining a third party supply of paroxetine (from either GUK or Tillomed).¹⁶⁵³ The CMA rejects Teva's submission. The relevant question is whether IVAX had real concrete possibilities to enter the UK paroxetine market independently of GSK. In answering that question, it is pertinent to consider whether there was a realistic possibility of IVAX supplying paroxetine independently of GSK, including by sourcing the product from a third party.
- B.27 Teva submitted that GUK would not have been in a position to supply it with generic paroxetine,¹⁶⁵⁴ on the basis that: (i) GSK was granted an interim injunction against GUK when it sought to enter the market; (ii) IVAX had not entered into an agreement to receive GUK supply; (iii) the *'couple or so telephone discussions'*¹⁶⁵⁵ recalled by [IVAX's Commercial Director] had not progressed to the level of formal negotiations; and (iv) [IVAX's Managing Director] was clear that there was no *'gentleman's agreement'*¹⁶⁵⁶ with GUK to supply paroxetine.¹⁶⁵⁷ GSK submitted that IVAX did not have a serious option of entering the market with a product sourced from GUK.¹⁶⁵⁸ GSK referred to [IVAX's Managing Director's] comment that the offer had been left *'on the table'*, but stated that this comment needs to be read alongside other parts of his witness statement which indicate there was no *'substance to the discussions'*.¹⁶⁵⁹
- B.28 Despite submissions that the GUK Product would have been the subject of litigation proceedings, the CMA observes that at the time IVAX entered into the IVAX-GSK Agreement, GUK had not been enjoined and the parties would likely have perceived the prospect of any such injunction to be low (see paragraph 3.279 and footnote 434).¹⁶⁶⁰
- B.29 The CMA also observes that, although GSK may have commenced litigation and sought an injunction against IVAX in the event of its launch, as set out at

¹⁶⁵³ Teva SO Written Response, paragraphs 97–101.

¹⁶⁵⁴ Teva SO Written Response (document 2750), paragraphs 102–105.

¹⁶⁵⁵ [redacted]WS (document 2332), section 5.

¹⁶⁵⁶ [redacted]WS (document 2334), paragraph 4.4.

¹⁶⁵⁷ Teva SO Written Response (document 2750), paragraphs 103.

¹⁶⁵⁸ GSK SO Written Response (document 2755), paragraph 5.31.

¹⁶⁵⁹ GSK SO Written Response (document 2755), paragraph 5.32.

¹⁶⁶⁰ [redacted]1 (document 2330), pages 28–29.

paragraphs D.66 to D.77, the CMA considers that an interim injunction was not an insurmountable barrier to entry, and therefore does not preclude a finding of potential competition. Further, by the time IVAX was negotiating the First Addendum to the IVAX-GSK Agreement (see paragraph 3.223), although GUK was then subject to an interim injunction, IVAX would have been fully aware that GUK was in possession of a generic paroxetine product that had a UK MA.

- B.30 The CMA considers that the number of, and formality of, discussions between IVAX and GUK is not central to determining whether or not GUK represented a potential source of supply of generic paroxetine for IVAX. If GUK was not a credible commercial option, there would have been no reason to keep it on the negotiating table. On the basis that IVAX continued to perceive GUK to be an option (albeit IVAX submitted this is not its preferred option) IVAX must logically have formed the view that GUK represented a potential source of supply. Further, the evidence demonstrates that both GSK and GUK considered IVAX's negotiations with GUK to be credible (see paragraphs 3.195 to 3.196).
- B.31 The CMA recognises that, at the time the IVAX-GSK Agreement was entered into, IVAX did not have complete information as to GUK's ability to supply generic paroxetine and that it may have been unable to determine with certainty whether or not the product GUK referred to was a 'bluff'. However, IVAX's actions in progressing negotiations with GUK (including on supply volumes) indicate that it considered that GUK was, potentially, in a position to supply generic paroxetine. Further, on entering into the IVAX-GSK Agreement, IVAX was sufficiently concerned that GUK would be able to supply generic paroxetine that GSK and IVAX entered into the Side Letter,¹⁶⁶¹ which provided IVAX with certain assurances in relation to GSK's conduct of the GUK Litigation.
- B.32 The CMA also accepts that, had IVAX lost any patent litigation with GSK (resulting from IVAX's entry into the market with a product sourced from GUK), and had its entry not been injuncted prior to such litigation, IVAX would have likely faced a claim for damages from GSK. As already outlined above (see paragraph B.24), the CMA notes that, despite this risk, IVAX had determined that it made commercial sense to leave the GUK option 'on the table'.¹⁶⁶² Although IVAX ultimately entered into the IVAX-GSK Agreement,

¹⁶⁶¹ Side Letter (document 0167).

¹⁶⁶² [redacted] WS (document 2334), paragraph 4.2.

this does not undermine the conclusion that it had real concrete possibilities to enter the UK paroxetine market with the GUK Product.

Supply from Tillomed

B.33 As set out at paragraphs 3.198 to 3.209, IVAX had:

- entered into discussions with Tillomed in 2001 regarding Tillomed supplying IVAX with generic paroxetine. These discussions involved senior employees, including [IVAX's Managing Director] and [Tillomed's Managing Director];
- entered into the IVAX-Tillomed Heads of Agreement, which was negotiated before (and, on the face of the document, signed on the day after) the IVAX-GSK Agreement.¹⁶⁶³ The IVAX-Tillomed Heads of Agreement specifically committed both parties to use reasonable endeavours to enter into a supply agreement for Tillomed to supply IVAX with paroxetine, with supply to commence on 1 December 2001.¹⁶⁶⁴

B.34 IVAX pursued these negotiations with the awareness that GSK held a number of patents regarding paroxetine and so would have been aware that it may have faced patent infringement claims from GSK in the future, and that certain patent concerns may arise in relation to product sourced from Tillomed.

B.35 The CMA is aware that the Hexal product, which was the product which Tillomed would have supplied in the UK,¹⁶⁶⁵ was recalled from the market in Denmark in June 2001.¹⁶⁶⁶ There is mixed evidence regarding the reasons for withdrawal: [GUK's General Manager] suggested that the withdrawal was pursuant to a settlement agreement between Hexal and GSK in Denmark¹⁶⁶⁷, whereas [IVAX's Head of New Business Development] and GSK indicated that this may have been due to unspecified '*impurity*'¹⁶⁶⁸ or '*technical*' issues

¹⁶⁶³ See [REDACTED]WS (document 2334), paragraphs 5.8–5.9, in which [IVAX's Managing Director] explained that, in fact, he specifically recalled signing the IVAX-Tillomed Heads of Agreement before he signed the IVAX-GSK Agreement. The CMA's file includes draft versions of the IVAX-Tillomed Heads of Agreement, dated in late September 2001, indicating that negotiations were ongoing at that point (see documents 1715 and 1716).

¹⁶⁶⁴ Following entry into the IVAX-GSK Agreement, the deal with Tillomed was 'flipped' to instead involve the supply of the GSK Product by IVAX to Tillomed rather than for Tillomed to supply IVAX with the Tillomed paroxetine product (see paragraph B.36 and paragraphs 3.206–3.209).

¹⁶⁶⁵ Tillomed response dated 4 December 2012 to the Section 26 Notice dated 14 November 2012 (document 2337).

¹⁶⁶⁶ See IVAX internal document entitled 'Seroxat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699). See also GSK presentation entitled 'Seroxat Salts Success Stories' (document 0092) for the timing of the Hexal product withdrawal.

¹⁶⁶⁷ [REDACTED]WS (document 0901), paragraph 25.

¹⁶⁶⁸ Minutes from IVAX paroxetine team meeting on 14 August 2001 (document 1709).

with the product.¹⁶⁶⁹ However, whilst [IVAX's Managing Director] suspected that he was not '*free of doubt*' regarding the status of the Tillomed product, he recalls thinking that Tillomed was a '*strong option*' from which to obtain supply of paroxetine (see paragraph 3.202). In any event, IVAX was aware of the withdrawal of the Hexal product by 14 August 2001,¹⁶⁷⁰ following which it decided to engage in negotiations – and then to enter into the IVAX-Tillomed Heads of Agreement with Tillomed.

- B.36 Consistent with this, on 8 January 2002 (approximately three months after the IVAX-GSK Agreement was entered into), Hexal's subsidiary GEA succeeded in obtaining a UK MA in relation to paroxetine, showing that the MCA considered in early 2002 that the Hexal product was deemed safe for human use in the UK and could therefore be launched in the UK.¹⁶⁷¹ Further, in the subsequent IVAX-Tillomed Supply Agreement, IVAX agreed to purchase exclusive rights to the Tillomed MA for paroxetine and to pay Tillomed a significant royalty of 50% of the net profit on all sales of paroxetine that IVAX made (including from the sale of GSK's paroxetine).¹⁶⁷² This led to IVAX making considerable transfers of value to Tillomed (see paragraphs 3.207 to 3.208).¹⁶⁷³ An agreement which foresaw these transfers of value to Tillomed and the transfer of the Tillomed MA to IVAX, supports the CMA's conclusion that IVAX was a potential competitor, with real concrete possibilities to enter the UK paroxetine market with a product sourced from Tillomed.

¹⁶⁶⁹ [REDACTED]WS (document 2333), paragraph 8.6. [IVAX's Head of New Business Development], however noted that '*I am not sure we [IVAX] ever really knew the reasons why the product was withdrawn*', although he believed that '*it was more from a manufacturing perspective*'. See also [REDACTED]WS (document 0150), paragraph 4.8 and [REDACTED]WS1 (GUK) (document 0885), paragraph 7.5.

¹⁶⁷⁰ Minutes from IVAX paroxetine team meeting on 14 August 2001 indicate that [IVAX's Managing Director], who was involved in the negotiation of the IVAX-Tillomed Heads of Agreement, may have been aware of this himself, either because it had been mentioned to him by [IVAX's Head of New Business Development] or because he was already aware of it from another source: '[REDACTED] [IVAX's Head of New Business Development] to ask [REDACTED] [IVAX's Managing Director] if he knows why *Gea product* [that is, the Hexal product] was *withdrawn from Danish market*' (see document 1709).

¹⁶⁷¹ See Tillomed response dated 4 December 2012 to the Section 26 Notice dated 14 November 2012 (document 2337). In addition, GSK internal documents state that Hexal did successfully re-launch the generic product in Sweden in July 2002 (see GSK presentation entitled '*Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec*' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100).

¹⁶⁷² Tillomed has confirmed that the UK MA was not formally granted until 8 January 2002 (see Tillomed response dated 4 December 2012 to the Section 26 Notice dated 14 November 2012 (document 2337)). However, the CMA considers that under the rules on mutual recognition, and following discussions with the MHRA on this issue, Tillomed would have been aware at the Day 90 stage in the process that a UK MA would be granted in the near future. At Day 90, the Concerned Member State (in this case, the UK) normally agrees to grant a national marketing authorisation for the relevant product, which is then granted formally at a later date (see paragraphs 3.85–3.89 for further information relating to the procedure for obtaining an MA). Therefore, by May 2001, Tillomed would have been aware that it would receive a UK MA for paroxetine in the near future.

¹⁶⁷³ Based on the CMA's calculations using data submitted by IVAX and Tillomed.

Representations in relation to product sourced from Tillomed

- B.37 Teva and GSK submitted that there is very limited evidence relating to Tillomed's potential ability to supply IVAX, and as to why the IVAX-Tillomed Heads of Agreement was concluded.¹⁶⁷⁴ They submitted that none of the witnesses have a '*strong recollection*' of negotiations with Tillomed.¹⁶⁷⁵ GSK submitted that the fact the agreement was '*flipped*' after the IVAX-GSK Agreement was signed suggests that Tillomed '*did not have access to a product or at least to a non-infringing product*'.
- B.38 The CMA considers that IVAX's actions in entering into the IVAX-Tillomed Heads of Agreement (and subsequently into the flipped agreement to purchase the Tillomed MA) strongly indicate that IVAX considered Tillomed to be a realistic source of supply. If that were not the case, it would have made no logical sense for IVAX to have entered into those agreements. Further, the CMA refers to [IVAX's Managing Director's] statement that Tillomed was a '*strong option*' (see paragraph 3.202). The CMA notes that it is not necessary to establish that Tillomed could, with certainty, have supplied generic paroxetine, but rather whether there were real concrete possibilities for IVAX to enter the market (under this option, with supply from Tillomed). Further, the CMA notes that, for the IVAX-Tillomed Heads of Agreement to be an effective insurance policy from IVAX's perspective, Tillomed would have had to be able to supply a paroxetine product.
- B.39 The CMA notes that, despite Teva and GSK's representations on the recollection of witnesses, [IVAX's Managing Director] recalled that Tillomed were regarded as a '*strong option*' and refers to IVAX being ready to enter into a supply agreement with Tillomed if negotiations with GSK had not progressed.¹⁶⁷⁶ There is nothing in [IVAX's Managing Director's] evidence to suggest that the IVAX-Tillomed Heads of Agreement reflected anything other than an assessment that there were real concrete possibilities for IVAX to enter the UK paroxetine market with supply from Tillomed. Although in his witness statement, [IVAX's Managing Director] stated that: '*I also have a vague recollection of feeling at some point in 2001 that Tillomed was less of an option in 2001*' in the same paragraph, he stated: '*At the same time as discussing matters with Tillomed, discussions continued with GSK. I recall that Tillomed became my insurance. My memory is that I kept both options open.*' To the extent that any doubts did exist regarding Tillomed's ability to act as a supplier, as claimed by IVAX, they were not so significant as to

¹⁶⁷⁴ See, for example GSK SO Written Response (document 2755), paragraph 5.41–5.42 and 5.48.

¹⁶⁷⁵ See, for example, GSK SO Written Response (document 2755), paragraphs 5.41–5.42 and 5.48.

¹⁶⁷⁶ [§]WS (document 2334), paragraph 5.3 and 5.5.

dissuade [IVAX's Managing Director] from devoting time to negotiating with Tillomed and progressing the IVAX-Tillomed Heads of Agreement.

- B.40 Second, Teva and GSK stated that Tillomed did not have an MA in the UK at the time the IVAX-Tillomed Heads of Agreement were entered into and that Tillomed did not have a credible product,¹⁶⁷⁷ on the basis that: (i) Tillomed's parent's paroxetine product had been withdrawn from the market in Denmark due to manufacturing issues; (ii) Hexal, Tillomed's source of paroxetine, was in fact a potential customer of GUK a few weeks before the signing of the IVAX-Tillomed Heads of Agreement, which GSK stated calls into question whether Tillomed really was a '*serious contender*';¹⁶⁷⁸ and (iii) the subsequent MA was obtained in the name of GEA rather than that of Tillomed.¹⁶⁷⁹
- B.41 The CMA considers it is apparent that, although uncertainty existed as to Tillomed's MA position at the time of the IVAX-GSK Agreement, [IVAX's Managing Director] was satisfied that there was sufficient potential in the Tillomed product that negotiations should continue and the IVAX-Tillomed Heads of Agreement entered into.
- B.42 In addition, the CMA notes that IVAX had sufficient confidence in the Tillomed product to agree, under the '*flipped*' IVAX-Tillomed Supply Agreement, to purchase the Tillomed MA and to make considerable payments and product transfers worth £2.85 million in the period between 2001 to 2004 (see paragraphs 3.206 to 3.208).
- B.43 Third, Teva and GSK submitted that, if IVAX had launched with a product sourced from Tillomed, an injunction would have been sought and IVAX would have faced litigation.¹⁶⁸⁰
- B.44 As already outlined above (see paragraph B.34), the CMA notes that despite the risk of litigation (and potential damages claim from GSK), IVAX nevertheless decided to progress negotiations with Tillomed, and to enter into the IVAX-Tillomed Heads of Agreement. Further, the fact that [IVAX's Managing Director] considered that supply from Tillomed was a form of '*insurance*' (see paragraph 3.205) or back-up (see paragraph 3.209) is

¹⁶⁷⁷ Teva SO Written Response (document 2750), paragraph 108. GSK SO Written Response (document 2755), paragraph 5.43–5.45.

¹⁶⁷⁸ Teva SO Written Response (document 2750), paragraph 108. GSK SO Written Response (document 2755), paragraph 5.51.

¹⁶⁷⁹ GSK SO Written Response (document 2755), paragraph 5.47.

¹⁶⁸⁰ Teva SO Written Response (document 2750), paragraph 111. GSK SO Written Response (document 2755), paragraph 5.56.

consistent with Tillomed being a realistic route to market for IVAX (had it not entered into the IVAX-GSK Agreement).

B.45 Although IVAX ultimately entered into the IVAX-GSK Agreement, this does not undermine the conclusion that it had real concrete possibilities to enter the UK paroxetine market with a product sourced from Tillomed.

ii) *GSK's response to IVAX's proposed market entry was to secure an agreement that would incentivise IVAX to defer its efforts to enter the market independently of GSK*

B.46 GSK's actions in response to IVAX's proposed market entry support the CMA's conclusion that IVAX was a potential competitor with real concrete possibilities to enter the UK paroxetine market independently of GSK.

B.47 As explained in detail at paragraphs B.63 to B.131, GSK's response to IVAX's proposed entry was to commit to make value transfers to IVAX in order to incentivise IVAX to defer its efforts to enter the market independently of GSK. By entering into the Agreements, GSK committed to make value transfers to IVAX and the other Generic Companies that totalled at least £50.9 million.¹⁶⁸¹ The average annual value that GSK committed to transfer to the Generic Companies was equivalent to 37% of GSK's annual UK paroxetine profits.¹⁶⁸² These transfers were commercially rational for GSK only on the basis that they would be used to induce the Generic Companies to delay their potential independent entry (see also paragraphs 6.56 to 6.60 and 6.175 to 6.178).

B.48 The fact that GSK chose to make substantial cash payments and other value transfers to IVAX, and to supply IVAX with restricted volumes of generic paroxetine in the manner that it did, demonstrates that GSK perceived IVAX's proposed entry to be credible and that IVAX was a potential competitor. Had there been no real concrete possibility for IVAX to enter the relevant market, there would have been no reason for GSK to enter the IVAX-GSK Agreement. The CMA refers to the points made in paragraph 6.57 to 6.60 which apply equally here.

¹⁶⁸¹ This is made up of £17.9 million to IVAX, £21.3 million to GUK and £11.8 million to Alpharma, and has been calculated on the basis that none of the Agreements were terminated early, and sales by IVAX and GUK substituted for sales by parallel importers. Had IVAX's and GUK's sales instead substituted for GSK's own sales in the UK, then the value that GSK committed to transfer to the Generic Companies was £59.6 million (made up of £22.3 million to IVAX, £25.5 million to GUK and £11.8 million to Alpharma). For calculations see paragraph B.63 for IVAX, paragraph 6.91 for GUK and paragraph 6.155 for Alpharma.

¹⁶⁸² Calculated compared to GSK's profits from selling Seroxat 20mg and 30mg (excluding parallel imports or sales pursuant to the Agreements) of £51 million in 2002 (see Tables 4.2 and 4.3). The average annual value transfer was £18.9 million, based on the committed value for each contract year under the Agreements, on the basis that sales by IVAX and GUK would substitute for sales made by parallel importers rather than GSK's own UK sales. See paragraphs B.70 and 6.57 for further information.

iii) *IVAX and GSK's internal assessments as to their prospects in any subsequent litigation and of IVAX entering the UK paroxetine market independently of GSK*

- B.49 The CMA considers that the reasoning and evidence set out above is sufficient to show that IVAX constituted a potential competitor to GSK in the UK paroxetine market at the time the IVAX-GSK Agreement was entered into. There were real concrete possibilities for IVAX to enter the market independently of GSK.
- B.50 Teva submitted that internal documents and witness evidence demonstrate that IVAX was not confident that it would be able to enter the market independently of GSK and that there was no realistic possibility of IVAX entering the market independently of GSK, such that IVAX cannot therefore be considered a potential competitor of GSK. In this regard, the CMA observes that the assessment of whether there were real concrete possibilities for an undertaking to enter the market is by its nature an objective assessment, and does not depend on the individual subjective perceptions of an undertaking's staff that may vary from one day to the next.
- B.51 For completeness only, the CMA has nevertheless also examined the internal documents of IVAX and GSK, and relevant witness evidence, in order to assess their views on the prospects of IVAX entering the UK paroxetine market independently of GSK.
- B.52 As set out below, the internal documents confirm the analysis regarding IVAX's position as a potential competitor set out above. They in fact show that there was genuine uncertainty on both sides as to GSK's prospects of being able to prevent IVAX from bringing a generic paroxetine product to market independently of GSK. The contemporaneous evidence indicates that IVAX would not have been willing to abandon its efforts to enter the market without sufficient compensation. They therefore confirm the conclusions from the objective evidence, considered above.

a) *IVAX's documents*

- B.53 Teva submitted that it believed the IVAX product infringed GSK's Hemihydrate Patent (due to the risk of conversion), and that it was not confident that it had a generic product to launch that carried a commercially acceptable degree of IP risk.¹⁶⁸³ In relation to GUK, Teva pointed to a lack of confidence in GUK to

¹⁶⁸³ Teva SO Written Response (document 2750), paragraphs 76–77, 83–84. See also GSK SO Written Response (document 2755), paragraphs 5.14–5.16, 5.33 and 5.48.

supply product, and a concern on the part of GUK that it may not prevail in the patent case.¹⁶⁸⁴ In relation to Tillomed, Teva referred to there being no recollection of Tillomed being a *'serious option'*, and submitted that Tillomed was unsure as to whether it would be in a position to supply IVAX with the required volumes of product.¹⁶⁸⁵

B.54 Teva's submissions on this issue do not reflect the position that emerges from the internal documents and witness evidence (below). The evidence shows that there was genuine uncertainty on both sides as to GSK's prospects of being able to prevent IVAX from bringing a generic paroxetine product to market independently of GSK. The evidence also shows that IVAX was keeping its options open in relation to sources of supply of paroxetine other than GSK and regarded those other options as credible alternatives.

B.55 First, [IVAX's Managing Director] noted in March 2001 that:

*'NHC [Norton Healthcare] claim 'there is sufficient information ... for a skilled man to reproduce' and therefore an anhydrous version can be made.'*¹⁶⁸⁶

B.56 This is consistent with [IVAX's Head of New Business Development]'s statement that he had no recollection that [X], IVAX's intellectual property expert, had any concerns about the *'anhydrous patents'*.¹⁶⁸⁷

B.57 The CMA notes that, despite conversion concerns, it is evident that IVAX considered that there was potential to overcome such issues, and was actively considering changes to its manufacturing processes with a view to doing so (see paragraphs 3.166 to 3.218 and B.6).

B.58 In relation to supply from GUK, [IVAX's Managing Director] stated that he did not accept there was *'gentleman's agreement'* for IVAX to obtain supply from GUK, and that he did not consider GUK to be a *'serious option'*. However, [IVAX's Managing Director] did acknowledge that GUK was an option which remained *'on the table'*¹⁶⁸⁸ (see paragraphs 3.196 to 3.197 and B.24).

¹⁶⁸⁴ Teva SO Written Response (document 2750), paragraphs 102–105. See also Slides for Teva SO Oral Hearing dated 14 October 2013 (document 3138R), slide 18.

¹⁶⁸⁵ Teva SO Written Response (document 2750), paragraphs 106 and 110. See also Slides for Teva SO Oral Hearing dated 14 October 2013 (document 3138R), slide 18.

¹⁶⁸⁶ [IVAX internal document entitled 'Seroxat: paroxetine: 14th March 2001' dated 14 March 2001 (document 1699).

¹⁶⁸⁷ [X]WS (document 2333), paragraph 4.18.

¹⁶⁸⁸ [X]WS (document 2334), paragraphs 4.2 and 4.4.

B.59 In relation to supply from Tillomed, [IVAX's Managing Director] considered that Tillomed remained an option:¹⁶⁸⁹

- [IVAX's Managing Director] recalled that Tillomed was a '*strong option*' for supply of paroxetine at that time (see paragraphs 3.202 and B.34).
- [IVAX's Managing Director] confirmed that, while he was not '*free of doubt*', he could not recall being aware of any patent infringement concerns with the Tillomed product on the basis that GSK had not forced it from the market outside of the UK. [IVAX's Managing Director] did not believe that he would have entered into the IVAX-Tillomed Heads of Agreement if there were reasons, such as patent concerns, why Tillomed would not have been in a position to supply IVAX:

*'I do not recall being aware of any issues with the Tillomed product at the time, specifically any IP issues. I cannot remember what I knew at this particular time about the Tillomed product, however I do not believe that I would have signed the Heads of Agreement with Tillomed if I considered that there were reasons to believe that Tillomed would not be able to supply IVAX.'*¹⁶⁹⁰

*'At that time, I think my understanding was that Tillomed did not have any IP issues with its product because the product that had been launched by Gea outside the UK and had not, until then, been forced off the market by GSK. On that basis, I considered the Tillomed product as a strong option.'*¹⁶⁹¹

- This is consistent with evidence from [REDACTED], Tillomed's Managing Director. Tillomed confirmed to the OFT that, subject to obtaining supplies from Hexal and obtaining regulatory approval, Tillomed had itself been intending to launch in the UK.
- [IVAX's Head of New Business Development] noted that he expected IVAX would have considered Tillomed to have a viable product in order to make royalty payments under the IVAX-Tillomed Supply Agreement:¹⁶⁹²

'In order to reach this agreement with Tillomed, I expect that IVAX considered that Tillomed must have had a viable product otherwise

¹⁶⁸⁹ [IVAX's Head of New Business Development] and [IVAX's Commercial Director] stated that they had no recollections of the negotiations with Tillomed and do not recall being involved in these negotiations: see [REDACTED]WS (document 2332), paragraphs 5.2–5.3, and [REDACTED]WS (document 2333), paragraph 5.5.

¹⁶⁹⁰ [REDACTED]WS (document 2334), paragraph 5.7.

¹⁶⁹¹ [REDACTED]WS (document 2334), paragraph 5.3.

¹⁶⁹² [REDACTED]WS (document 2333), paragraphs 8.5–8.6.

IVAX would not have done a deal. Presumably IVAX felt there was sufficient validity in Tillomed's claims to make it worthy of IVAX paying Tillomed 50% of its profit. However, this is conjecture on my part. I cannot recall whether this was the case or not.

If IVAX had thought the Tillomed product was definitely not viable, it is highly likely that it would have told Tillomed that there was no deal on the table, unless there were other 'trade offs' under discussion. However, in the absence of any trade-offs, it is my assumption that there must have been an element of belief between IVAX and GSK that Tillomed had a product that it could potentially bring to market notwithstanding the withdrawal of the Gea product from Denmark. I am not sure we ever really knew the reasons why the product was withdrawn, although I believe it was more from a manufacturing perspective. However, there will probably have been a belief that Tillomed could potentially come to the market with a product that might not infringe the GSK product. Therefore, it was probably in IVAX's interests to consider doing a deal with Tillomed.'

b) GSK's documents

B.60 Internal GSK documents also indicate uncertainty within GSK as to its prospects of preventing IVAX from entering the UK paroxetine market independently of GSK. See Annex E Section B which equally applies in the case of the IVAX-GSK Agreement.

C. Expected impact of generic entry

B.61 As set out at paragraphs 3.394 to 3.398, at the time the IVAX-GSK Agreement was entered into, GSK manufactured all paroxetine sold within the UK. Had IVAX successfully entered the market with generic paroxetine sourced independently of GSK, true generic competition would have been expected to result in significant declines in prices and in the market share of the originator (in this case GSK).¹⁶⁹³ Both effects are typical following generic entry in the pharmaceutical sector: see paragraphs 3.47 to 3.63 where the CMA discusses the process and benefits of generic competition.

¹⁶⁹³ As set out at paragraphs 3.394–3.398, at the time of the GUK-GSK Agreement was entered into GSK manufactured all paroxetine sold within the UK.

B.62 As set out in paragraph 3.59, both GSK and IVAX expected the impact of true generic competition to be as described in the previous paragraph.¹⁶⁹⁴ In particular, in an expert report produced for GSK for the purposes of the GUK Litigation in September 2001, that is before the IVAX-GSK Agreement was concluded, [X] (an independent pharmaceutical consultant) considered that the expected impact of generic entry on Seroxat would be 'serious', leading to both significant declines in paroxetine prices and a sharp decline in GSK's market share. Further information on [GSK's independent expert's] conclusions can be found at paragraph 3.161.

D. The value transfers from GSK to IVAX

B.63 In total, under the IVAX-GSK Agreement GSK agreed to make cash payments and other value transfers to IVAX of at least £17.9 million over its three year term.¹⁶⁹⁵ The value transfers were as follows:

- 'promotional allowance' payments that totalled £10.15 million over the term of the IVAX-GSK Agreement;¹⁶⁹⁶ and
- a restricted volume of paroxetine,¹⁶⁹⁷ in relation to which GSK sacrificed its profit margin, and instead transferred this margin to IVAX. Over the three year term of the Agreement, GSK stood to sacrifice at least £7.7 million.¹⁶⁹⁸

¹⁶⁹⁴ This is further supported by an email from [Merck's Head of Patents and Raw Material Support Group] to [the Chief Executive of Merck Generics Group], [GUK's General Manager], [GUK's Managing Director], [Commercial Director of Merck Generics] and [GUK's Head of Research and Development] dated 29 November 2001 (document 0940). When considering whether GSK would be amenable to GUK entering the market by paying GSK a royalty of GUK's profits, [Merck's Head of Patents and Raw Material Support Group] noted that '[d]isadvantage [sic] to GSK, they lose volume and control' and suggested that 'I suppose we could agree to maximum volumes, if needed, to assist a settlement [sic]'.
¹⁶⁹⁵ The CMA has calculated that the approximate amount GSK in fact sacrificed in making value transfers to IVAX was between £15.1 million and £17.9 million in total. (Calculated as: 3,200,000 + 3,450,000 + 3,500,000 + (770,000/12) x 23 x ([price] - 8.45), where 23 is the number of months which the IVAX-GSK Agreement was in effect prior to generic entry (between December 2001 – November 2003) and the [price] was either £11.80 (an estimate of the price per pack of parallel imported paroxetine which GSK's UK subsidiary would have been credited with, see footnote 1713) or £13.70 (the weighted average Seroxat 20mg pack price between January to March 2002).

¹⁶⁹⁶ Calculated as: 3,200,000+3,450,000+3,500,000. See IVAX-GSK Agreement (document 0168), clause 4 and subsequent Addenda dated from 15 February 2002 to 28 February 2003 (Addenda (documents 0205, 0318, 0359 and 0384).

¹⁶⁹⁷ IVAX-GSK Agreement (document 0168), clause 7.3.

¹⁶⁹⁸ See footnote 1713 which contains detailed calculations.

i) GSK's decision to make each of the value transfers to IVAX cannot be explained on the basis of their stated purpose

a) The 'promotional allowance'

B.64 During the IVAX-GSK Agreement, GSK committed to pay IVAX a supposed 'promotional allowance' of £450,000 in the first month of each contract year, and between £250,000 and £300,00 per month thereafter. This was expressly stated to be for the '*promotional activities required to support the distribution and marketing of the PRODUCT*'.¹⁶⁹⁹ These payments started in December 2001, and were payable to November 2004, and totalled £10.2 million.

B.65 For the reasons set out below, the CMA does not accept that the purpose of the promotional allowance was to fund marketing expenditure to be carried out by IVAX:

- There was no link between the 'promotional allowance' and the sale of product: GSK made the payments in question irrespective of whether IVAX sold any of the paroxetine supplied to it by GSK.¹⁷⁰⁰
- Despite the scale of the 'promotional allowance' that GSK paid to IVAX, GSK has confirmed that it did not monitor or control spending by IVAX on marketing and promotion.¹⁷⁰¹ Teva has confirmed that it is not aware of GSK having monitored IVAX's marketing expenditure.¹⁷⁰²
- In a meeting with the OFT in December 2011, [GSK's Finance Director A] stated that generic suppliers were not expected to engage in marketing and promotional activity in order to sell generic medicines.¹⁷⁰³
- IVAX had no need to market generic paroxetine, as it could rely on the substantial marketing investment made by GSK, as outlined by GSK in the GUK Litigation.¹⁷⁰⁴

¹⁶⁹⁹ IVAX-GSK Agreement (document 0168), clause 5 and the subsequent Addenda (Addenda (documents 0205, 0318, 0359 and 0384).

¹⁷⁰⁰ IVAX-GSK Agreement (document 0168), clause 5 and the subsequent Addenda (Addenda (documents 0205, 0318, 0359 and 0384).

¹⁷⁰¹ See GSK Second Response, Part Two (document 0734), paragraph 10.6.

¹⁷⁰² Part one of the response dated 30 April 2012 to the Teva Second Section 26 Notice (document 2043), question 2.

¹⁷⁰³ See Minutes of meeting between GSK and the OFT on 19 December 2011 (document 0688), paragraph 34.

¹⁷⁰⁴ See [redacted]WS2 (GUK), Exhibit [redacted]6 (document 0887), paragraph 10. See also SB Skeleton Argument in support of the GUK Interim Injunction (document 0910), recitals 39–40, and Minutes of meeting between GSK and the OFT on 19 December 2011 (document 0688), paragraph 34, in which [GSK's Finance Director A] stated that generic companies (or distributors) were not expected to engage in marketing and promotional activity in order to sell generic medicines.

- [IVAX's Sales and Marketing Manager], in his witness statement, has confirmed that IVAX did not require this level of marketing support for paroxetine and that he questioned why it was in the IVAX-GSK Agreement.¹⁷⁰⁵

'On the basis of my overall knowledge of generic marketing, I consider that a marketing budget for a product such as paroxetine would be relatively modest. It was very unusual for a generic product to be launched with significant product support. ... I am pretty sure that I asked at the time, when I saw the supply agreement with GSK, about the purpose of this product support payment. I would have asked because I would not have required this level of marketing support to invest in the marketing of paroxetine, so would have questioned why it was in the agreement.'

- Under the terms of the IVAX-GSK Agreement, IVAX was subject to a volume restriction (see paragraphs B.69 to B.79). Given the resulting limits on IVAX's ability to meet increases in demand, IVAX had no incentive to spend the promotional allowance on marketing paroxetine.

B.66 Moreover, in the economic context of the pharmaceutical sector, the payment of promotional allowances to IVAX could not in any case have been expected to generate value to GSK, other than as part of an anti-competitive strategy. For example, to the extent that IVAX did use such transfers to market the paroxetine supplied to it by GSK to wholesalers and pharmacies (of which there is no evidence to suggest that it did: see paragraph B.65), the result would have been a decrease in GSK's sales of Seroxat, but no increase to GSK's overall sales of paroxetine.¹⁷⁰⁶

- IVAX would have had little incentive to invest its promotional allowance in marketing to GPs. Such expenditure may have generated more paroxetine prescriptions, but IVAX's ability to generate sales of its product would have relied on its ability to convince pharmacies to dispense its product rather than GSK's branded Seroxat.
- To the extent that IVAX instead used its 'promotional allowance' to promote sales of its product to wholesalers and pharmacies, this would have had no impact on the overall sales of paroxetine, which would only

¹⁷⁰⁵ Witness statement of [IVAX's Sales and Marketing Manager], signed 16 August 2014 (document 3235R), paragraph 9.1.

¹⁷⁰⁶ This is consistent with a statement made by [GSK's independent expert], see footnote 81.

be increased if more GPs could be persuaded to prescribe it more frequently.

- Marketing to wholesalers/pharmacies would therefore impact only on the proportion of paroxetine that was dispensed as generic paroxetine rather than as branded Seroxat. For example, where a pharmacy receives a prescription for paroxetine, such marketing may in principle make them more likely to dispense paroxetine supplied by IVAX than Seroxat supplied by GSK.
- On that basis, the effect of any marketing of paroxetine by IVAX would be to increase sales of paroxetine supplied by IVAX at the expense of Seroxat supplied by GSK. Rather than generate value to GSK, such marketing would in fact decrease GSK's sales of Seroxat, to its detriment.
- Consistent with this, GSK has confirmed that it did not expect IVAX to market for the benefit of GSK.¹⁷⁰⁷

B.67 The CMA also does not accept that the purpose of the promotional allowance was to fund price discounts or to offset the transfer price for accounting purposes. Although [GSK's Finance Director A]¹⁷⁰⁸ and [IVAX's Commercial Director]¹⁷⁰⁹ have stated that the marketing allowance could be used for that purpose, there can have been no expectation that the promotional allowance would in practice have been used to fund discounts and/or provide for a lower supply price, as the promotional allowance was a fixed sum that came without any connection to the quantity of paroxetine sold by IVAX. As a result, once

¹⁷⁰⁷ See GSK Second Response, Part Two (document 0734), paragraphs 10.1–10.6.

¹⁷⁰⁸ Witness statement of [GSK's Finance Director A] dated 1 August 2013 (document A 0059), paragraph 4.5. (GSK SO Written Response (document 2755), Annex 2. See also GSK SO Written Response (document 2755), paragraphs 5.124 and 5.125. In this regard, GSK refers to [IVAX's Commercial Director]'s statement that IVAX's finance team allowed him to regard the allowance as lowering the relevant cost of goods sold, the need for IVAX to compete with parallel imports of Seroxat, and to [GSK's Finance Director A's] witness statement as follows: *'I recall [that] the marketing and promotional payments were ultimately for IVAX, and indeed all the Generic Companies, to use as they saw fit. Indeed, once each of the Agreements was reached it was for the Generic Companies to decide what they wanted to use the funds for – whether for example as marketing funds to target particular kinds of pharmacies or as extra margin to allow price discounting'*. (GSK SO Written Response (document 2755), (paragraph 5.125)).

¹⁷⁰⁹ Teva cited the evidence of [IVAX's Commercial Director] in support of the proposition that IVAX saw the promotional allowance as reducing its costs of goods ([GSK]WS (document 2332)). In addition, Teva noted that [IVAX's Head of New Business Development's] witness statement corroborates this: *"there will have been posturing from both sides"* and that *"somehow [GSK and IVAX] would have arrived at an agreed price that was mutually acceptable"*. ([GSK]WS (document 2333), paragraph 9.21). Teva SO Written Response (document 2750), paragraph 172. GSK similarly cited the witness statement of [IVAX's Commercial Director], GSK SO Written Response (document 2755), paragraph 5.127 and GSK written response dated 2 December 2014 to the SSO (document 3668), paragraphs 3.27–3.30. Further, GSK submitted that generic companies will typically have smaller budgets for marketing as the promotion of their product is generally targeted at wholesalers and pharmacies through the use of discounts and targeted financial promotion (rather than a significant focus on promotional activity with the medical profession) (GSK SO Written Response (document 2755), paragraphs 5.123–5.125).

the Agreement was made, this sum was economically indistinguishable from any other cash available to IVAX. Unlike a lower supply price, the promotional allowance would have had no potential to increase IVAX's incentives to compete with GSK.¹⁷¹⁰ Further:

- Under the terms of the IVAX-GSK Agreement, IVAX was subject to a volume restriction (see paragraphs B.69 to B.79). Given the resulting limits on IVAX's ability to meet increases in demand, IVAX had no incentive to use the promotional allowance to fund discounts below its supply price.
- Consistent with this, the CMA observes that IVAX charged prices that were materially above the supply price of £8.45, such that it did not use the promotional allowance to fund discounts below its supply price of £8.45,¹⁷¹¹ and the marketing allowances instead contributed to IVAX's profits during the period of the Agreement.
- Had IVAX used the promotional allowance to fund discounts below its supply price, it would have made less profit from supplying paroxetine than had it made no sales and retained the marketing allowance.¹⁷¹²

B.68 On the basis of the evidence analysed above, the CMA finds that the purpose of the 'promotional allowance' could not have been to fund marketing to be carried out by IVAX, or to fund discounts to its resale price. There were no legitimate benefits to GSK of transferring the 'promotional allowance' to IVAX, and IVAX had no reason to use the promotional allowance for marketing or for discounting.

b) *The effective transfer from GSK of profit margins by means of agreements permitting the supply by IVAX of restricted volumes of product to the market in place of GSK*

B.69 The arrangement permitting IVAX to supply a restricted volume of GSK product, giving IVAX a predictable margin, also falls to be regarded as a form of value transfer. This arrangement, in the relevant commercial context, was not a normal supply agreement, intended to bring about legitimate benefits to GSK (for example, lower distribution costs or an increase in the number of

¹⁷¹⁰ The CMA observes that while IVAX's finance department and [IVAX's Commercial Director] may well have considered the relative profitability of the IVAX-GSK Agreement by considering what impact the marketing allowance would have on its average supply cost, the marketing allowance cannot therefore have been expected to increase IVAX's incentives to market its restricted product volumes at a lower price.

¹⁷¹¹ In particular, IVAX's weighted average selling price for paroxetine 20mg was £12.12 per pack between November 2001 and November 2003.

¹⁷¹² For example, for each unit of product that was sold below the supply price of £8.45, an incremental loss would be suffered and less of the promotional allowance would be retained. In such a scenario, paroxetine profits would be higher if no further sales were made and the promotional allowance was retained.

customers that could be supplied). The distribution margin earned by IVAX on the restricted volume of product was, in reality, a mechanism for achieving a value transfer from GSK to IVAX.

B.70 This transfer of a restricted volume of paroxetine amounted to a 'value transfer' because, as a consequence of the volume restriction described at clause 7.3 of the IVAX-GSK Agreement (and the impact this would have on prevailing prices in the market) GSK was, in practice, simply transferring to IVAX the margin that it would have otherwise earned on such volumes. In the same way as a payment, GSK was able to use this mechanism to make a value transfer to IVAX through a means that would not result in a meaningful increase in the price competition it was facing on the market:

- As set out in further detail in paragraph B.71, GSK was already able to distribute the product throughout the UK, and the IVAX-GSK Agreement did not provide for any opportunities to increase supply or to lower its distribution costs.
- As such, in committing to transfer a restricted volume of paroxetine from GSK to IVAX, GSK committed to sacrifice a profit margin on the sales of the product transferred from GSK to IVAX in the range of £7.7 to £12.1 million (depending on the proportion of sales that IVAX made that were at the expense of imported GSK product or products sold by GSK UK).¹⁷¹³
- For IVAX, the returns associated with this value transfer could be forecast with near certainty because, as a consequence of the volume restriction, IVAX would have no incentive to set a price that was materially below prevailing levels. That is because if IVAX had adopted price levels that were materially below the market level, the volume restriction would have left it unable to satisfy the resulting increase in demand. IVAX could therefore be expected to price at prevailing market levels, and to earn the resulting margin across the maximum 770,000 packs of paroxetine per year that GSK agreed to transfer to IVAX.¹⁷¹⁴

¹⁷¹³ Calculated as: $770,000 \times 3 \times ([\text{price}] - 8.45)$, where the [price] was either £11.80 (an estimate of the price per pack of parallel imported paroxetine which GSK's UK subsidiary would have been credited with) or £13.70 (the weighted average Seroxat 20mg pack price between January to March 2002). This assumes that the Agreement would not be terminated early.

The price of £11.80 is based on a price of 0.63 EUR per tablet (see GSK presentation entitled 'Seroxat Price Strategy Gothenburg 29th August' by [GSK's Pricing Manager for Europe] dated 29 August 2002 (document 0313), slide 16) in France (where [GSK's Finance Director A] estimated most paroxetine imported into the UK was from, see for example [§]WS2 (GUK) (document 0182), paragraph 3.2) converted into pounds sterling using the average exchange rate in the year to August 2002.

¹⁷¹⁴ IVAX-GSK Agreement (document 0168), clause 7.3.

- Consistent with this, IVAX's entry onto the market with GSK product had no discernible impact on market prices (see paragraphs 3.384 to 3.390).

B.71 The transfer of a restricted volume of paroxetine could not have been expected to generate legitimate benefits for GSK:

- at the time the IVAX-GSK Agreement was entered into, GSK was already able to distribute its products (including Seroxat) throughout the UK. The additional sub-distribution agreement with GUK therefore did not provide for opportunities to increase supply or to lower GSK's distribution costs;¹⁷¹⁵
- any strategy aimed at increasing the supply of paroxetine was reliant on persuading GPs to issue more prescriptions for paroxetine, and could not be achieved by entering into a supply agreement with IVAX; and
- consistent with this, it is clear that, by imposing volume restrictions on the purchases that IVAX could make from GSK, the intention was not to encourage the development of a supply channel involving GUK.

B.72 Consistent with the analysis outlined above, the CMA observes that the volume restriction was in practice effective in constraining IVAX's market share (see paragraph B.74). Further, the transfer of a restricted volume of paroxetine did in practice provide for a means to remunerate IVAX that did not result in an increase in the competitive constraints faced by GSK and a material decrease in paroxetine prices to pharmacies following IVAX's market entry with GSK product (see paragraph 3.387).

Representations on the restricted volume of paroxetine

B.73 Teva and GSK submitted that: (i) there was no binding volume restriction;¹⁷¹⁶ (ii) GSK and IVAX could agree to increase the volumes;¹⁷¹⁷ (iii) the 770,000

¹⁷¹⁵ GSK documents that discuss entry into sub-distribution agreements make no reference to efficiencies or gains to be made through increased distribution, but rather, focus on the need to protect GSK's price and patent position. See, for example, GSK presentation entitled 'Seroxat Patent Challenge' by [GSK's Finance Director A] and [GSK's Head of Regulatory Affairs] dated 5 February 2001 (document 0123), and [redacted]WS2 (GUK) dated 20 October 2001 (document 0182) / [redacted]WS2 (Alpharma) 30 July 2002 (document 0289).

¹⁷¹⁶ Teva SO Written Response (document 2750), paragraph 186. GSK SO Written Response (document 2755), paragraph 5.152.

¹⁷¹⁷ GSK written response dated 2 December 2014 to the SSO (document 3668), paragraph 3.24 and GSK SO Written Response (document 2755), paragraph 5.157.

volume commitment was based on a 'forecast' provided by IVAX;¹⁷¹⁸ and (iv) the volume commitment gave GSK production and commercial certainty.¹⁷¹⁹

B.74 None of these submissions are supported by the facts. It bears emphasising that IVAX was contractually entitled to buy no more than 770,000 packs from GSK over 12 months. That was the maximum number of packs that IVAX could buy under the IVAX-GSK Agreement, which it did. In addition, the CMA refers to the following matters:

- GSK was under no obligation under the IVAX-GSK Agreement to provide additional packs to IVAX. The IVAX-GSK Agreement, whilst stating that IVAX would provide forecasts, limited the volume of product to be supplied to IVAX by GSK so that it did not exceed 770,000 packs '*unless otherwise agreed*'.¹⁷²⁰
- GSK had no incentive to supply greater volumes to IVAX during the IVAX-GSK Agreement. Any additional sales by IVAX would have been at the expense of sales and profits of GSK's product (as generics were not capable of influencing total market demand for paroxetine, which was determined by GP prescribing practices).
- GSK has not denied that the limit of 770,000 packs was a contractual restriction. In particular, in response to a question from the CMA regarding the reasons for the inclusion of the volume restrictions in the Agreements with the Generic Companies, GSK stated that '*it had no obligation to provide unlimited volumes to the Generic Suppliers – and we remain of that view today. If a patent holder settles a dispute on a basis that includes a supply agreement, it does not have to subsidise unlimited competition to itself. The volumes were negotiated and agreed*'.¹⁷²¹
- The volume restriction was, in fact, binding on IVAX in the sense that during the IVAX-GSK Agreement and prior to generic entry IVAX ordered the maximum volume of packs available to it. Teva has provided data that demonstrates that IVAX received 98% of its volume allowance in the first contract year of the IVAX-GSK Agreement, and 101% of the allowance in

¹⁷¹⁸ Teva SO Written Response (document 2750), paragraph 181; GSK SO Written Response (document 2755), paragraphs 5.153–5.157.

¹⁷¹⁹ Teva referred to [IVAX's Commercial Director's] witness statement dated 2 September 2012 ([§]WS (document 2332), paragraph 6.21–6.22) '*so that it could prepare the required volume for delivery*'. GSK SO Written Response (document 2755), paragraphs 5.158–5.161.

¹⁷²⁰ IVAX-GSK Agreement (document 0168), clause 7.3.

¹⁷²¹ GSK Second Response, Part Two (document 0734), paragraph 11.4.

the second contract year.¹⁷²² IVAX itself, in internal correspondence whilst the IVAX-GSK Agreement was in place, recognised that the volumes it could obtain from GSK were *'limited'*.¹⁷²³

- During the IVAX-GSK Agreement, IVAX either did not seek or was not successful in seeking additional volumes (for its own supply) from GSK.¹⁷²⁴
- The limited supplies under the IVAX-GSK Agreement are consistent with the evidence relating to the limited supplies under the GUK-GSK Agreement and Alpharma-GSK Agreement (for which IVAX acted as sub-distributor):
 - In both cases these volume restrictions were binding (see paragraphs 7.29 to 7.30 (GUK) and 7.80 to 7.82 (Alpharma), in that neither GUK nor Alpharma ever made purchases from GSK that exceeded the volume allowance included in their respective Agreements with GSK. GUK ordered its full allowance from GSK for each of the first three contract years of the GUK-GSK Agreement, and Alpharma ordered the full allowance in the one full year that the Alpharma-GSK Agreement was in operation.
 - When negotiating the GUK-GSK Agreement, GUK requested significantly more product than GSK was ultimately willing to provide to it under the terms of the finalised GUK-GSK Agreement. In a letter from [GUK's General Manager] to [IVAX's Commercial Director] dated 24 January 2002, [GUK's General Manager] wrote: *'As you know, one of the principal sticking points has been that GlaxoSmithKline, through yourselves, has been unwilling to meet our required demand of 1 million packs per year'*.¹⁷²⁵
 - GSK agreed to supply additional volume to Alpharma, but only in the specific situation that the additional volume discharged a different commitment for GSK to transfer £500k of value to Alpharma (see paragraph 6.165). Had there been no restriction on the supply of GSK's paroxetine to Alpharma, there would have been no reason for Alpharma

¹⁷²² See paragraph B.144 for a description of the data.

¹⁷²³ Moss Pharmacy contact report dated 20 March 2003 (document 1827).

¹⁷²⁴ This is despite evidence that, in a Moss Pharmacy contact report dated 20 March 2003 IVAX noted an action point for [IVAX employee] *to discuss [...] the potential for increased volumes with [IVAX's Commercial Director] .'* Moss Pharmacy contact report dated 20 March 2003 (document 1827).

¹⁷²⁵ See letter from [GUK's General Manager] to [IVAX's Commercial Director] dated 24 January 2002 (document 0965).

to accept the additional volume in place of the £500k that GSK had committed to transfer to it.

B.75 The matters set out in the previous paragraph show that the volumes supplied under the IVAX-GSK Agreement did not represent a genuine forecast of IVAX's product requirements. In addition:

- Teva's submission¹⁷²⁶ that the figure of 770,000 packs was its forecast demand ignores the fact that this figure remained unchanged throughout the three-year term of the IVAX-GSK Agreement. A genuine forecast would have been reasonably responsive to changes in market conditions, such as the authorised entry of GUK and AlphaPharma.
- It is implausible that the figure of 770,000 packs was a forecast of IVAX's product requirements throughout the IVAX-GSK Agreement. A lengthy forecasting period would be unlikely to be accurate and is decidedly different from other supply agreements entered into by IVAX, which either did not include stated maximum volumes or provided for non-binding, rolling forecasts, rather than a volume restriction.¹⁷²⁷
- The IVAX-GSK Agreement did not specify a mechanism for 'updating forecasts'; the volumes could be varied only with GSK's agreement.
- Even if the figure of 770,000 packs had initially been based on a forecast by IVAX, the terms of the IVAX-GSK Agreement were clear and the volumes that IVAX could obtain from GSK were clearly restricted. That being so, unlike an ordinary supply agreement based on forecasts, IVAX was unable to compete to expand its share beyond that allocated to it.

B.76 GSK's submission that the volume restriction provided it with greater production certainty does not alter the fact that IVAX could purchase a restricted volume from GSK only, and that this constituted a transfer of value from GSK to IVAX. In any event, the restriction on IVAX's annual purchase volumes, as opposed to monthly purchase patterns, would have few benefits to GSK's production planning. IVAX was free to (and did) purchase variable levels of stock from month to month, and such variation was accommodated by GSK and provided for in the IVAX-GSK Agreement. The CMA infers that annual volume restrictions, agreed to and sustained by IVAX and GSK over a

¹⁷²⁶ Teva written response dated 21 November 2014 to the SSO (document 3645), section 3.2.3.

¹⁷²⁷ Part two of the response dated 20 July 2012 to the Section 26 Notice dated 12 June 2012 sent to Teva (document 2124), question 9.

period of nearly three years cannot reasonably be explained by production planning requirements.

- B.77 The CMA has considered GSK's submission that the above analysis would imply that any supply agreement would involve a value transfer.¹⁷²⁸ The CMA considers that a key distinction between the IVAX-GSK Agreement and a potentially pro-competitive supply agreement is the volume restriction (confining supply to a limited amount of product) within the economic context of the present case, specifically where (i) GSK was already in a position to distribute the product throughout the UK, (ii) there were no legitimate economic advantages to GSK from the arrangement, and (iii) there were no incentives on IVAX to compete on price or otherwise to do more than substitute - to the extent permitted - for sales by GSK. For the reasons outlined above, the volume restriction ensured that in this context the transfer of GSK's product was essentially the same as a cash payment from GSK to IVAX, in that it provided a means by which GSK could transfer value to IVAX, but without providing for meaningful increases in the actual competitive constraints GSK faced in the relevant market.
- B.78 In contrast, had the IVAX-GSK Agreement not included the volume restriction, IVAX would have had some scope to choose how much paroxetine to purchase and sell in order to maximise its profits and would have had an increased incentive to compete on price to do so. Under such a scenario, it would have been open to IVAX to offer price decreases as a means of increasing its sales to maximise its profits, and the returns it would earn would be a function of how effectively it competed with GSK. In such a scenario, the losses suffered by GSK could have been far greater than the losses it made by transferring a restricted volume of product to IVAX as: (i) additional supplies to IVAX would have resulted in further margin losses on those sales; and (ii) the resulting competition would have been expected to result in materially lower prices (and profit margins) on those sales that GSK did retain. Under such a scenario, the margin would not simply be transferred from GSK to IVAX. Rather, GSK would have been expected to suffer sales losses and margin decreases that would have been associated with more effective competition and lower prices, and purchasing wholesalers and pharmacies would have benefited from more effective competition and the material price decreases that would have been expected to follow. The associated returns generated by IVAX would have been derived from its efforts to compete

¹⁷²⁸ GSK's written response to SO dated 7 August 2013 (document 2755), paragraph 5.140.

meaningfully on the market (albeit with GSK product) without the constraint of restricted volumes.

B.79 The CMA notes that, consistent with the above, volume restrictions of the type included in the IVAX-GSK Agreement do not appear to be a feature of other agreements entered into by IVAX over the relevant period.¹⁷²⁹ Instead those agreements typically either include no volume provisions or non-binding, rolling forecasts, rather than a volume restriction.

(ii) *The overall level of the value transfers cannot be explained on any other commercial basis that was not anti-competitive, and the value transfers were commercially rational only on the basis that they would induce IVAX to delay its potential independent market entry*

B.80 There is no other basis (which GSK or Teva have suggested in response to the Investigation, or otherwise that the CMA can discern) on which the IVAX-GSK Agreement could legitimately have involved value transfers totalling at least £17.9 million from a market incumbent to a potential competitor.

B.81 As set out below, the CMA finds that the avoidance of costs associated with the litigation (including both the costs of the litigation itself and those relating to deferring the risk of irreversible damages) cannot plausibly explain the level of value transfers made by GSK under the terms of the IVAX-GSK Agreement. The CMA finds therefore that GSK's decision to commit to make the value transfers totalling at least £17.9 million can only be explained by its desire to induce IVAX to delay its potential independent generic entry.

B.82 In carrying out this assessment, it is important to recall that, because the IVAX-GSK Agreement deferred rather than resolved the underlying questions of patent validity and infringement, the value transfers that GSK made during the term of the IVAX-GSK Agreement did not enable GSK to avoid the costs associated with their litigation, but only to defer them. Although the conduct and outcomes of future litigation could not be forecast with certainty, the three year IVAX-GSK Agreement left the contested issues unresolved and this meant that the costs and damages exposure associated with their litigation would either be deferred to subsequent litigation during the term of those Agreements or, failing that, would be deferred to subsequent litigation with IVAX. In order to avoid those costs, GSK and IVAX would have needed to

¹⁷²⁹ The CMA has reviewed similar IVAX supply agreements concluded between 2000 to 2005, all of which do not provide stated maximum volumes. More typical requirements would be for the originator to use 'reasonable endeavours' to meet orders or that the originator would not be required to meet orders over a stated percentage above previous forecasts (part two of the response (dated 20 July 2012) to the Section 26 Notice dated 12 June 2012 sent to Teva (document 2124), question 9).

enter into a subsequent agreement, for a duration as long as the patents under dispute, but their avoidance would not be achieved by the IVAX-GSK Agreement and the value transfers it included.

B.83 It should also be observed that GSK has not submitted that its decision to commit to the value transfers can, objectively, be explained solely by a desire to avoid the costs and exposure relevant to litigating in response to IVAX's proposed entry. For example, in its representations, GSK stated that its *'rationale for settlement of the Patent Disputes was in each instance essentially the defence of its valid patent rights and their commercial value (the status quo), and for this it was prepared to compromise based on its assessment of an uncertain litigation outcome. Each Generic Company sought early entry to the UK market for a paroxetine product and each had its own particular conditions for compromise which had to be accommodated to resolve the Patent Disputes.'*¹⁷³⁰

a) The value transfers cannot be explained by the avoidance of the costs and disruption of litigation

B.84 GSK submitted that its expected litigation costs put *'the sums paid under the settlements into proportion'*.¹⁷³¹ In the context of the IVAX-GSK Agreement, GSK has estimated that it would have incurred total litigation costs of £1.786 million had it pursued litigation in response to IVAX's potential independent market entry.¹⁷³²

B.85 For the reasons set out below, the CMA does not consider that the avoidance of litigation costs and disruption can itself explain GSK's decision to make such substantial value transfers to IVAX. In the CMA's view, the value transfers only made commercial sense to GSK on the basis that they would enable it to defer the threat of true generic competition.

B.86 The CMA notes, first of all, that even on the basis of GSK's own estimate, the £17.9 million (at least) that GSK committed to transfer to IVAX was significantly more than the estimated legal costs of £1.786 million, such that avoiding those costs can in no way explain the value transfers that GSK made to IVAX.

¹⁷³⁰ GSK Written SO response (document 2755), paragraph 4.26.

¹⁷³¹ GSK Second Response, Part Two (document 0734), paragraph 5.3(b).

¹⁷³² GSK Second Response, Part Two (document 0734), paragraphs 5.1–5.16.

- B.87 Second, the litigation costs estimated by GSK are a significant overstatement of the litigation costs that GSK avoided by entering into the IVAX-GSK Agreement.
- B.88 Third, the CMA emphasises that the IVAX-GSK Agreement did not relieve GSK of the burden of litigating the patent issues, because the IVAX-GSK Agreement could not and did not prevent other generic suppliers from litigating them in the future, nor did GSK even resolve its dispute with IVAX by, for example, committing not to contest IVAX's independent generic entry at a specified future date. The CMA observes that the only scenarios under which litigation with IVAX would be avoided would have been (i) extensions to the Agreement and the payment of further value transfers until 2016 when the Anhydrate Patent was due to expire; or (ii) the contested issues did not need to be revisited because litigation with another party either clarified the relevant issues and/or removed either parties' incentive to contest the issues further. However, in relation to (i), the CMA observes that the IVAX-GSK Agreement was for three years, and the value transfers over that period would not have enabled GSK to avoid litigation with IVAX and cannot therefore be explained on this basis. In relation to (ii), it remains the case that litigation of the contested issues is only deferred until they are clarified by subsequent litigation, such that the value transfers made to incentivise IVAX to delay its challenge can again not have had the purpose of avoiding the costs of litigating those issues.¹⁷³³ The estimated IVAX litigation costs were not therefore avoided as a consequence of the IVAX-GSK Agreement, but merely deferred.
- B.89 Fourth, had GSK been confident in its patent position, as it submitted to the CMA during the Investigation, it would have expected to prevail before the Courts and recover at least a significant proportion of its litigation costs. Although it would also have had to take into account the (*ex hypothesi* lower) risk of being unsuccessful and paying a proportion of IVAX's litigation costs, the net effect of the English rule¹⁷³⁴ on costs should have been to reduce GSK's expected litigation costs if it had been confident in its case.

¹⁷³³ The CMA also observes that, even on the basis of GSK's submission in this regard, it remains the case that the IVAX-GSK Agreement only achieved the deferral of the relevant litigation costs, as it implies that after the term of the IVAX-GSK Agreement, IVAX could only have entered the market following further litigation with GSK.

¹⁷³⁴ Under the English rule, the law which governs the allocation of court costs and attorney fees, the losing party in litigation bears the costs of both parties.

- B.90 Fifth, the CMA points that the risk identified by GSK of losing any litigation against IVAX is precisely the risk of GSK being exposed to true generic competition.
- B.91 GSK also submitted, in general terms, that *'[l]itigation is a burden to the business in terms of costs and a distraction of management and scientists' time from the daily running of the business'*.¹⁷³⁵ GSK stated that as well as direct costs, litigation also diverts scientist, patent attorney and management time which can be disruptive to the business, and that GSK *'needs to focus its resources on its business operations'* in determining its approach.¹⁷³⁶ GSK explained that *'[i]t is impossible to quantify in verifiable figures the huge diversion in management time and the general disruptiveness of litigation to the company as a whole'*.¹⁷³⁷
- B.92 There is no indication from the contemporaneous evidence that this general assertion was a relevant factor in GSK's decision-making at the time of entering into the Agreements, or that it could plausibly explain the value transfers.
- B.93 To the contrary, in those documents that explain GSK's rationale, the focus is on preventing true generic competition (see, for example, paragraphs B.102 to B.103). In his explanations of the rationale for the Agreements, [GSK's Finance Director A] did not mention that an assessment of these factors was made, nor that GSK considered that, having quantified them, such factors justified a commitment to make value transfers totalling at least £17.9 million.
- B.94 In any case, as with the litigation costs themselves, any disruption was not avoided by the IVAX-GSK Agreement, but simply deferred until the issues concerning GSK's patent position became the subject of subsequent litigation.
- B.95 The cost and disruption of prospective litigation cannot therefore explain GSK's decision to commit to making value transfers to IVAX of at least £17.9 million, or more generally its decision to commit to make value transfers totalling at least £50.9 million to the Generic Companies.
- B.96 Consistent with the analysis outlined above, GSK itself submitted that *'resolution of the patent dispute rather than avoidance or recovery of litigation and management costs was the main purpose of the IVAX-GSK Agreement'*.¹⁷³⁸

¹⁷³⁵ GSK Second Response, Part Two (document 0734), paragraph 8.1(d).

¹⁷³⁶ GSK Second Response, Part Two (document 0734), paragraph 8.10.

¹⁷³⁷ GSK Second Response, Part Two (document 0734), paragraph 5.4.

¹⁷³⁸ GSK written response dated 2 December 2014 to the SSO (document 3668), paragraph 3.39.

b) The value transfers cannot be explained by avoiding the risks of irreversible damages

B.97 GSK submitted that the IVAX-GSK Agreement was negotiated based on its assessment of the risks of the patent dispute and GSK had to make a commercial business decision faced with this uncertainty. In particular, GSK was aware of the irreversible damage that entry by an infringing generic product would do to its business and GSK was also aware of the cost and uncertainty of litigation, including doubts as to the likelihood of obtaining an interim injunction.¹⁷³⁹

B.98 The CMA does not accept that the potential for 'irreversible damages' can explain GSK's decision to make value transfers to IVAX over the term of the IVAX-GSK Agreement.

- The concerns outlined by GSK cannot explain its decision to enter into the IVAX-GSK Agreement and to make the associated value transfers, as by the time it renewed the Agreement for a further two years (on the same terms as it initially entered into the Agreement on),¹⁷⁴⁰ GSK would have been aware that any entry by IVAX was likely to have been subject to an injunction such that the same risk of damages would no longer exist. This is because, by the time of the renewal in February 2002, GSK had already successfully obtained an injunction to prevent GUK from entering the market with generic paroxetine and would have been entitled to expect that any entry on IVAX's part would also have been enjoined.¹⁷⁴¹ Despite this, GSK was willing to renew the IVAX-GSK Agreement on exactly the same terms, and it can therefore be inferred that the risks outlined by GSK were not a significant factor in its consideration of the terms on which it would enter into the First Addendum to the IVAX-GSK Agreement (see paragraph 3.223).
- GSK had not even sought an injunction or cross-undertaking prior to entering into the IVAX-GSK Agreement. Both measures would have enabled GSK to avoid the risks of suffering damages at minimal cost, yet neither was pursued before GSK agreed to enter into the IVAX-GSK

¹⁷³⁹ GSK SO Written Response (document 2755), paragraph 5.116(a). GSK also referred to a witness statement in which [GSK's Finance Director A] states that GSK would not have been able to restore prices to prior levels, and to the views expressed by Jacobs J in the Apotex Judgment that *'there would be formidable difficulties in SB's way if it tried to get back to its present position after a major collapse in prices'*.

¹⁷⁴⁰ First Addendum (document 0205).

¹⁷⁴¹ The injunction was granted on 23 October 2001 (see paragraph 3.127). GSK submitted that it found the GUK Interim Injunction *'reassuring'*. GSK Second Response, Part Two (document 0734), paragraph 4.24.

Agreement and to instead commit to make value transfers to IVAX that eventually totalled at least £17.9 million.¹⁷⁴²

- Consistent with this, the CMA considers that it would have been reasonable to expect that the majority, if not all, of the damages suffered by GSK could have been recovered, and observes that court processes exist to provide for this. In this regard, there is no basis to assume that GSK would have been unable to recover appropriate compensation for any damages suffered.
- In any case, GSK has not provided a reasoned explanation as to why, following any entry by IVAX, GSK would have been unable to restore prices to pre-existing levels.¹⁷⁴³ In this regard, the CMA observes that GSK's previous dominant market position would have been restored and, as the only supplier of paroxetine in the market, it would have been in a position to increase prices accordingly. Moreover, it would not have faced a regulatory constraint from the PPRS against increasing its paroxetine selling price, as there would have been no requirement for GSK to lower its list price during a period of temporary 'at risk' generic entry¹⁷⁴⁴ (see paragraphs 3.104 to 3.105). Further, it is not clear why a subsequent price rise would have resulted in reputational damage with pharmacies, as it could have been made clear to pharmacies that the subsequent price decrease was a result of unlawful patent infringement. The CMA therefore agrees with [Alpharma Ltd's Director of Sales and Marketing's] statement in the Alpharma Litigation that '*from [his] understanding of the industry there is no reason why prices cannot be subsequently increased if the patent is ultimately found to be valid*'.¹⁷⁴⁵ Moreover, the IVAX-GSK

¹⁷⁴² Contemporaneous GSK evidence from Project Dyke anticipated that '*court injunctions*' would be one means by which GSK could maintain a '*monopolistic position*' for paroxetine (GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100). When considering its approach regarding Gea/Hexal planning to launch a paroxetine product in the UK [redacted], GSK's Patent Attorney, in an internal GSK email dated 6 March 2001, explained that GSK '*can and will seek an interim injunction in the UK Courts on a quia timet basis*' (Email from [GSK's Patent Attorney] to [GSK's Senior Vice President Patents & Trademarks] and others dated 6 March 2001 (document 0127), regarding Gea/Hexal). This statement predated the IVAX-GSK Agreement by over six months.

¹⁷⁴³ In relation to Jacob J's view (as cited by GSK) that GSK would have faced 'significant difficulties' in restoring prices to the pre-existing levels, the CMA observes that the difficulties referred to appear to relate to the likely collapse of GSK's Agreements with IVAX, GUK and Alpharma. We note, though, that this issue would have had no relevance to the position at the time of GSK's decision to enter into the IVAX-GSK Agreement, as it was the first to be concluded with the Generic Companies.

¹⁷⁴⁴ The CMA observes that even when independent generic entry took place in December 2003, GSK did not reduce its list price for either Seroxat 20mg or Seroxat 30mg; list prices for both tablet strengths were not reduced until January 2005 (See Figure 5: Seroxat 20mg and 30mg list prices, Jan 2000-Dec 2006, Annex 3 to GSK SO Written Response (document 2757), Consumer welfare analysis – Impact of the supply agreements on the NHS: A report by Charles River Associates dated 6 August 2013).

¹⁷⁴⁵ [redacted]WS2 (document 1325), paragraph 30.

Agreement did not in any case enable GSK to avoid an exposure to damages, but only to delay it (see paragraph B.82).

- Finally, even if GSK did consider that it would face irreversible damage in the event that IVAX entered 'at risk', that cannot justify side-stepping the legitimate court process and paying a potential competitor to delay its efforts to enter the market independently of GSK.

B.99 The CMA therefore does not consider that the cost and disruption of prospective litigation, or the avoidance of irreversible damages, can explain GSK's decision to commit to making value transfers to IVAX of at least £17.9 million, or more generally its decision to commit to make value transfers totalling at least £50.9 million to the Generic Companies.

c) *The value transfers incentivised IVAX to enter into the IVAX-GSK Agreement*

B.100 By entering into the IVAX-GSK Agreement, IVAX's actions demonstrate that, having considered the various risks and returns associated with each of its options, IVAX was satisfied that entering into, adhering to, and renewing the IVAX-GSK Agreement provided it with an expected return¹⁷⁴⁶ that was greater than that associated with entering the UK paroxetine market independently of GSK. On this basis, it must have been the case that IVAX was satisfied that the prospect of future value transfers (in the prevailing contract and/or within a renewed contract) provided it with sufficient incentive to accept the supply terms in the IVAX-GSK Agreement and to defer its efforts to launch generic paroxetine (for the reasons outlined at paragraph B.112, GSK was only incentivised to renew the IVAX-GSK Agreement for as long as IVAX (or any other generic supplier) deferred the launch of generic paroxetine.¹⁷⁴⁷

B.101 The necessary consequence of the value transfers was not only to incentivise IVAX to enter into the IVAX-GSK Agreement and to defer its own potential generic entry, but also to incentivise IVAX to accept supply terms that were less competitive than it would have been willing to accept in their absence. In the IVAX-GSK Agreement, IVAX accepted a cost of goods of £8.45 per

¹⁷⁴⁶ IVAX's 'expected return' would represent the average of the profits associated with the potential outcomes of its entry strategy (for example, the revenue and costs associated with each outcome relevant to its strategy (such as winning or losing any litigation, and the possible timing of its entry), and the probability of each outcome.

¹⁷⁴⁷ Having determined that accepting the value transfers and entering into the IVAX-GSK Agreement was its most profitable option, IVAX would necessarily have had no incentive to facilitate another company's generic entry by transferring its rights under the Tillomed MA to another company or to use the MA itself once it was formally granted. Generic entry on the part of IVAX or another company would have served to undermine the IVAX-GSK Agreement (see paragraphs B.110–B.112).

pack¹⁷⁴⁸ and a limited volume of 770,000 pack per year. However, it is clear that, absent the value transfers that were made to incentivise IVAX to defer its independent generic entry, an alternative supply agreement could only have provided IVAX with comparable expected returns had it provided IVAX with supply terms that enabled it to compete more effectively with GSK (for example, a higher volume of product and a lower supply price).

(iii) *The evidence on subjective intentions supports the objective evidence that the purpose of the GSK value transfers was to induce IVAX to delay its efforts to enter the market independently of GSK*

B.102 On the basis of the documents outlined at paragraphs 6.134 to 6.135 (which also apply to GSK's intentions in relation to the IVAX-GSK Agreement), the CMA considers that in its negotiations with IVAX, GSK's intention was to use payments and other value transfers to induce IVAX to delay its efforts to enter the market independently of GSK.

B.103 Relevant representations are considered at F.17 to F.20.

B.104 The CMA considers that witness statements from IVAX's employees, and internal documents provided by IVAX (see below), confirm that IVAX approached the IVAX-GSK Agreement on the basis that it was not prepared to defer its efforts to enter the market independently of GSK unless it received sufficient compensation from GSK, and that it understood that entering into the IVAX-GSK Agreement would enable GSK and IVAX to preserve high market prices.

B.105 For example, in an IVAX presentation that outlined the benefits of 'Originator Deals', including the IVAX-GSK Agreement, it was noted that such agreements mean that '[the] *companies can work together to improve product value*' and that one of two advantages (the other being the avoidance of litigation costs) is that '*higher market prices are often maintained*'.¹⁷⁴⁹ By constraining the volumes that IVAX could purchase from GSK, the CMA observes that the two parties were able to '*work together*' to reach an

¹⁷⁴⁸ The CMA notes that although the supply price to IVAX was subsequently revised in the Heads of Agreement and Second Addendum also (Heads of Agreement between GSK and IVAX dated 14 March 2002 (document 0217), clause 3 and Second Addendum (document 0318), clause 2.9), this was to reflect the fact that IVAX was receiving product as bulk rather than packaged supply and as such it did not comprise additional margin available to IVAX. Therefore the CMA has continued to treat the supply price as £8.45 for the purposes of this section and throughout this Decision.

¹⁷⁴⁹ See Teva presentation entitled 'IVAX UK in-licensing presentation to IVAX US' dated 23 January 2002 (document 1760).

agreement that would ensure that *'high market prices'* are maintained (see paragraph B.69 to B.79).

B.106 [IVAX's Commercial Director] described in his witness statement the negotiation of the promotional allowance. He focused on making sure that, in return for the IVAX-GSK Agreement including a high cost of goods sold, IVAX would receive promotional allowances that would enable it to earn an acceptable return. Indeed, absent such compensation in the form of the marketing payments, [IVAX's Commercial Director] indicated that IVAX would not have been willing to accept the IVAX-GSK Agreement:¹⁷⁵⁰

'Had GSK offered purely an £8.45 supply price, without a marketing contribution, that would not have been acceptable to IVAX because the supply price was too high.'

B.107 [IVAX's Head of New Business Development] stated in his witness statement that he believed that the value transfers were calculated using IVAX's estimate of what it would have made had IVAX entered the market independently of GSK. In particular, [IVAX's Head of New Business Development] considered that the *'promotional allowance'* was likely to have been paid in compensation for IVAX accepting a higher cost of goods sold than it could have secured had it sourced generic paroxetine independently of GSK. It was effectively compensation for IVAX accepting GSK's plan to protect the market price:¹⁷⁵¹

'Under Clause 5 of the Supply Agreement, GSK also agreed to pay IVAX a 'promotional allowance' of £3.2 million. I believe that this clause was agreed based on a negotiation with GSK following discussions between [IVAX's Commercial Director] and [GSK's Finance Director A], effectively keeping the market price above £8.45 and reimbursing IVAX for the profit it would have made by selling its own product, due to having a much lower cost of goods than £8.45. However, I was not party to these discussions.

I assume that IVAX would have said to GSK that its cost of goods might have been 'X'. GSK would have probably said, "We're not prepared to supply you at X, we're prepared to supply you at a higher price, Y." to which IVAX would have responded: "Well at that price we're not making as much profit as if we will if we launch our own product,". There will probably have been posturing from both sides, and

¹⁷⁵⁰ [REDACTED]WS (document 2332), paragraph 6.18.

¹⁷⁵¹ [REDACTED]WS (document 2333), paragraphs 9.20 and 9.21.

with IVAX probably suggesting that “We’ll just go ahead and launch our own product”. That would probably have been our negotiating position and somehow we would have arrived at an agreed price that was mutually acceptable.’

(iv) *The IVAX-GSK Agreement was designed to be an alternative to independent generic entry*

B.108 For the reasons set out below, the CMA finds that the IVAX-GSK Agreement was designed to be an alternative to IVAX’s independent generic entry, such that, by incentivising IVAX to enter into and sustain the IVAX-GSK Agreement, the value transfers necessarily incentivised IVAX to defer its own potential generic entry.

B.109 This sub-section first considers the terms of the IVAX-GSK Agreement and concludes that, at the time the IVAX-GSK Agreement was entered into and subsequently renewed, it could not reasonably have been expected that supply under the IVAX-GSK Agreement would have been sustained, or that the IVAX-GSK Agreement would have been renewed, in the event of independent generic entry by IVAX (or another party). It then considers IVAX’s conduct having entered into the IVAX-GSK Agreement. Finally, this sub-section considers the approach of both parties to the IVAX-GSK Agreement and concludes that the parties intended and/or understood the IVAX-GSK Agreement to be an alternative to independent entry by IVAX.

a) *The terms of the IVAX-GSK Agreement were incompatible with independent generic entry*

B.110 An objective examination of the terms of the IVAX-GSK Agreement demonstrates that the IVAX-GSK Agreement was designed to be an alternative to IVAX’s independent generic entry, such that (i) IVAX would necessarily defer its efforts to enter the market with a generic product for as long as it continued to purchase paroxetine under the IVAX-GSK Agreement, and (ii) the IVAX-GSK Agreement would not be renewed in the event of IVAX’s (and/or another firm’s) generic entry.

B.111 Although the IVAX-GSK Agreement did not contain any contractual commitment on IVAX’s part not to launch an independent generic paroxetine, it is clear from the terms of the IVAX-GSK Agreement that the IVAX-GSK Agreement was not designed to co-exist with independent generic entry by IVAX (or any other party). Moreover, as explained below, it cannot reasonably have been expected that supply under the IVAX-GSK Agreement would have been sustained, or that the IVAX-GSK Agreement would have been renewed, in the event of independent generic entry by IVAX.

B.112 In particular, an objective examination of the terms of the IVAX-GSK Agreement¹⁷⁵² demonstrates that the only reasonable expectation as to the outcome of independent generic entry by IVAX (or one of its competitors) would have been as follows:

- (a) IVAX would have had no incentive to take supply from GSK under the terms of the IVAX-GSK Agreement (and would have had the option of terminating the IVAX-GSK Agreement under the termination provision, which was included at its request).¹⁷⁵³
- Had IVAX successfully entered the market and begun to sell even modest volumes of generic paroxetine sourced independently of GSK, it would have been reasonable to expect many other entrants to follow suit and for true generic competition to emerge (see paragraphs B.61 to B.62). True generic competition was expected to result in significant price falls, such that had IVAX continued to take supply from GSK at a price of £8.45, it would have made losses on each unit sold. Had true generic competition emerged, IVAX would no longer therefore have had any incentive to make purchases from GSK under the terms of the IVAX-GSK Agreement. Moreover, had the market price of paroxetine dropped below £8.45, as would have been expected in the event of true generic competition, IVAX would have been entitled to terminate the IVAX-GSK Agreement.
 - The inclusion of a price related termination provision (whereby IVAX was entitled to terminate the IVAX-GSK Agreement if the market price fell below £8.45)¹⁷⁵⁴ demonstrates that the parties did not intend the IVAX-GSK Agreement to coexist with independent generic entry. The termination clause was designed to allow IVAX to terminate the IVAX-GSK Agreement in the event of independent generic entry by any party, as such entry was expected to result in a decrease of the market price to below £8.45. Given that, for the reasons set out above, IVAX would have had no incentive to enter the UK paroxetine market independently until such time as another competitor did so (and triggered the expected decline in prices), the CMA infers that this

¹⁷⁵² A summary of the terms of the IVAX-GSK Agreement are set out in paragraph 3.219–3.227. As noted above, the terms included a supply price of £8.45 per pack and a limited volume of up to 770,000 packs of product.

¹⁷⁵³ Email from [GSK's Associate General Counsel for Europe] to [GSK's Patent Attorney] dated 2 October 2001 (document 0165), entitled 'Re: Supply Agreement'.

¹⁷⁵⁴ IVAX-GSK Agreement (document 0168), clause 3.2.

clause was intended to safeguard IVAX against the effects of independent generic entry by another competitor.¹⁷⁵⁵

- These consequences must have been clear to both parties on entering into the IVAX-GSK Agreement, and are consistent with views expressed by GSK and Mr Justice Jacob in the context of the GUK patent litigation and by IVAX when considering the outcome of the Apotex litigation:

- [GSK's Finance Director A's] witness statement in the GUK litigation confirms GSK's view that, whilst IVAX had not agreed not to supply its own generic paroxetine, GSK's expectation was that IVAX would do so if and when true generic competition emerged, as a result of another competitor entering the market.¹⁷⁵⁶

'Norton has not agreed not to supply its own generic paroxetine rather than the SB- supplied product. If price competition among generic suppliers of paroxetine makes the distribution of the SB-supplied product uneconomic – which I believe will happen if GUK launches its product – then I expect Norton and those of its sub-distributors who can, will abandon the SB supplied product and sell their own generic product.'

- The judgment in *SmithKline Beecham Plc v Generics (UK) Ltd* (Jacob J.) on 23 October 2001 reflects that evidence. Jacob J held:¹⁷⁵⁷

'I must also consider the effect on Norton. They are free to enter the generic market with product other than that bought from the patentees. The evidence indicates that they were close to doing it, one way or another, with a product within the patent or without – I am not quite sure. If the price is chased down, Norton might switch from the patentees to someone else.' (emphasis added)

- IVAX also understood prior to independent generic entry that the IVAX-GSK Agreement would become unsustainable in the event that true generic competition emerged. In December 2003, when

¹⁷⁵⁵ Indeed, Teva [itself] noted at paragraph 142 of its response to the SO that 'IVAX could not have been certain of other suppliers' positions and in these circumstances, it is not surprising that it negotiated the unilateral right to terminate the Agreement in the event that the cost of goods became no longer commercially viable' (Teva SO Written Response (document 2750))

¹⁷⁵⁶ [redacted] WS2 (GUK) (document 0182), paragraph 2.9.

¹⁷⁵⁷ *SmithKline Beecham Plc v Generics (UK) Limited*, transcript of hearing before Jacob J, dated 23 October 2001 (document 0911), page 8.

IVAX was considering the implications of the High Court's invalidation of the Anhydrate Patent, but before it became aware of the termination of the interim injunction against Apotex and the subsequent entry by Neolab and Waymade, [IVAX's Sales and Marketing Manager] wrote that:

'Under this scenario [where GSK lose an appeal against the High Court's judgment] Neolab/Waymade will launch immediately and the price will almost certainly drop to below £8.45 (the market is already over supplied).

This will require a raft of actions from IVAX

....

1. [W]e cancel orders (thus terminating our agreement) for IVAX bulk supply (unless we are able to negotiate a new price with GSK)¹⁷⁵⁸

- In fact, it was the subsequent emergence of true generic competition that led to the termination of the IVAX-GSK Agreement (see paragraph 3.228 to 3.230).
- (b) GSK would have had no incentive to renew the IVAX-GSK Agreement. As set out in more detail in paragraphs B.63 to B.109, the value transfers could not have been expected to provide any benefits to GSK other than those associated with delaying the threat of true generic competition. The value transfers were commercially rational only on the basis that they would provide for a restriction of competition (that is, delaying the threat of true generic competition). Had true generic competition emerged, GSK would therefore have had no incentive to renew the IVAX-GSK Agreement and continue to make such value transfers to IVAX.

b) IVAX's subsequent conduct in the UK paroxetine market

B.113 The CMA considers that IVAX's subsequent conduct in the UK paroxetine market is consistent with the CMA's conclusion that the IVAX-GSK Agreement was designed to be an alternative to independent generic entry by IVAX.

¹⁷⁵⁸ Email from [IVAX's Sales and Marketing Manager] to [Medical Director, Teva UK Ltd] dated 16 December 2003 (document 1888), entitled 'Paroxetine – Update'.

B.114 During the course of the IVAX-GSK Agreement, IVAX made no further efforts to enter the UK paroxetine market independently, either with its own product or with a product supplied by a third party:

- While IVAX initially retained plans to continue to develop its own paroxetine product, an IVAX internal communication in October 2001, shortly after the IVAX-GSK Agreement was entered into, explained that these plans were confined to developing a product for launch in readiness for the expiry of GSK's patent and in the event that GSK's patent was successfully challenged (at which point true generic competition would emerge and IVAX would be entitled to terminate the IVAX-GSK Agreement (see further paragraph B.112):¹⁷⁵⁹

'Paroxetine Tablets (In House Development)

Progress: Deal signed with GSK for 12 months supply of paroxetine in IVAX livery. [...] Deal will be reviewed and may be renewed for a further 12 months.

IVAX will continue to develop it's [sic] own formulation in the event that (a) GSK's patent is successfully challenged and (b) in readiness for the 2006 formulation patent expiry.

Plans: Ensure that all steps are in place for launch on 1st December.' (emphasis added)

- Any further attempts by IVAX to enter the market independently of GSK in the UK would require an MA in the UK. IVAX had already obtained an Irish MA and it was open to IVAX to submit this for mutual recognition in the UK. However, [IVAX's Head of New Business Development] confirmed in an email of 18 July 2003 to colleagues in other IVAX businesses within Europe that the IVAX product was '*never [...] submitted for MR into any other states*'.¹⁷⁶⁰ Indeed, it would appear that, following entry into the IVAX-GSK Agreement, IVAX only considered going through the mutual recognition as a '*back-up*'.¹⁷⁶¹

¹⁷⁵⁹ Document entitled 'New Product Delivery (In House Development & Licensed In) Monthly Report – October 2001' (document 1719), page 9.

¹⁷⁶⁰ Email from [IVAX's Head of New Business Development] to [IVAX employee, Sweden] and others dated 18 July 2003 (document 1858).

¹⁷⁶¹ Email chain between [IVAX's Sales and Marketing Manager], [IVAX employee, Sweden], [IVAX's Commercial Director], [Regulatory Affairs, IVAX], [IVAX's Head of New Business Development], [IVAX's Head of Regulatory Affairs], and [IVAX's Research & Development Director] dated 9 April to 6 May 2002 (document 1773).

- Further, following IVAX's acquisition of exclusive rights to the Tillomed MA,¹⁷⁶² IVAX would also have had the option to seek to manufacture a product by reference to that MA. However, it did not do so.¹⁷⁶³ Indeed, IVAX apparently discontinued all further steps to use either of the MAs available to it, either to manufacture a product for supply into the UK itself,¹⁷⁶⁴ or for supply by another generic supplier, during the term of the IVAX-GSK Agreement.
- Even though IVAX was subject to a binding volume constraint for the duration of the IVAX-GSK Agreement (see paragraph B.74), and had received requests for additional volumes from customers,¹⁷⁶⁵ it chose not to seek to supply generic paroxetine from other sources, and continued only to purchase the product under the terms of the IVAX-GSK Agreement.¹⁷⁶⁶
- After entering into the IVAX-GSK Agreement, the existing Heads of Agreement between IVAX and Tillomed was '*flipped*' such that, rather than concluding an agreement where IVAX would obtain supplies of paroxetine from Tillomed, IVAX agreed to supply GSK-sourced paroxetine to Tillomed.¹⁷⁶⁷ This meant that IVAX relinquished an option which would have enabled it to obtain a supply of paroxetine (see paragraphs B.33 to B.45).
- More generally, throughout the term IVAX-GSK Agreement, IVAX purchased paroxetine exclusively from GSK.¹⁷⁶⁸

B.115 IVAX's actions as regards the entry of other potential generic competitors are also consistent with the CMA's conclusions in this regard in that they demonstrate that IVAX subsequently sought to restrict independent generic entry on the part of other suppliers rather than continue its independent efforts to enter the paroxetine market. It is clear that, following entry into the IVAX-

¹⁷⁶² See paragraph B.36.

¹⁷⁶³ Teva confirmed that no MAs for paroxetine were obtained by IVAX or Teva UK between 2004 and 2006 (Part two of the response dated 21 March 2014 to the Section 26 Notice dated 25 February 2014 sent to Teva (document D 167), question 3b).

¹⁷⁶⁴ Indeed, Teva only obtained UK MAs with respect to its own paroxetine formulation in November 2006 (Part two of the response dated 21 March 2014 to the Section 26 Notice dated 25 February 2014 sent to Teva question 3b and Annex 3.1 (documents D 167, D 168, D 168A, D 168B and D 168C)).

¹⁷⁶⁵ Moss Pharmacy contact report dated 20 March 2003 (document 1827).

¹⁷⁶⁶ Part one of the response dated 30 April 2012 to the Teva Second Section 26 Notice (document 2043), questions 1– 5.

¹⁷⁶⁷ As described at paragraphs 3.207–3.209.

¹⁷⁶⁸ Part two of the response dated 4 May 2012 to the Teva Second Section 26 Notice, with Annexes 1–3 (documents 2049 and 2050), which sets out IVAX's sales volumes in relation to paroxetine; part two of the response dated 21 March 2014 to the Section 26 Notice dated 25 February 2014 sent to Teva (documents D 167 and D 167A), which sets out IVAX's orders from GSK.

GSK Agreement, GSK and IVAX had a joint interest in seeking to delay independent entry by other potential competitors in order to attempt to maintain prices at prevailing levels:

- In the IVAX-Tillomed Supply Agreement, IVAX acquired exclusive rights to Tillomed's MA for paroxetine and agreed to pay a royalty to Tillomed amounting to 50% of IVAX's net profit on GSK supplied paroxetine. Tillomed was therefore unable to enter the market with a generic paroxetine product using the MA for which it had sold the rights to IVAX. In his witness statement to the OFT, [IVAX's Head of New Business Development] said that he considered this arrangement to be 'unusual':¹⁷⁶⁹

'In order to reach this agreement with Tillomed, I expect that IVAX considered that Tillomed must have had a viable product otherwise IVAX would not have done a deal. Presumably IVAX felt there was sufficient validity in Tillomed's claims to make it worthy of IVAX paying Tillomed 50 per cent of its profit. However, this is conjecture on my part. I cannot recall whether this was the case or not.

If IVAX had thought the Tillomed product was definitely not viable, it is highly likely that it would have told Tillomed that there was no deal on the table, unless there were other "trade offs" under discussion. However, in the absence of any trade-offs, it is my assumption that there must have been an element of belief between IVAX and GSK that Tillomed had a product that it could potentially bring to market notwithstanding the withdrawal of the Gea product from Denmark. ... However, there will probably have been a belief that Tillomed could potentially come to the market with a product that might not infringe the GSK product. Therefore, it was probably in IVAX's interests to consider doing a deal with Tillomed.'

- In May 2002, on learning of Alpharma's intention to enter the market with an independent generic product, IVAX reported this to GSK, resulting in GSK sending a warning letter to Alpharma on 27 May 2002. According to [GSK's Finance Director A's] witness statement in the Alpharma Litigation:¹⁷⁷⁰

'On Wednesday 22 May 2002, I received two telephone calls; one from [Commercial Director] of Ivax and one from [GUK's General Manager]. [GUK's General Manager] and [IVAX's Commercial Director] each told

¹⁷⁶⁹ See [REDACTED]WS (document 2333), paragraph 8.5 and 8.6.

¹⁷⁷⁰ See [REDACTED]WS1 (Alpharma) (document 0241), paragraphs 7.1–7.2.

me that he had been contacted by a representative of AAH. AAH Plc is one of the UK's largest wholesalers of pharmaceutical products and is the wholly owned subsidiary of GeHe AG, the second largest such wholesaler in Germany.

That representative had, I was told by both [GUK's General Manager] and [IVAX's Commercial Director], asked for a quotation for the supply of generic paroxetine to compare with a quotation given to AAH by the Defendant [Alpharma] for supply from 01 June 2002 onwards. After the matter had been investigated as far as possible internally at GSK, [GSK's external lawyers] were instructed to send a warning letter to Alpharma, which was sent on 27 May 2002.'

B.116 Following GSK's Agreements with each of GUK and Alpharma, IVAX agreed to act as GSK's distributor for the purposes of those Agreements. IVAX was aware of the context in which the GUK-GSK and Alpharma-GSK Agreements were reached (to settle the pending patent litigation) and was aware that the relevant Agreements contained an express restriction on GUK and Alpharma's independent generic entry.¹⁷⁷¹ The GUK-GSK and Alpharma-GSK Agreements were of benefit to IVAX as they removed the threat of generic entry by those Parties. As explained above, independent generic entry would have undermined the profitability of the IVAX-GSK Agreement and would likely have resulted in its termination.

B.117 It would have been illogical for IVAX to agree to act as a distributor to GUK and Alpharma if it envisaged entering the market independently, given that the result of IVAX's independent entry would have been to make those sub-distribution agreements unsustainable (as the market price would fall below the price at which GUK and Alpharma were purchasing from IVAX).

c) GSK's and IVAX's intentions

B.118 The CMA considers that the following evidence demonstrates that GSK's intention was that, IVAX, rather than continuing its efforts to launch generic paroxetine in the UK, would instead agree to enter the UK paroxetine market only with GSK product:

¹⁷⁷¹ IVAX received a draft of the GUK settlement on 12 March 2002 before it was agreed (Fax from [IVAX's Commercial Director] to [GSK's Associate General Counsel for Europe] dated 12 March 2002 attaching draft letter to Generics (UK) Limited (document 1764)). IVAX would also have had sight of the GSK-Alpharma Agreement for the purposes of entering into the IVAX-Alpharma Agreement (Alpharma-IVAX Agreement (document 1806)).

- As explained in paragraphs 3.144 to 3.154, GSK initiated 'Project Dyke'. That project was tasked with defending Seroxat from generic competition and with maintaining patent protection for Seroxat. One of its aims was to '*Maintain [its] monopolistic position*', with GSK identifying '*Third party supply agreement[s]*' (including the IVAX-GSK Agreement) as one of the ways of achieving that aim.¹⁷⁷²
- GSK's Finance Director, [X], stated in court proceedings in June 2002 that: '*I believe that Ivax, in deciding to enter into the Ivax Agreement, had to make a commercial decision between their desire for the substantial profit which they could make by launching Generic Paroxetine, but with the risk that they could be subject to patent infringement proceedings and an injunction, on one hand, and on the other, a lower profit by being a distributor of Distributed Paroxetine without that risk or expense.*'¹⁷⁷³ In other words, GSK regarded the IVAX-GSK Agreement as an alternative to IVAX competing independently of GSK in the UK paroxetine market.
- GSK has submitted that the IVAX-GSK Agreement provided it with 'certainty' in relation to its future revenues and profitability.¹⁷⁷⁴ Such certainty could only arise from an expectation that IVAX would not also launch its own independent generic product.
- Internal GSK documents show that GSK viewed the Agreements as '*mechanisms*' to transfer value to the Generic Companies and thereby the Agreements had '*stopped [the recipients] entering the market*'.¹⁷⁷⁵

B.119 The CMA considers that IVAX was aware of GSK's intentions in entering into the IVAX-GSK Agreement and IVAX understood and accepted that the IVAX-GSK Agreement was designed to be an alternative to independent generic entry by IVAX.

B.120 First, IVAX was aware that GSK intended for the IVAX-GSK Agreement to be an alternative to independent generic entry by IVAX. IVAX was aware that,

¹⁷⁷² GSK presentation entitled 'Overview of Generic Defences and Impact on Price Strategy Oncology ETEG 2nd Dec' by [GSK's Pricing Manager for Europe] dated 2 December 2002 (document 0100).

In its response to the SSO (GSK written response dated 2 December 2014 to the SSO (document 3668), paragraph 4.4 with reference to GSK SO Written Response (document 2755), paragraph 4.54), GSK submitted that [GSK's Pricing Manager for Europe's] comments did not relate to the IVAX-GSK Agreement, on the basis that [GSK's Pricing Manager for Europe's] role was at a European level and he would not have been directly involved with UK settlements. The CMA observes that the document does relate to the UK, and discusses the threat faced in the UK as well as the strategies being deployed in the UK (and across Europe) in response.

¹⁷⁷³ See [X]WS1 (Alpharma) (document 0241), paragraph 6.4.

¹⁷⁷⁴ GSK Second Response, Part Two (document 0734), paragraphs 8.3(b) and 8.7–8.9.

¹⁷⁷⁵ [GSK's Finance Director B's] electronic transcribed note and handwritten original note contained in 'Non-confidential 3rd questionnaire response - seroxat financial information' undated (document 0081).

from GSK's perspective, the relevant question was whether to enter into an agreement with IVAX, or to see IVAX enter the UK paroxetine market with a product sourced independently of GSK. In his witness statement, [REDACTED], IVAX's Commercial Director, considered the GSK perspective to be as follows:¹⁷⁷⁶

'The question for GSK was whether to supply IVAX with paroxetine or to refuse and for IVAX to purchase paroxetine from one of the other companies that was offering paroxetine (for example, GUK or Tillomed). Had GSK not supplied IVAX, GSK would have been walking away from around 15% of the market or whatever the market share that IVAX would probably have obtained had it entered the market and displaced that business.'

B.121 Second, the evidence demonstrates that IVAX understood and accepted that the IVAX-GSK Agreement was designed to be an alternative to independent generic entry by IVAX.¹⁷⁷⁷ As outlined below, IVAX's approach to the negotiations with GSK was premised on the supply agreement with GSK and independent generic entry being alternative options. IVAX's approach to the negotiations was to make clear that, in the absence of an agreement with GSK, IVAX would seek to bring an independent generic product to market.

B.122 IVAX had several meetings with GSK at which it represented that it was in a position to launch paroxetine imminently and that it did not infringe GSK's patents. In negotiating the IVAX-GSK Agreement, IVAX's approach was to make clear that in the absence of any such agreement, IVAX would launch a paroxetine product sourced independently of GSK. In his witness statement, [IVAX's Commercial Director] has explained that:¹⁷⁷⁸

'I do not recall the precise discussions that I had with [GSK's Finance Director A], however, I recall that IVAX's negotiating position with GSK was that: "I want to launch a version of paroxetine, I have a number of options, but if I take the supply from you that gives you an opportunity to earn some profit on that supply because you retain volume which is good for your facility, you make a profit on it because you are supplying IVAX and actually, on the basis that we can reach good commercial terms, I would rather take supply from yourself rather than a competitor, but I do have a couple of other options available."

¹⁷⁷⁶ See [REDACTED]WS (document 2332), paragraph 6.20.

¹⁷⁷⁷ The CMA has also demonstrated in paragraphs 5.65–5.77 why, given the terms of the Agreement, IVAX must have understood the IVAX-GSK Agreement to be an alternative to independent generic entry.

¹⁷⁷⁸ See [REDACTED]WS (document 2332), paragraph 6.12.

B.123 [IVAX's Head of New Business Development], former Head of Business Development at IVAX, stated in his witness statement that the context of the discussion of the IVAX-GSK Agreement was that, in the absence of an agreement, IVAX would seek to bring a product to market and that there would be litigation as to whether that product infringed GSK's patents and/or whether GSK's patent claims were valid:¹⁷⁷⁹

'In my view, once IVAX presented the MA, GSK's main defence was the IP position. Clearly GSK's position was, and I remember at every meeting it was almost underlined, "We believe in the validity of our position and we will injunct you if you try and launch your product to the market." Every meeting we would say, "We absolutely believe in the validity of our product and that we do not infringe your patent." However, we both understood there was a risk on either side around either of us being right or wrong.'

B.124 In a note in March 2001, [redacted], IVAX's Managing Director, considered various options for entering the UK paroxetine market.¹⁷⁸⁰ These included a '[redacted] launch in Ireland' (which would facilitate a launch in the UK, following the mutual recognition process) or a 'supply agreement', which were presented as alternative options (one involving IVAX testing the patent, and the other involving IVAX recognising the patent).

Representations on whether the IVAX-GSK Agreement was designed to be an alternative to independent generic entry

B.125 In relation to IVAX's subsequent conduct on the market, IVAX submitted that there was a more plausible unilateral commercial rationale whereby, given the difficulties that IVAX had encountered in developing its own product, it may not have been economically rational to have undertaken significant and costly development associated with IVAX entering independently of GSK.¹⁷⁸¹

B.126 The CMA observes that, at the time IVAX entered into the IVAX-GSK Agreement, IVAX was a potential competitor to GSK that was actively exploring a variety of potential routes to market. The evidence does not therefore indicate that, absent the IVAX-GSK Agreement, IVAX would not

¹⁷⁷⁹ See [redacted]WS (document 2333), paragraph 6.10.

¹⁷⁸⁰ IVAX internal document entitled 'Seroxat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699).

¹⁷⁸¹ Teva written response dated 21 November 2014 to the SSO (document 3645), section 3.2.4.

have continued to take steps to enter the UK paroxetine market independently of GSK.

- B.127 GSK submitted that IVAX did make further efforts to enter independently following the IVAX-GSK Agreement.¹⁷⁸² According to GSK, IVAX '*clearly stated*' at the time of signing the IVAX-GSK Agreement that it planned to continue to develop a product and that it in fact carried through with such intention as evidenced by its in-house team continuing to develop a non-infringing independent source of paroxetine until January 2004.¹⁷⁸³ GSK submitted that IVAX's efforts were ultimately terminated because of factors independent of the IVAX-GSK Agreement, such as stability issues and an inability to develop a product that did not infringe GSK's patents (which explains why IVAX did not apply for mutual recognition on the Irish MA).¹⁷⁸⁴ Finally, GSK noted that the reason IVAX did not supply paroxetine from any other sources during the term of the IVAX-GSK Agreement is because there were no other lawful sources.¹⁷⁸⁵
- B.128 As outlined at paragraph 3.187, although IVAX initially retained plans to continue to develop its own paroxetine product, these plans were confined to developing a product for launch in readiness for the expiry of GSK's patent or in the event that GSK's patent was successfully challenged. Irrespective of the difficulties encountered by IVAX in developing its own product, it is evident that IVAX was a potential competitor at the time it entered into the IVAX-GSK Agreement, and that on entering into the IVAX-GSK Agreement it deferred its efforts to enter the market independently of GSK. This is further confirmed by IVAX's conduct as described at paragraphs B.113 to B.117.
- B.129 GSK submitted that the claim that had IVAX begun to sell even modest independent volumes it would have made losses on the supplied volumes is speculative.¹⁷⁸⁶
- B.130 The CMA observes that IVAX selling independently is a scenario that could only have arisen under conditions in which generic paroxetine either was not contested by GSK or deemed legal by the courts. In this scenario, it was expected that true generic competition would result in significant price falls (see paragraphs B.61 to B.62) to levels below the supply price of £8.45

¹⁷⁸² GSK written response dated 2 December 2014 to the SSO (document 3668), paragraph 5.2

¹⁷⁸³ GSK written response dated 2 December 2014 to the SSO (document 3668), paragraphs 5.2 (a) and (b), citing document entitled 'API Working Team 2 Meeting' dated 27 January 2004 (document A 0040R).

¹⁷⁸⁴ GSK written response dated 2 December 2014 to the SSO (document 3668), paragraphs 5.2 (c) and (d).

¹⁷⁸⁵ GSK written response dated 2 December 2014 to the SSO (document 3668), paragraph 5.2 (e).

¹⁷⁸⁶ GSK written response dated 2 December 2014 to the SSO (document 3668), paragraph 5.4.

included with the IVAX-GSK Agreement. The CMA observes that this scenario is consistent with GSK's expectations at the time (see paragraph B.112).

(v) Conclusion

B.131 For the reasons set out above, the CMA finds that the IVAX-GSK Agreement was designed to be an alternative to IVAX's independent generic entry, such that, by incentivising IVAX to enter into and sustain the IVAX-GSK Agreement, the value transfers necessarily incentivised IVAX to defer its own potential generic entry.

E. Assessment of likely effects of the value transfers made by GSK to IVAX

B.132 In this Section the CMA sets out its detailed assessment of the effects on competition of GSK's conduct in making value transfers to IVAX pursuant to the IVAX-GSK Agreement, for the purposes of the CMA's findings under Chapter II of the Act against GSK.

B.133 In summary, the CMA finds that the likely effect of GSK's conduct in making value transfers to IVAX was to restrict competition between 3 October 2001 and at least 30 November 2003. In particular, the CMA finds that:

- The context at the time of the IVAX-GSK Agreement was as follows:
 - As set out at paragraphs B.3 to B.60, at the time the IVAX-GSK Agreement was entered into IVAX was a potential competitor to GSK in the UK paroxetine market. IVAX was pursuing entry strategies aimed at entering the market with generic paroxetine sourced independently of GSK.
 - As set out at paragraphs B.61 to B.62, had true generic competition emerged, such competition was expected to result in significant decreases in paroxetine prices in the UK and a decline in GSK's market share.
 - GSK held a dominant position in the UK paroxetine market.
- The value transfers in the IVAX-GSK Agreement had the likely effect of inducing IVAX to delay its potential independent entry and the associated price decreases. As regards the structure of the market, the IVAX-GSK Agreement also had the likely effect of assisting GSK in preserving the patent entry barriers faced by IVAX and other potential entrants and thereby enabling GSK to maintain its dominant position.

- IVAX's entry as a distributor of GSK product was not likely to materially increase the actual competitive constraints faced by GSK. As a consequence of the volume restriction, IVAX's entry was likely to have no meaningful impact on actual competition in the UK paroxetine market.¹⁷⁸⁷
- Developments observed in the UK paroxetine market during the term of the IVAX-GSK Agreement are consistent with this analysis: (i) IVAX deferred its efforts to enter the market independently of GSK and (ii) IVAX's restricted entry as a GSK distributor had no material impact on market prices.
- Absent the value transfers in the IVAX-GSK Agreement to incentivise IVAX to delay its potential entry, IVAX would have remained a potential competitor that was pursuing its efforts to enter the market independently of GSK. IVAX's competitive behaviour would not have been distorted by value transfers made to incentivise a delay to IVAX's potential entry. The realistic and likely outcomes are that IVAX would have continued with its efforts to enter the UK paroxetine market independently of GSK, or else it would have entered into an alternative settlement agreement with less restrictive terms.
- The absence of other relevant sources of competition to GSK meant that the IVAX-GSK Agreement assisted GSK in preserving its dominant position, given:
 - that at the time the IVAX-GSK Agreement was entered into, GSK did not face true generic competition; and
 - the limited number of further potential entrants.

B.134 This Section sets out, in relation to the IVAX-GSK Agreement:

- GSK's competitive position;
- the restrictive effects of the Agreement;
- the counterfactual; and

¹⁷⁸⁷ Even if it had been the case that such entry materially constrained GSK, the CMA considers it likely that in the counterfactual the terms of entry and/or supply would have been less restrictive. That is because in the absence of a value transfer made to incentivise the deferral of potential entry, it is reasonable to expect that IVAX's acceptance of any settlement agreement would have required more competitive terms because GSK would have been required to offer more competitive terms to IVAX to provide IVAX with alternative sources of remuneration and a sufficient incentive to settle (see paragraph B.180)

- other relevant sources of competition to GSK.

B.135 A number of the representations in relation to the effect of the IVAX-GSK Agreement are discussed in this Section. Representations of relevance to all of the Agreements are presented in Annex I.

i) *GSK's competitive position*

B.136 As set out at Part 4, the relevant market is the supply of paroxetine in the UK.

B.137 As set out at paragraphs 4.98 to 4.128, the CMA finds that, at least between January 1998 and November 2003 (the month before independent generic entry began, see paragraph 3.21), GSK held a dominant position in the UK paroxetine market.

B.138 In the context of the IVAX-GSK Agreement, GSK had an interest in protecting its dominant position, as there had been no launch of independent generic paroxetine and therefore GSK was able to sustain far higher profits than was likely to be the case following generic entry (see paragraphs 3.161 to 3.164).¹⁷⁸⁸

ii) *The restrictive effects of the IVAX-GSK Agreement*

a) *The likely effect of the value transfers was to induce delays to the potential emergence of true generic competition and to assist GSK in preserving its dominant position*

B.139 As set out at paragraphs B.108 to B.130, the value transfers included within the IVAX-GSK Agreement incentivised IVAX (i) to defer its efforts to enter the market supplying generic paroxetine sourced independently of GSK, for the term of the Agreement, and/or (ii) not to facilitate independent generic market entry by another company.¹⁷⁸⁹ As set out at paragraphs B.63 to B.131, the CMA has considered the purpose of the value transfers from GSK to IVAX, and concluded that the value transfers were made to incentivise IVAX to defer its efforts to enter the UK paroxetine market independently of GSK.

B.140 In the absence of the value transfers described above (and in the absence of a more competitive settlement), IVAX would not have been incentivised to

¹⁷⁸⁸ This is consistent with GSK's strategy regarding defence strategies to protect Seroxat from generic entry (see paragraphs 3.144–3.154).

¹⁷⁸⁹ Teva submitted that IVAX had not been granted an MA at the time of the Agreement (Teva SO Written Response (document 2750), footnote 213). The CMA notes at the time of entering into the IVAX-GSK Agreement IVAX had acquired exclusive rights to the use of Tillomed's MA (see paragraph 3.207). As set out at paragraphs B.111–B.112, having determined that accepting the value transfers and entering into the IVAX-GSK Agreement was its most profitable option, IVAX would necessarily have had no incentive to facilitate another company's generic entry by transferring its MA to another company.

accept the terms of the IVAX-GSK Agreement. IVAX was a potential competitor that was otherwise seeking to enter the UK paroxetine market independently of GSK (see paragraphs B.3 to B.60), and was unlikely to have been incentivised to defer its potential independent entry without sufficient compensation. This analysis is supported by IVAX's internal documents (see paragraphs B.104 to B.107), which indicate that absent sufficiently high value transfers from GSK, IVAX was minded to maintain its efforts to enter the market independently of GSK.

B.141 As set out at paragraph B.88, the CMA observes that there was no commitment from GSK that it would refrain from patent litigation proceedings if, after the expiry of the IVAX-GSK Agreement, IVAX sought to supply its own generic paroxetine product. As such, while the threat of IVAX's potential independent generic entry was delayed by the Agreement, the Agreement's terms were such that IVAX would continue to face the prospect of litigation (see paragraphs 4.116 to 4.123) in the event that it entered the UK paroxetine market with a generic paroxetine product sourced independently of GSK, even after the expiry of the Agreement.

B.142 The likely effect of the IVAX-GSK Agreement, including the value transfers, was to incentivise IVAX to delay its efforts to independently enter the market. By delaying IVAX's potential independent generic entry and associated challenge to GSK's patent position, the likely effect of the IVAX-GSK Agreement was also to assist GSK in preserving the patent entry barriers faced by other potential entrants,¹⁷⁹⁰ which would continue to face the prospect of litigation in the event that they sought to enter the UK paroxetine market with a generic paroxetine product sourced independently of GSK (see also paragraphs B.188 to B.189). The IVAX-GSK Agreement therefore made the independent entry of competitors onto the market more difficult, thereby interfering with the structure of competition on the market.

¹⁷⁹⁰ Teva submitted that the suggestion that the IVAX-GSK Agreement assisted GSK in preserving entry barriers is speculative because the prospect of a successful outcome in litigation was uncertain and there is no evidence that IVAX considered litigation in detail (Teva SO Written Response (document 2750), paragraph 201). Teva also noted that the IVAX-GSK Agreement did not stop potential suppliers from launching 'at risk' or challenging GSK's patents (Teva SO Written Response (document 2750), paragraph 202). As set out at paragraph B.3, IVAX was a potential competitor at the time of its entry into the IVAX-GSK Agreement, and as set out at footnote 1850, GSK has confirmed that had IVAX entered the market GSK would have litigated, and the CMA therefore considers it reasonable to infer that litigation would have likely commenced had IVAX attempted to enter the market. To that extent, the delay to IVAX's potential market entry served to delay the processes relevant to entering the market. The CMA notes that the ultimate outcome of any subsequent litigation, when assessed *ex post*, does not alter that position. See also paragraph B.112.

b) *The likely effect of IVAX's entry as a GSK distributor was no material increase to the actual competitive constraints faced by GSK*

B.143 The transfer of a restricted volume of product from GSK to IVAX was not likely to materially increase the actual competitive constraints faced by GSK in the supply of paroxetine in the UK.

B.144 As set out at paragraph B.63, under the terms of the IVAX-GSK Agreement, GSK transferred value to IVAX by supplying it with a restricted volume of paroxetine, and IVAX was able to purchase no more than 770,000 packs each year¹⁷⁹¹ from GSK.¹⁷⁹² For the reasons set out at paragraph B.70, the transfer of a restricted volume of product¹⁷⁹³ itself represented a value transfer that involved GSK transferring to IVAX the margin it would otherwise have earned on such volumes. In the same way as a payment, GSK was able to use this mechanism to make a value transfer to IVAX through a means that would not meaningfully increase the price competition it was facing in the market. Consistent with this, the likely effect of the transfer of a restricted volume of paroxetine was no material increase in the actual competitive constraints faced by GSK and no meaningful impact on the degree of actual competition in the UK paroxetine market:

- In the event that IVAX reduced its prices to a level that was materially below the level of its competitors in the UK paroxetine market (namely GSK and parallel importers of Seroxat), the associated increase in its orders would have resulted in IVAX quickly reaching the volume restriction of 770,000 packs of paroxetine 20mg, thereby harming its reputation with customers by not being able to meet customers' orders.¹⁷⁹⁴

¹⁷⁹¹ Although the volume restriction for IVAX increased in subsequent Addenda of the Agreement (see paragraphs 3.223–3.227), the increases were simply to allow for supply to GUK, Alpharma and [X]. The allocation to IVAX did not increase beyond 770,000 packs per year.

¹⁷⁹² As noted at paragraph B.73, [IVAX's Commercial Director] alleged that the volume limitation was a forecast rather than a restriction. For the reasons set out in paragraph B.74, the CMA does not accept this argument.

¹⁷⁹³ GSK submitted that the volume restriction was not restrictive in the way the CMA contends, and that there was no evidence that the Generic Companies sought additional supplies. See paragraph B.154 for the CMA's responses to these points.

¹⁷⁹⁴ One rationale put forward by IVAX to explain why it would be willing to sell at prices below marginal cost for a period of time is to maintain its reputation by providing its customers with continuity of supply. If IVAX stopped supplying, another company selling paroxetine could obtain business for other products in IVAX's product lines as well and IVAX could lose sales across its range. See note of meeting between the OFT and Teva on 24 April 2012 (document 2035), paragraph 45. The CMA agrees that creating goodwill amongst customers may be sufficiently valuable to IVAX for it to be willing to accept a loss per product, if sales in other areas were high enough to offset any per unit loss. However, the CMA considers this argument applies to any supply price regardless of the level at which it is set. Moreover, the benefit gained through the goodwill generated will be equally valuable regardless of the price level. Therefore, all being equal, a higher supply price in the contract will result in a higher floor price for IVAX.

- Were IVAX to lower its prices to materially below prevailing levels, its profits would be lower than would have otherwise been the case, because IVAX would be making a lower mark-up on each pack sold without being able to sell additional packs. As a result of the volume restriction, IVAX's incentive to reduce prices below the prevailing price at the time, the parallel import price of £13,¹⁷⁹⁵ would have been minimal.
- As IVAX could not sell more than 770,000 packs, it could not expand its market share by volume beyond 13% of the UK paroxetine market.¹⁷⁹⁶ Therefore, having secured customers to whom it would make its allocation of paroxetine sales,¹⁷⁹⁷ IVAX would have had no incentive to compete for other customers to whom GSK was supplying Seroxat. As a result, the impact that sales by IVAX could have on GSK's market share of UK-supplied paroxetine was capped, helping to protect GSK's share of the UK paroxetine market.
- Because of the volume restriction, IVAX's potential market shares were capped.

B.145 As a further consequence of the volume restriction, GSK would have had little incentive to respond to IVAX's entry (or, for the same reasons, the subsequent entries of GUK and Alparma) by competing on price:

- The majority of GSK's existing customers were unlikely to be the subject of an approach from IVAX given the volume restriction that IVAX was subject to and the expectation that IVAX's sales would in part replace those of parallel importers (see paragraph B.149).
- GSK's own pricing policy was not to pre-emptively decrease its price to gain market share: *'Experience shows that GSK should not drop prices pre-emptively. This only forces a price war. Optimal strategy for branded products generally to follow price reduction rather than lead.'*¹⁷⁹⁸ Consistent with this, it was likely that GSK would not drop its prices below

¹⁷⁹⁵ [REDACTED]WS2 (GUK) (document 0182), paragraph 3.3.

¹⁷⁹⁶ Calculated based on the market size in the 12 months to October 2001, based on data supplied by relevant parties.

¹⁷⁹⁷ See paragraph B.149 for an explanation of why it was expected that IVAX's sales as a GSK distributor would replace sales by parallel importers.

¹⁷⁹⁸ GSK presentation entitled 'Seroxat Brand Planning, Europe' by [GSK's Brand Manager (Neurosciences) Europe] dated December 2002 (document D 124), page 34. [GSK's Finance Director A's] witness statements during the Alparma Litigation also imply that GSK would react to price falls rather than leading them: *'A further result of the price of Generic Paroxetine falling substantially would be that GSK would be obliged to respond by increasing its brand equalisation discounts for as many of its customers as possible.'* ([REDACTED]WS1 (Alparma) (document 0241), paragraph 9.8) and *'GSK's brand equalisation discounts are only offered in reaction to market pressures, principally the prices charged by parallel importers. [...] It is bizarre to suggest that GSK would offer such discounts without having to do so.'* (emphasis in original) ([REDACTED]WS2 (Alparma) (document 0289), paragraph 2.2).

those charged by IVAX, as it would have been aware that, had it done so, IVAX would continue to match GSK's prices until prices were competed down close to approximately £8.45 per pack (that is, the cost per pack for the Generic Companies) such that GSK would make substantially lower profits overall. GSK's most profitable response to the restricted entry of the Generic Companies was therefore to preserve its prices at prevailing levels. Consistent with this, prices remained broadly constant during the term of the IVAX-GSK Agreement (see paragraph B.166).

- Had GSK instigated price cuts that limited the margins available to IVAX, IVAX would (other things being equal) have a decreased incentive to extend its Agreement beyond the relevant expiry date.
- Were GSK to reduce its prices to a level below £8.45, IVAX would have been entitled to terminate its Agreement with GSK and continue its efforts to enter the UK paroxetine market independently of GSK.¹⁷⁹⁹

B.146 Consistent with this, contemporaneous evidence demonstrates that both IVAX and GSK considered that the expected impact of a supply agreement¹⁸⁰⁰ containing volume restrictions would be continued price stabilisation:¹⁸⁰¹

¹⁷⁹⁹ As set out at paragraphs B.108–B.131, IVAX was incentivised by the IVAX-GSK Agreement to delay its efforts to enter the market independently.

¹⁸⁰⁰ This is also consistent with evidence that GSK's expectation was that the supply agreements would lead to price stabilisation. For example, in 2001, a GSK internal presentation considering the 'Seroxat Patent Challenge' concluded that entering into a supply agreement would lead to a '*Generic price 75% MSP to compete with PI [Parallel Imports]*' (GSK presentation entitled 'Seroxat Patent Challenge' dated 5 February 2001 (document 0123), page 4) and [GSK's Finance Director A] confirmed in a post-SSO witness interview that in planning it was assumed that the generic selling price would be 75% of the MSP ([§]1 (document 4008R), page 32). In GSK Third Response (document 0750) GSK indicates that 'MSP' refers to the list price at the time of £17.76. Consistent with this a Seroxat Brand Planning document dated December 2002 noted for the UK that: '*GSK-Norton co-marketed version of Seroxat available with a price of approx. 70% of branded version. [...] Early indications are that total Seroxat revenues are holding up well.*' (GSK presentation entitled 'Seroxat Brand Planning, Europe' by [GSK's Brand Manager (Neurosciences) Europe] dated December 2002 (document D 124), page 25). [GSK's Finance Director A] further stated that the intention of the supply agreements was to allow GSK to meet its budget agreed over a three-year planning horizon. [GSK's Finance Director A] stated that GSK was not anticipating multiple generics entering the market and competing on price for several years, and it sought to maintain that position of '*some level of certainty*' ([§]1 (document 4008R), pages 15–16). Consistent with this, an internal GSK document dated January 2004 indicated that unrestricted competition independently of GSK would result in substantial price declines: '*The Apotex court ruling means the UK competitive environment is significantly altered. We now expect the [sic] to face a generic not supplied by GSK, leading to aggressive price competition*' (GSK document entitled 'Synthon STP' dated 16 January 2004 (document 0456)).

¹⁸⁰¹ GSK submitted that witness statements in patent litigation suggesting that the impact of the IVAX-GSK or GUK-GSK Agreements was not, or was not likely to be, substantial are of no evidential value. GSK stated that the relevant comments were made by comparison to true generic competition and the associated irreversible price decline, whereas the relevant counterfactual is the maintenance of a presumptively valid patent. (GSK SO Written Response (document 2755), paragraphs 8.28–8.29). The CMA does not agree that these points undermine the statements' evidential value because: (i) the statements in question directly relate to the impact of the Agreements, and as such are therefore relevant, and (ii) the CMA does not consider that the context undermines the statements as they merely articulate that the impact of the Agreements was expected to be minimal compared to the situation at the time (that is, prior to any independent generic entry having taken place).

- For example, in a witness interview with the OFT, [IVAX's Head of New Business Development]¹⁸⁰² confirmed that the expected impact of the restricted volumes available was price stabilisation:

'The impact of IVAX selling additional packs of course would be price destabilisation, because you are potentially providing more than what is required by the market and competing to make sales, unless GSK reduced their own volume of sales. I expect that is why GSK would not agree to additional packs being sold by IVAX. To this extent, the clause probably had the effect of stabilising prices, at least to some degree.'

- A strategy document indicates that GSK considered that the expected impact of the Agreements would be price stabilisation at prevailing price levels:¹⁸⁰³

'Price Defence Strategy: Defences undertaken to date are crucial to protect Seroxat prices:

*...Co-marketing strategies avoid generic reference pricing (e.g. UK, Ger, Den, Netherlands, and Spain) and **allow participation in generic market without undermining Seroxat price.**' (emphasis added)*

B.147 The evidence indicates that IVAX ordered from GSK the maximum number of packs that it was entitled to under the volume restriction for the duration of the IVAX-GSK Agreement¹⁸⁰⁴ prior to independent generic entry,¹⁸⁰⁵ and that without the volume restriction IVAX would have been able to sell higher quantities of paroxetine:

¹⁸⁰² [REDACTED]WS (document 2333), paragraph 9.15.

¹⁸⁰³ GSK presentation entitled 'Seroxat Brand Planning, Europe' by [GSK's Brand Manager (Neurosciences) Europe] dated December 2002 (document D 124), page 34. As set out at paragraph 3.147, GSK also referred to 'supply agreements' as 'co-marketing agreements'.

¹⁸⁰⁴ The CMA notes that GSK stated that '*It is important to appreciate that Ivax only ever asked for a fraction of this entitlement. In other words, far from being restricted, Ivax had available to it far greater volumes than it actually called for. The volume quota in the agreement therefore did not have the effect of a "restriction" on quantities available.*' (GSK Second Response, Part Two (document 0734), paragraph 11.3). GSK subsequently provided data which showed that this was not the case, such that the Generic Companies did order the full allocation of volumes available to them in 2002 and 2003 (source: CMA calculations based on PDF 'Apotex damages disclosure document 171' undated document (2525), attached to the response dated 30 January 2013 to the Section 26 Notice dated 18 December 2012 and sent to GSK (document 2515)).

¹⁸⁰⁵ Although the volume restriction was still effective and in place in the third year of the Agreement, IVAX did not purchase all of its volume allowance during that year and in that sense it did not serve to bind the purchases IVAX made over the course of the 12 month period. Generic entry occurred in December 2003 at the same time as the start of the third contract year, and thereafter IVAX received 28% (143,615 packs) of the pro-rated volumes available in the third year of the Agreement until it ended in June 2004. Following generic entry, IVAX would no longer have been able to profitably supply paroxetine that was sourced at the £8.45 supply price specified in the IVAX-GSK Agreement, and it can be inferred that it is for the reason that IVAX decided to stop purchasing paroxetine from GSK.

- Data on IVAX's orders¹⁸⁰⁶ shows that during the IVAX-GSK Agreement, IVAX received 755,261 packs in the first contract year and 776,800 packs in the second contract year. These volumes equate to 98% and 101% of the restricted volume in each year respectively.¹⁸⁰⁷
- In 2003 Moss Pharmacy was seeking additional supply from IVAX. In a note of its discussion with Moss Pharmacy, IVAX recorded that its response to Moss Pharmacy's request had been: *'at this stage there [sic] it was not possible for us to offer reduced prices on this line as all the limited volumes we were getting were being sold immediately at our market price.'*¹⁸⁰⁸

B.148 The evidence also confirms that price stability was in fact observed:

- As explained in paragraph B.166, the IVAX-GSK Agreement did not have a material impact on prices in the market: there was no material fall in prices following either the introduction of the Agreement or during its term. For example, paroxetine 20mg and Seroxat 20mg prices in the three months after IVAX's entry pursuant to the IVAX-GSK Agreement were both around 1% higher compared to the three months before IVAX's entry.
- [GSK's Finance Director A] indicated in a witness statement dated 22 October 2002 that prices had not fallen after IVAX, GUK and Tillomed had

¹⁸⁰⁶ Part two of the response dated 21 March 2014 to the Section 26 Notice dated 25 February 2014 sent to Teva (document D 167 and D 167A). The relevant product volumes relate to finished packs of paroxetine for onward sale by IVAX delivered to IVAX's storage facility and received (i) directly from GSK; and (ii) from IVAX's Waterford facility. Although Teva has also provided data on IVAX's sales of paroxetine, the CMA considers that it is order data which is important to an assessment of whether the volume restriction was binding because IVAX was restricted in the amount it could purchase from GSK.

¹⁸⁰⁷ The CMA has calculated contract years as being from November to October of each year. The CMA considers that it is reasonable to calculate the volumes on this basis as it is consistent with: (i) the data which shows that IVAX first received product in November 2001; and (ii) Clause 7.1 of the IVAX-GSK Agreement which indicates that product was supplied in advance of each month of the Agreement: *'Prior to commencement of this Agreement IVAX shall send to [GSK] its twelve month forecast of its likely sales volume requirements of the PRODUCT as shown in Schedule III. Such forecast shall indicate the estimated monthly requirements of IVAX and in respect of the first month shall be firm orders. Requirements for the duration of this Agreement to be updated on a monthly basis. Purchase orders will be provided by IVAX to cover the first month's requirement of the PRODUCT and thereafter on a monthly rolling basis.'* (IVAX-GSK Agreement (document 0168)).

The fact that IVAX's orders exceeded its allowance by 1% in the second contract year should not be considered as evidence that the volume restriction was not binding. Rather, this 1% deviation represents a reasonable margin of error, in particular given that the data analysed is based on volumes of finished product received from the IVAX Waterford facility, rather than the purchases actually made from GSK in relation to the relevant contract year. Consistent with this, Teva has stated that *'This data is not, however, a direct proxy of the total amount of product received by IVAX from GSK. As an example it is inevitable that amounts of bulk paroxetine products would have been damaged whilst being processed at Waterford and damaged in transit. Accordingly some wastage must be assumed.'* (Part two of the response dated 21 March 2014 to the Section 26 Notice dated 25 February 2014 sent to Teva (document D 167)).

¹⁸⁰⁸ Moss Pharmacy contact report dated 20 March 2003 (document 1827).

entered the market as GSK sub-distributors:¹⁸⁰⁹ *‘Ivax would be unlikely to want to undercut the existing price paid by customers for parallel imported paroxetine. This is the price to which GSK was already discounting a number of brand equalisation deals [...] I believe the current situation, therefore, is that the price at which both Ivax and its sub-distributors sell Distributed Paroxetine has remained stable since the coming into effect of the Ivax Agreement.’*¹⁸¹⁰

B.149 As set out in paragraph B.144, another likely effect of the volume restriction was that IVAX’s entry as a GSK distributor would have only a limited impact on GSK’s market share. In part, this would be because sales by GSK’s distributors would replace sales by parallel importers.¹⁸¹¹ This was anticipated by both GSK and the Generic Companies. For example:

- An internal GSK presentation (undated) in relation to co-marketing agreements in Germany stated: *‘Our assumption was that a co-marketing deal or a supply agreement will reduce PIs [Parallel Imports]’.*¹⁸¹²
- [GUK’s General Manager] stated in a witness statement dated 15 October 2001 in the GUK Litigation in relation to IVAX’s entry as a GSK distributor: *‘SB is therefore targeting the PI [parallel imports] sector of the market, through Norton [IVAX], which is the typical strategy of any generic company coming to market in the UK.’*¹⁸¹³

¹⁸⁰⁹ [REDACTED]WS1 (Apotex) (document 0333), paragraphs 6.5 and 6.7. GSK submitted that what was meant by this statement was that the price had not decreased further since the original low prices at which IVAX and GUK respectively had sold authorised generic paroxetine into the market, and the focus of this witness statement, given that it was made in litigation during October 2002, was on the lack of further price decreases rather than the original price decrease. (GSK SO Written Response (document 2755), paragraph 8.38). The CMA considers that the interpretation it has given to this statement is accurate given both: (i) the context in which this statement was made that GSK considered that IVAX would be unlikely to undercut prices as compared to existing levels; and (ii) the evidence presented at paragraph B.166 that paroxetine prices did not fall materially following IVAX’s entry as a GSK distributor.

¹⁸¹⁰ See also [GSK’s Finance Director A’s] statement in the litigation with the Apotex Parties: *‘The Distributed Paroxetine sold by Ivax and its sub-distributors does not displace parallel imported SEROXAT on price, but because there is a demand for UK packaging.’* ([REDACTED]WS2 (Apotex) (document 0352), paragraph 3.2).

¹⁸¹¹ GSK submitted that the Generic Companies more than displaced parallel imports, and took 20 percentage points of 20mg volume share from GSK (GSK SO Written Response (document 2755), paragraphs 8.18–8.20). It is not the CMA’s case that sales made by the Generic Companies pursuant to the Agreements would displace only sales by parallel importers. The CMA notes that the data submitted by GSK on this point is consistent with that which the CMA has included in Figures 3.4 and 3.5.

¹⁸¹² GSK presentation entitled ‘Generic offence strategy in Germany’ by [GSK’s Head of Marketing (CNS Gastro & Urology)] (document 0094), slide 10.

¹⁸¹³ [REDACTED]WS (document 0901), paragraph 33.

- In 2001, a GSK internal presentation considering the ‘*Seroxat Patent Challenge*’ concluded that entering into a supply agreement would lead to a ‘*Generic price 75% MSP to compete with PI [Parallel Imports]*’.¹⁸¹⁴

B.150 As a GSK distributor, IVAX’s sales were expected to replace sales by parallel importers because, prior to entering into the Agreements, GSK was protecting its market share by offering discounts similar to brand equalisation deals to larger customers, and could adopt the same approach in response to sales made by its distributors. For example, in the GUK Litigation [GSK’s Finance Director A] stated that:¹⁸¹⁵ *‘In order to maintain our market share against these lower priced products [parallel imported paroxetine], we offer our customers discounts similar to brand equalisation deals’*. However, it was not practical for GSK to negotiate brand equalisation deals with all customers, as noted by [GSK’s Finance Director A]: *‘there is a large number of pharmacists - about 40% of the market - in respect of whom it is impracticable to negotiate such discounts [brand equalisation discounts]*’.¹⁸¹⁶ This meant that parallel importers or generic suppliers were more likely to be able to supply those customers that GSK could not retain by offering discounts. For example, [GUK’s General Manager] stated that: *‘many of our customers will not have built up stocks of Seroxat from parallel importers in recent months in the expectation that GUK will launch its paroxetine product.’*¹⁸¹⁷

B.151 The evidence confirms that GSK was successful in protecting its market share of UK-supplied Seroxat sales by replacing sales by parallel importers with sales by the Generic Companies as its distributors:

- For example, in 2002, [GSK’s Finance Director A] stated that:¹⁸¹⁸ *‘Before the coming into effect of the Ivax Agreement, about 40% of paroxetine dispensed against prescriptions in the UK was parallel imported. I believe that Distributed Paroxetine sold by Ivax and its sub-distributors has now largely displaced that parallel imported product.’*¹⁸¹⁹

¹⁸¹⁴ GSK presentation entitled ‘Seroxat Patent Challenge’ dated 5 February 2001 (document 0123). In GSK Third Response (document 0750) GSK indicates that ‘MSP’ referred to the list price of £17.76.

¹⁸¹⁵ [REDACTED]WS2 (GUK) (document 0182), paragraph 3.2.

¹⁸¹⁶ [REDACTED]WS1 (Alpharma) (document 0241), paragraph 5.4.

¹⁸¹⁷ [REDACTED]WS (document 0901), paragraph 47.

¹⁸¹⁸ [REDACTED]WS1 (Apotex) (document 0333), paragraph 6.8. The CMA notes that the figure of 40% as the market share of parallel importers at the time is too high, see footnote 1820.

¹⁸¹⁹ See also [REDACTED]WS2 (Alpharma) (document 0289), paragraph 3.1: *‘Ivax, GUK and Tillomed [...] have taken much of the parallel importers’ customer base ...’* and [REDACTED]WS2 (document 1325), paragraph 29: *‘In any event, the volume of parallel imports appear to have been reduced significantly and I think it is undoubtedly true that their market share has been replaced by that of the generics [IVAX and GUK].’*

- As explained in paragraph B.167, sales of parallel imports began to decline after IVAX's entry into the UK paroxetine market as a GSK distributor such that the impact on GSK's market share for the supply of finished product to pharmacies/wholesalers was limited.¹⁸²⁰

GSK's and Teva's Representations

B.152 GSK¹⁸²¹ and Teva¹⁸²² submitted that the Agreements resulted in Teva's early entry into the market and introduced more price competition into the supply of paroxetine in the UK. The parties stated that for this reason the effect of the Agreement cannot have been to restrict competition. This sub-section addresses those submissions.

Volume restrictions

B.153 GSK's and Teva's representations regarding the volume restrictions were as follows:

- The volume restrictions were not restrictive because the volumes supplied to the Generic Companies were substantial,¹⁸²³ and were not binding, based on there being no evidence that IVAX ever approached GSK for increased volumes following entry into the Agreement.¹⁸²⁴
- The Moss Pharmacy contact report relied on by the CMA is in the context that IVAX claimed to have limited volumes as it did not want to match the price offered by Alpharma, and was not evidence of refusal by GSK to increase volumes.¹⁸²⁵ In this context GSK and Teva¹⁸²⁶ referred to [IVAX's

¹⁸²⁰ The CMA notes that during the GUK Litigation, [GSK's Finance Director A] stated that 'a substantial proportion (about 40%) of the SEROXAT (paroxetine) dispensed in the UK is in the form of parallel imports' ([GSK]WS1 (GUK) (document 0885), paragraph 3.3). This implies that GSK's market share (for the supply of finished product to pharmacists/wholesalers) was 60% during 2001. However, as set out in Tables 3.4 and 3.5, GSK's market share, based on data submitted by GSK, was significantly higher than this, 79% by value and 77% by volume in 2001. At this time GSK remained the sole manufacturer of paroxetine sold in the UK (with a market share by value or volume of 100% at the production level).

¹⁸²¹ For example, GSK stated 'Far from restricting competition, the GSK Agreements accelerated early entry of generic paroxetine to the UK market'. See GSK SO Written Response (document 2755), page 142. See also GSK SO Written Response (document 2755), paragraphs 4.6, 4.15, page 158, paragraphs 5.132, 5.167, page 257 summary box and paragraph 8.58. See also GSK submission to the OFT dated 27 June 2012 (document 0746), section 5.

¹⁸²² Teva SO Written Response (document 2750), paragraphs 191, 198 and 258. See also minutes of meeting between Teva and the OFT dated 18 October 2012 (document 2356), paragraph 43.

¹⁸²³ GSK SO Written Response (document 2755), paragraphs 1.142 and 8.19.

¹⁸²⁴ GSK SO Written Response (document 2755), paragraph 8.35, with reference to paragraph 5.163. GSK also referred to [GSK's Finance Director A's] witness statement that he has no recollection that IVAX ever sought additional volumes (Witness statement of [GSK's Finance Director A] dated 1 August 2013 (document A 0059), paragraph 4.14).

¹⁸²⁵ GSK SO Written Response (document 2755), paragraphs 5.164–5.165.

¹⁸²⁶ Slides for the Teva SSO Oral Hearing dated 10 December 2014 (document 3705), slide 27.

Sales and Marketing Manager's] statement in an email to [IVAX's Commercial Director] that *'GSK supply to our forecast, this is not constrained by anything other than GSK's capacity to manufacture.'*¹⁸²⁷

B.154 The CMA remains satisfied that the volume restriction was binding, in the sense that IVAX ordered the maximum number of packs that it was contractually entitled to, for the reasons set out at B.147, and makes the following additional points:

- The CMA observes that the volume restrictions were binding and that the Generic Companies would have taken more product had it been offered to them. The CMA considers that GSK found no evidence that the Generic Companies requested additional volumes because the Generic Companies understood, given that the volume restrictions were terms required by GSK in the Agreements, that they could not expect any request for additional volumes to be granted. This is despite evidence that, in a Moss Pharmacy contact report dated 20 March 2003, IVAX noted an action point for [IVAX employee] *to discuss [...] the potential for increased volumes with [IVAX's Commercial Director].*¹⁸²⁸
- As regards the claim that IVAX was reluctant to match Alpharma's prices, the CMA notes that there was no material decrease in prices following the Generic Companies' entry pursuant to the Agreements (see paragraph B.166). Given the extent to which prevailing prices remained above the supply price paid by IVAX to GSK and the margins available to IVAX at prevailing prices, it would not have been in IVAX's interests to refuse to lower its prices and not to seek further supply (were it not subject to a volume restriction) because this would simply mean IVAX would lose its sales to its lower-priced rival. Further, as set out at paragraph B.74, the CMA does not accept the submission that volumes were supplied according to IVAX's forecast. In particular, the CMA considers it implausible that a volume limit spanning three years, and that remained unchanged despite significant market changes including the market entry of both GUK and Alpharma, could have represented a genuine forecast of IVAX's level of demand.

¹⁸²⁷ Email from [IVAX's Sales and Marketing Manager] to [IVAX's Commercial Director] dated 8 November 2002 (document 1802), and the attached email chain.

¹⁸²⁸ Moss Pharmacy contact report dated 20 March 2003 (document 1827).

Supply Price

B.155 GSK and Teva submitted that the supply price was at a level such that IVAX was able to compete effectively with GSK:

- GSK stated that the supply price allowed for a substantial margin compared to prevailing prices, to enable the Generic Companies to exert downward pressure on prices, which they did.¹⁸²⁹ GSK submitted that the Generic Companies had the ability to sell at competitive prices, on the basis of: (i) the supply price allowing for margins of 35 to 45% against prevailing prices, and (ii) marketing allowances being available for discounting against the supply price.¹⁸³⁰
- Teva submitted that as a first independent generic entrant IVAX would have had limited incentives to reduce its price greatly as prices in the pharmaceutical industry will be determined by the number of generic suppliers who have entered the market.¹⁸³¹

B.156 Regarding GSK's and Teva's submissions in relation to the supply price being at a competitive level:

- The CMA does not accept that the margins available could reasonably have been expected to be used for discounting. As explained above (see paragraph B.144) the CMA finds that, as a consequence of the binding volume restriction, IVAX was not incentivised to charge a price that was materially below prevailing levels. Instead, as explained at paragraph B.70, the transfer of a restricted volume of paroxetine, and the associated margins, constituted a value transfer. For the reasons set out at paragraph B.67 the CMA considers that the marketing allowances did not increase IVAX's incentive to offer lower prices. Consistent with these analyses, the CMA observes that the IVAX-GSK Agreement did not have a material impact on prevailing prices in the relevant market.
- The CMA accepts that prices are unlikely to fall substantially when only one generic supplier has entered the market. However, the CMA considers that IVAX's initial price level was likely to have been sustained for a short period only (see paragraphs 3.59 to 3.63) because IVAX's entry would have been followed by the entry of others. For example, IVAX's generic

¹⁸²⁹ GSK SO Written Response (document 2755), summary box page 257 and paragraphs 5.145–5.149.

¹⁸³⁰ GSK SO Written Response (document 2755), paragraphs 5.147 and 8.24–8.26.

¹⁸³¹ Teva SO Written Response (document 2750), paragraph 206. See also Slides for Teva SO Oral Hearing dated 14 October 2013 (document 3138R), slide 43, in which Teva cites empirical studies demonstrating that the entry of first generic supplier has a modest effect on prices.

entry was likely to prompt the entry of other suppliers (either with their own product or with product in-licensed from IVAX). Therefore the CMA considers that focussing on the price impact of IVAX as a sole entrant represents an inappropriate approximation of the impact of its independent entry and of true generic competition, which would have been expected to result in significant price decreases over time. For example, the CMA observes that, as predicted by GSK's own expert witness, [§], there were rapid price declines (of 52% in the first six months following independent entry) as the independent entry of Apotex (through its distributors) was followed by entry of other generic suppliers (see paragraph 3.21).

Competitive pressure on GSK

B.157 GSK and Teva submitted that the decline in parallel import volumes was evidence of increased competitive pressure due to the Agreements:

- Even if the volume restrictions were binding, the additional sales would have increased competition faced by parallel importers and put downwards pressure on prices, resulting in more pressure for brand equalisation deals or switching away from GSK.¹⁸³²
- GSK's share of sales volumes declined during the Agreements, which, GSK submitted, implies that it faced increased competitive pressure over the period.¹⁸³³
- The Generic Companies more than displaced parallel imports, and took 20 percentage points of 20mg volume share from GSK.¹⁸³⁴

B.158 The CMA does not consider that GSK's falling share of sales volumes can be attributed to an increase in competitive pressure. For the reasons set out at paragraphs B.143 to B.150, the transfer of a restricted volume of product to the Generic Companies could not reasonably have been expected to expose GSK to a material increase in the actual competitive constraints it faced. The market share losses suffered by GSK were the consequence of its allocation of volumes of paroxetine to the Generic Companies. However, the adoption of these volume restrictions ensured that a meaningful increase in the competitive constraints that GSK faced was not likely to (and did not) emerge following the Generic Companies' entry as suppliers of GSK product and that

¹⁸³² GSK SO Written Response (document 2755), paragraphs 8.16–8.17.

¹⁸³³ GSK SO Written Response (document 2755), paragraphs 8.21–8.23.

¹⁸³⁴ GSK SO Written Response (document 2755), paragraphs 8.18–8.20 and 8.38. Teva SO Written Response (document 2750), paragraphs 253–254.

the Generic Companies did not face incentives to price below prevailing levels (see paragraph B.144).

B.159 By contrast, it is consistent with the volume restrictions being a mechanism to transfer value to IVAX (and the other Generic Companies) that GSK's market share fell, that IVAX would gain a market share permitted by its volume allowance, and that IVAX's entry as a supplier of GSK product would have no material impact on prevailing market prices.

B.160 GSK further submitted that the fact that IVAX was expected to target the parallel import price does not mean that the Agreements were not likely to have a material effect because the parallel import price was below GSK's net actual prices for Seroxat in both 2001 and 2002.¹⁸³⁵

B.161 As set out at paragraph 3.115, prior to IVAX's entry pursuant to the IVAX-GSK Agreement, GSK was competing with parallel importers by offering rebates similar to brand equalisation deals to its customers. The CMA notes that GSK was doing so to match the prices charged by parallel importers and that, contrary to GSK's submission, the parallel import price was at a broadly similar level to GSK's net price for Seroxat in both 2001 and 2002. Further, the CMA observes that prices did not fall materially following IVAX's entry pursuant to the IVAX-GSK Agreement, or during the term of the Agreements (see paragraph B.166).

c) *The market developments observed during the IVAX-GSK Agreement*

B.162 Although not a necessary part of the analysis of the likely effects of the IVAX-GSK Agreement, the CMA considers that the developments observed during the term of the Agreement reveal that there was no material increase in the actual competitive constraints faced by GSK, and the threat of true generic competition was deferred. Developments in the UK paroxetine market during the period of the Agreements are set out at paragraphs 3.380 to 3.398.

B.163 In relation to the deferral of potential competition, the evidence set out at paragraphs 3.382 to 3.383 demonstrates that as a consequence of the IVAX-GSK Agreement, IVAX deferred its efforts to enter the UK paroxetine market. In particular, IVAX did not supply generic paroxetine that was sourced independently of GSK in the period December 2001 to June 2004. Further, having entered into the IVAX-GSK Agreement, IVAX chose not to continue

¹⁸³⁵ GSK SO Written Response (document 2755), paragraph 8.38.

with the development of its own product with a view to entering independently during the term of the IVAX-GSK Agreement¹⁸³⁶ or to progress negotiations with Tillomed and GUK, whom it had identified as other possible suppliers of generic paroxetine (see paragraphs B.113 to B.117). Independent generic entry did not take place until after Apotex had eventually prevailed in litigation with GSK in December 2003.

B.164 Before setting out the analysis relating to pricing, it is noted that GSK has identified two databases (Unison and CIMS – see paragraph 3.385) containing sales data on paroxetine relating to the relevant period. There is no material discrepancy between the sales value figures report in the Unison and CIMS data from 2002 onwards, but for 2001, Unison reported paroxetine sales of £60.8 million whereas CIMS reported paroxetine sales of £67.9m, a difference of £7.089 million or approximately 10%.¹⁸³⁷ It is therefore necessary to determine which of the two databases should be used in relation to 2001.

B.165 In this regard, it is apparent that the Unison data represents the reliable data source in relation to sales made in 2001¹⁸³⁸ and as such it is the data which the CMA has used for its analysis:¹⁸³⁹

¹⁸³⁶ GSK submitted that IVAX did make further efforts to enter independently following the IVAX-GSK Agreement (GSK written response dated 2 December 2014 to the SSO (document 3668), paragraph 5.2). See paragraph B.128 for the CMA's response to this submission.

¹⁸³⁷ Response dated 19 February 2015 to the Section 26 Notice dated 4 February 2015 sent to GSK (document 3872).

¹⁸³⁸ Consistent with this, GSK's CIMS data strongly suggests that for all pharmacies (excluding Boots and wholesalers) rebates were excluded in the period up to 31 December 2001. Prior to that point, the relevant prices are near constant, which would be consistent with the relevant prices excluding the payment of rebates that would cause fluctuations in the average prices paid by each customer. After that point, there is considerable variability in the month to month prices charged to customers, which is consistent with the pricing data then including rebates. The CMA notes that this indicates that the issues are wider than described by GSK, which suggested that the issue of rebates being excluded was limited only to pharmacies supplied via wholesalers (see GSK SO Written Response (document 2755), paragraph 8.27; part one of the response dated 19 January 2015 to the Section 26 Notice dated 19 December 2014 sent to GSK (document 3759), question 4; Response dated 19 February 2015 to the Section 26 Notice dated 4 February 2015 sent to GSK (document 3872), question 4a).

¹⁸³⁹ The CMA notes that the evidence indicates that the CIMS data was not net of rebates in 2001, and that this explained the difference between the sales values reported by CIMS and those reported by Unison:

- GSK identified that rebates were paid by GSK to pharmacies supplied via wholesalers (GSK SO Written Response (document 2755), paragraph 8.27) and that it is likely there would have been many such rebates in relation to Seroxat at the time (part one of the response dated 19 January 2015 to the Section 26 Notice dated 19 December 2014 sent to GSK (document 3759), paragraph 3.9). GSK identified an internal sales spreadsheet (based on CIMS data) from December 2001 which included some management accounting adjustments which amounted to approximately £7 million (that is, the approximate discrepancy between the Unison and the CIMS data), and were labelled as rebates. Further, some of the rebates were labelled as 'B/G rebates' which GSK suggested might mean "branded/generic" rebates which could be rebates paid under brand equalisation deals or rebates to meet competition from parallel imports under arrangements similar to brand equalisation deals (part three of the response dated 1 May 2015 to the Section 26 Notice dated 30 March 2015 sent to GSK (document 3941), paragraph 2.18). GSK was able to reconstruct the 2001 Unison sales figure for Seroxat and five other medicines by making adjustments to the 2001 CIMS sales figure for known rebates adjustments recorded in a contemporaneous sales spreadsheet. (part three of the response dated 1 May 2015 to the Section 26 Notice dated 30 March 2015 sent to GSK (document 3941), paragraph 2.14).

- GSK has described the Unison data as *'GSK's global financial reporting system for consolidation. [...] Unison is reconciled to its source data monthly and is externally audited annually. As such it represents the most accurate overall number for GSK sales of paroxetine / Seroxat'*.¹⁸⁴⁰ GSK further stated that *'Unison comprises the highest quality financial statement that GSK holds. At the time of preparation, it would have been subject to full financial control processes including (i) reconciliation back to source records; and (ii) accounting period cut offs. Unison data would have been reviewed and signed off by (i) the relevant finance director during the course of the year; and (ii) external auditors during preparations for the annual accounts'*.¹⁸⁴¹
- In contrast, the CIMS data was described as a *'sales management dataset'*¹⁸⁴² which was *'unaudited and, because of the passage of time, there are no records still available that can be examined to check the accuracy of particular figures in the CIMS data'*.¹⁸⁴³

B.166 On this basis, the evidence demonstrates that, as a consequence of the IVAX-GSK Agreement, GSK did not face an increase in the actual competitive constraints it faced until independent generic entry took place in December 2003:

- The pricing data indicates that IVAX's entry as a GSK distributor had no meaningful impact on paroxetine 20mg price levels. During the IVAX-GSK Agreement, IVAX priced at, or very close to, prevailing levels.¹⁸⁴⁴ Paroxetine 20mg price levels remained fairly constant throughout the

• GSK's position following its investigation supports this: although GSK was unable to provide a definitive position, GSK has concluded *'GSK Finance now believes it is unlikely that the explanation [for the differences between the CIMS and Unison data of £7.089m in 2001] has to do with provisions taken in 2001 that were reversed in 2002. It seems more likely that the Unison figure for 2001 is net of rebates that were not recorded in CIMS, although sufficiently granular data no longer exists to prove the position either way'*, part three of the response dated 1 May 2015 to the Section 26 Notice dated 30 March 2015 sent to GSK (document 3941), paragraph 2.8.

• Consistent with this, as set out in footnote 1838, GSK's data strongly suggests that for all pharmacies (excluding Boots and wholesalers) rebates were excluded in the period up to 31 December 2001.

¹⁸⁴⁰ Part one of the response dated 14 November 2014 to the Section 26 Notice dated 21 October 2014 sent to GSK (document 3610), paragraph 1.4.

¹⁸⁴¹ Part one of the response dated 14 November 2014 to the Section 26 Notice dated 21 October 2014 sent to GSK (document 3610), paragraph 1.5.

¹⁸⁴² Part three of the response dated 1 May 2015 to the Section 26 Notice dated 30 March 2015 sent to GSK (document 3941), paragraph 2.2.

¹⁸⁴³ Part three of the response dated 1 May 2015 to the Section 26 Notice dated 30 March 2015 sent to GSK (document 3941), paragraph 2.3.

¹⁸⁴⁴ In considering developments in prices throughout the term of the Agreements, the CMA has used data provided by the relevant parties on the actual prices, net of discounts and rebates where available, at which branded and generic paroxetine was sold. The CMA does not consider that assessing Drug Tariff reimbursement prices would be sufficient for this purpose given that the Drug Tariff is not necessarily an accurate reflection of actual prices, as it does not take into account, for example, discounts and rebates or parallel import prices (see also paragraphs I.2–I.7). For a fuller description of the data used, see footnote 611.

period during which IVAX was supplying paroxetine as a GSK distributor until December 2003 when independent generic entry began. For example, paroxetine 20mg and Seroxat 20mg prices in the three months after IVAX's entry pursuant to the IVAX-GSK Agreement were both around 1% higher compared to the three months before IVAX's entry.¹⁸⁴⁵

- GSK did not face any actual competition at the manufacturer level. GSK remained the sole manufacturer of paroxetine sold in the UK throughout the term of the Agreements and prior to independent generic entry which began in December 2003 (with a market share by value or volume of 100% at the production level).

B.167 The impact of IVAX's entry as a GSK distributor on GSK's market share was limited as a consequence of the volume restriction included in the IVAX-GSK Agreement. Following IVAX's entry under the IVAX-GSK Agreement and prior to independent generic entry, GSK retained an average market share for the supply of finished product to pharmacies/wholesalers of 71% by value (or 66% by volume).¹⁸⁴⁶ By contrast, IVAX only obtained an average market share for the supply of finished product to pharmacies/wholesalers of 11% by value (or 12% by volume) during the period between its entry under the IVAX-GSK Agreement in December 2001 and November 2003, the last month prior to independent generic entry. At the same time, as set out at paragraph 3.392, sales of parallel imports began to decline.¹⁸⁴⁷

GSK and Teva's representations

B.168 GSK and Teva¹⁸⁴⁸ submitted that prices to pharmacies decreased as a consequence of the IVAX-GSK Agreement by 10% at the time of IVAX's entry pursuant to that Agreement.

B.169 The CMA notes that GSK's and Teva's submissions are based on price analysis using the 2001 data from CIMS which, for the reasons set out above, the CMA does not consider to be a robust data source for analysing price changes that occurred in 2001.

B.170 Moreover, the CMA notes that the supposed fall in prices would not undermine a finding that the likely effect of the IVAX-GSK Agreement was to

¹⁸⁴⁵ This is based on a comparison of weighted average paroxetine 20mg and Seroxat 20mg prices in the period August 2001 to October 2001 with November 2001 to January 2002.

¹⁸⁴⁶ Calculated between December 2001 and November 2003, based on data submitted by relevant parties.

¹⁸⁴⁷ There was no market expansion following IVAX's entry into the UK paroxetine market as a GSK distributor, and nor could GSK have reasonably expected it to result in expansion (see paragraph B.69).

¹⁸⁴⁸ GSK SO Written Response (document 2755), paragraph 8.27, Teva SO Written Response (document 2750), paragraphs 252–256.

restrict competition. This is because, where value is transferred to incentivise a potential entrant to delay its efforts to independently enter a market, the resulting outcome is likely to be more restrictive than would have been the case in the absence of value transfers. For example, it is evident that GSK considered that using value transfers to incentivise IVAX to enter on the restrictive terms of the IVAX-GSK Agreement would result in a more profitable, and less competitive outcome, than it would otherwise have faced had IVAX's strategy not been distorted by the use of value transfers.

iii) *The counterfactual*

B.171 This sub-section examines the competitive landscape that was likely to have existed in the absence of the IVAX-GSK Agreement.

B.172 Absent the IVAX-GSK Agreement, IVAX would have continued to be a competitive threat and remained a potential competitor to GSK that was pursuing its efforts to enter the market independently of GSK.¹⁸⁴⁹ IVAX's competitive behaviour would not have been distorted by value transfers made to incentivise a delay to IVAX's potential entry. The realistic and likely outcomes are that IVAX would have pursued its strategy of independent entry (and resulting litigation with GSK) or, alternatively, that IVAX would have entered into a settlement on terms that were not 'bought' using the value transfers, and that legitimately reflected the uncertainty regarding GSK's patent claims.

a) *IVAX seeks to enter the UK paroxetine market independently of GSK*

B.173 Had IVAX not entered into the IVAX-GSK Agreement (or an alternative settlement agreement, see paragraphs B.179 to B.182), the prospect of IVAX's potential independent entry would have been maintained (see paragraph B.3). In the absence of the IVAX-GSK Agreement, IVAX would have had a greater incentive to continue with its efforts to independently enter the UK paroxetine market and to continue to defend any litigation. In that case, the prospect of IVAX's independent entry, and of true generic competition, would have been maintained and the process necessary to determining whether it could have entered the UK paroxetine market would have continued.

¹⁸⁴⁹ As explained at paragraph B.3, at the time the IVAX-GSK Agreement was entered into, the CMA finds that IVAX was a potential competitor to GSK.

B.174 Had IVAX declined to settle, it is likely that litigation would have been commenced prior to IVAX's entry,¹⁸⁵⁰ and the process necessary to determining the validity of the relevant patent claims, and whether IVAX's product was non-infringing, would have commenced.

B.175 The progression of such litigation proceedings would have been of relevance to other potential competitors, in addition to IVAX, as it would have provided greater clarity as to the validity of the Anhydrate Patent, and the terms on which a generic product was found to be non-infringing.¹⁸⁵¹ Further, it would also have affected GSK's incentive to pursue litigation against other companies that sought to supply generic paroxetine in the UK. For example, IVAX noted that if it was successful in patent litigation with GSK the relevant *[p]rinciples will be established for all*¹⁸⁵² and similarly GSK acknowledged,

¹⁸⁵⁰ For example, [GSK's Finance Director A] stated in GUK Litigation in relation to IVAX that: *'It was likely that this material would infringe one of SB's patents, and, if we had evidence that Norton was infringing, or was about to infringe, we would commence proceedings and apply for an interim injunction.'* ([redacted]WS2 (GUK) (document 0182), paragraph 2.3), and GSK stated that: *'had it [IVAX] persisted in launching a generic, GSK would have litigated.'* (GSK Second Response, Part Two (document 0734), paragraph 4.19). Teva submitted that litigation was not inevitable on the basis that (i) no proceedings were threatened or ongoing; (ii) IVAX was unlikely to raise proceedings proactively; and (iii) IVAX was risk adverse and had absolutely no record of launching 'at risk' (Slides for Teva SO Oral Hearing dated 14 October 2013 (document 3138R), slide 29, and Transcript of Teva SO Hearing dated 14 October 2013 (document 3010R), page 32). Notwithstanding Teva's submissions, the CMA considers that given GSK's approach set out in this footnote it is reasonable to assume that had Teva continued with its preparations to enter the market independently, the outcome would have been litigation.

¹⁸⁵¹ By way of example, after the Apotex Parties successfully demonstrated a product was non-infringing, several generic suppliers entered the UK paroxetine market (see paragraph 3.21).

¹⁸⁵² IVAX internal document entitled 'Seraxat: Paroxetine: 14 March 2001' dated 14 March 2001 (document 1699). In relation to this document, GSK submitted that given that the outcome of litigation was uncertain, such a note says nothing about the likely competitive effects of the Agreement. GSK stated that because any judgment would have been focussed on infringement issues, it would not be determinative of whether other generic suppliers would infringe GSK's patents with their own products (GSK SO Written Response (document 2755), paragraphs 8.34 and 9.21). Similarly, Teva submitted that even if IVAX had been successful in litigation this would not necessarily have lowered entry barriers for other generic suppliers as a non-infringement finding would not have invalidated the patent or allowed other entrants to enter (Slides for Teva SO Oral Hearing dated 14 October 2013 (document 3138R), slide 30)).

The CMA does not accept these submissions for the following reasons:

- The CMA considers that, had litigation taken place following GSK's disputes with any of IVAX, GUK or Alparma, any judgments were highly likely to have a significant bearing on the potential for other generic suppliers to then enter the market. For example, an earlier finding concerning the validity of the Anhydrate Patent claims, or infringement of the relevant generic product, would have provided all potential entrants with clarity as to the terms on which generic suppliers could enter the market.
- Had any such judgment found that parties such as IVAX, GUK or Alparma could enter the market without infringing valid patent claims, the barriers to entry would have been substantially reduced for other generic suppliers. Those generic suppliers would have had a clear insight into the boundaries applicable to their own generic entry, and whether their own product was likely to be regarded as non-infringing, and if not what changes should be focussed on to ensure non-infringement. Further, successful generic entry on the part of IVAX would have significantly reduced GSK's incentive to challenge subsequent generic entry because of the erosion in market share and prices that would take place as a consequence of IVAX's unrestricted generic entry and also because IVAX's entry would have necessitated a finding of invalidity in relation to relevant claims of the Anhydrate Patent, thereby reducing its prospects of success in challenging other claims. Given the ability of other firms for 'in-licensing' from a firm that has developed the relevant product (see paragraph 3.188) (and the apparent frequency of that practice (for example, when preparing for its independent market entry IVAX had sought to in-license a product by purchasing paroxetine from Tillomed and subsequently agreed to sub-license its product to Tillomed; [IVAX's Head of New Business Development] stated in a witness statement in-licensing was common at the time; GUK was planning to sub-license to others (see paragraph 3.261); and Alparma had sub-licensed its product from Medis)) other firms

with respect to Alpharma, that independent entry by a generic supplier would lower entry barriers for other generic suppliers: *'Alpharma's presence on the market would be a signal that they need no longer fear an injunction.'*¹⁸⁵³

B.176 It is therefore likely that, had the litigation progressed and had IVAX successfully defended its product launch before the Courts, other generic suppliers would have entered soon after.¹⁸⁵⁴ For example, GSK expected that entry by one generic supplier would *'result in the introduction of other generic products onto the marketplace shortly thereafter with a further wave following as little as 7 months later once relevant marketing authorisations are in place.'*¹⁸⁵⁵ In September 2001, [GSK's Finance Director A] stated that he believed *'that a number of suppliers of generic paroxetine will enter the UK marketplace within the next few months.'*¹⁸⁵⁶

B.177 At the time the IVAX-GSK Agreement was entered into, Tillomed had developed a generic paroxetine product (see paragraph 3.199), GUK was about to obtain an MA (see paragraph 3.254) and Alpharma had applied for an MA for its generic product (see paragraph 3.323). True generic competition, between GSK and a number of generic competitors, would

could have entered the market using product supplied from the generic companies involved in the supply of the product found to be non-infringing. In this context, GSK's profits would have been expected to be substantially lower, such that continuing to challenge further entry would have been of little value to GSK. It is presumably for this reason that, at the point at which only the Apotex product had been found not to infringe the two patent claims that were, at that point, held valid by the courts, a number of generic suppliers entered the market with generic paroxetine and GSK decided not to contest that entry (see paragraphs 3.135–3.136).

¹⁸⁵³ [redacted]WS2 (Alpharma) (document 0289), paragraph 6.2.

¹⁸⁵⁴ Although a judgment may have related only to a specific product that did not infringe GSK's paroxetine patents a judgment in IVAX's favour was likely to prompt further entry and to substantially limit GSK's incentive to pursue further litigation against other parties. For example, there was the potential that IVAX could supply or sublicense its product such that there was the potential for other generic suppliers to enter the market (given that licensing was relatively common at the time, see paragraph 3.188). For example, IVAX had already agreed to supply its paroxetine product to Tillomed. Independent generic entry by multiple suppliers would have been expected to result in the substantial price declines that GSK was seeking to avoid by pursuing litigation, limiting GSK's incentive to pursue further litigation in response to further entry. Conversely, had GSK prevailed in litigation because multiple claims of the anhydrate patent were held valid, this had the potential to disincentivise other generic suppliers from pursuing independent entry. This is consistent with the views of [GSK's Finance Director A], who explained that: *'[t]he market could continue as it was if GSK won litigation but if it lost the patent then everything would go. There would be intense competition from the generics in the near future. GSK therefore decided, to provide for some period of certainty, to enter into supply agreements'* (Note of meeting between the OFT and GSK dated 19 December 2011 (document 0688), paragraphs 19 and 20). The CMA also notes that entry by one or more generic suppliers would change the risk and damages profile such that other generic suppliers may also have entered, as happened following the Apotex litigation. For example, (i) GSK's incentive to litigate in response to further entry would have been limited following the entry of IVAX and Tillomed, as their independent generic entry would have been expected to result in the substantial price declines that GSK was seeking to avoid; and (ii) other potential entrants would have had less concern that their entry would expose them to a significant damages claim from GSK, as the entry of other firms would have already caused substantial price declines. This is consistent with GSK's statement that independent entry from Alpharma would be a signal to other generic companies that they need no longer fear an injunction (GSK SO Written Response (document 2755), paragraph 8.50).

¹⁸⁵⁵ [redacted]WS1 (GUK) (document 0885), paragraph 7.10.

¹⁸⁵⁶ [redacted]WS1 (GUK) (document 0885), paragraph 8.6.

inevitably have resulted in substantially lower prices and reduced market shares for GSK (see paragraphs 3.59 to 3.63 and 3.161 and 3.164).

B.178 In summary, it would have been reasonable to expect that had IVAX declined to enter into the IVAX-GSK Agreement (or an alternative settlement agreement, see paragraphs B.179 to B.182) and instead remained a potential competitor that was seeking to enter the UK paroxetine market independently of GSK, litigation with GSK would have immediately commenced. As a consequence, both GSK's expected returns¹⁸⁵⁷ and market-wide returns would have been lower due to the threat of IVAX's successful independent generic entry. An ongoing litigation process would have preserved (rather than deferred) the potential for true generic competition and the associated price declines.

b) *GSK and IVAX enter into a settlement agreement on less restrictive terms*

B.179 The alternative outcome in the counterfactual is that GSK and IVAX would have entered into a settlement agreement on less restrictive terms.

B.180 For example, had GSK offered a settlement agreement that did not involve value transfers that had the purpose of incentivising IVAX to defer its efforts to enter the market independently of GSK, it is reasonable to expect that IVAX would have required an agreement that included other terms that would provide it with sufficient incentive to settle the expected litigation at the expense of its ongoing efforts to enter the market with generic paroxetine. Absent recourse to value transfers which had the purpose of delaying the potential emergence of true generic competition, GSK would have been required to offer more competitive terms to IVAX to provide IVAX with alternative sources of remuneration and a sufficient incentive to settle.¹⁸⁵⁸

B.181 Any such settlement agreement could have taken one of a number of forms (for example, on the basis of an alternative supply agreement, agreeing a date on which IVAX could launch its generic product or allowing IVAX to enter on condition that it pays a royalty to GSK). The CMA is satisfied that the negotiation of an alternative settlement agreement, including more

¹⁸⁵⁷ That is, the average of its possible profits going forward, taking account of the potential revenue and costs associated with each possible outcome (for example, the success or otherwise of independent generic entry), and the likelihood associated with each.

¹⁸⁵⁸ This is consistent with the views of [GSK's Finance Director A] who stated that GSK used the marketing allowance so that a higher supply price could be adopted. One of GSK's objective was to ensure that list prices in the UK did not deteriorate, because this would also have an impact on the price paid in other countries whose reimbursement systems benchmarked their prices against UK prices: [redacted]1 (document 4008R), pages 30–31.

competitive entry terms, was a realistic outcome in the counterfactual. For example, GUK and Alparma both internally considered the possibility that a settlement agreement with GSK could include the payment of a royalty to GSK in return for GSK granting it a non-exclusive licence to sell its product (see paragraphs 3.289 and 3.346).¹⁸⁵⁹ Alparma also put to GSK the suggestion that they could agree an appropriate date (prior to the date of patent expiry) on which Alparma could launch its own product, but such an approach was rejected by GSK (see paragraphs 3.355 to 3.357).¹⁸⁶⁰ Moreover, settlement agreements that do not raise competition concerns are common in the pharmaceutical sector. For example, the CMA notes that empirical evidence from the United States supports the proposition that branded and generic suppliers can settle their patent disputes without using payments and similar value transfers that are made with the purpose of inducing delays to potential generic entry.¹⁸⁶¹

B.182 In summary, it would have been reasonable to expect that in the counterfactual any agreement that IVAX and GSK entered into would not have included the terms that IVAX only accepted in return for value transfers from GSK, and would have provided for more competitive terms as a result.

c) Representations

B.183 The SO Addressees submitted that the CMA has arbitrarily selected only those counterfactuals that would be more competitive than in the case of the Agreements, rather than the realistic and likely scenarios.¹⁸⁶² The CMA does not accept these submissions, and considers other outcomes to be unrealistic and unlikely.

¹⁸⁵⁹ The CMA notes that agreeing a licencing arrangement as part of a settlement agreement was not uncommon. For example, in a meeting with the OFT on 7 February 2012, GUK noted that: *'it was also quite common for there to be some sort of licence in return for compensation but the terms of the licence would be a matter for negotiation. [GUK's legal representative] thought that the key factors in the negotiation would be: (i) whether GSK believed that they would win/lose; (ii) the strategy with Norton and whether GUK could blow this out of the water; (iii) the cross-undertaking in damages so if GSK lost they would have exposure to pay damages to GUK; and (iv) GSK's ability to supply the product.'* (Note of meeting between the OFT and GUK dated 7 February 2012 (document 1210), paragraph 16).

¹⁸⁶⁰ The CMA acknowledges that Alparma's proposal in this example also included the suggestion that GSK make a value transfer to Alparma as part of the settlement. Without taking a view on the legitimacy of this settlement proposal, the CMA considers that this proposal nonetheless illustrates the principle that Alparma was open to other types of settlement, and deemed an early entry agreement to be a sufficiently credible option to put to GSK during negotiations.

¹⁸⁶¹ See footnote 1169.

¹⁸⁶² Merck submitted that the CMA had not considered the full range of scenarios and *'arbitrarily selects [...] only those scenarios that it considers would have led to more competitive outcomes than actually occurred.'* (Merck SO Written Response (document 2764), paragraph 5.13). Teva submitted that the CMA seemed to have 'cherry picked' its counterfactuals (Teva SO Written Response (document 2750), paragraph 238).

B.184 For example, at the time the IVAX-GSK Agreement was entered into, IVAX was a potential competitor that was seeking to enter the market independently of GSK (see paragraph B.3). There is no evidence that, absent the value transfers from GSK that IVAX was ending its efforts to enter the market independently of GSK. The evidence set out at paragraphs B.3 to B.60 indicates that IVAX was continuing its strategy of bringing generic paroxetine to market independently of GSK. Furthermore, GSK itself recognised that continued litigation was an option had an alternative settlement not been reached. For example, GSK stated that if no settlement was reached *‘the result would have been a continued dispute and ultimately litigation.’*¹⁸⁶³

B.185 In this context, the CMA considers it highly unlikely and unrealistic that GSK and IVAX would have entered into a settlement agreement that provided for a similarly (or more) restrictive outcome than that which resulted from the IVAX-GSK Agreement. Absent recourse to value transfers which had the purpose of delaying the potential emergence of true generic competition, IVAX would have required alternative more competitive terms to ensure its returns were sufficient to accept an alternative settlement rather than continuing to seek independent entry (see also paragraphs B.179 to B.182).

d) Conclusion

B.186 The analysis set out at paragraphs B.63 to B.131 demonstrates that the purpose of the value transfers (totalling at least £17.9 million to IVAX and at least £50.9 million to the Generic Companies overall) was to induce IVAX to defer its efforts to enter the UK paroxetine market independently of GSK. GSK had therefore determined that, if IVAX had been permitted to remain a potential competitor that was continuing with its efforts to enter the market, GSK faced the prospect of lower expected profits¹⁸⁶⁴ than if GSK were to make value transfers to incentivise IVAX to delay its efforts to enter independently. Put another way, GSK itself considered that, absent the IVAX-GSK Agreement, the competitive outcomes associated with IVAX’s position as a potential competitor provided for a far greater constraint than GSK faced having entered into the IVAX-GSK Agreement.

B.187 Consistent with this, the CMA is satisfied that, absent the IVAX-GSK Agreement, IVAX would have continued to be a threat, and remained a potential competitor to GSK that was seeking to enter the UK paroxetine

¹⁸⁶³ GSK SO Written Response (document 2755), paragraph 4.21(c).

¹⁸⁶⁴ That is, the average of its possible profits going forward, taking account of the potential revenue and costs associated with each possible outcome (for example, the success or otherwise of independent generic entry), and the likelihood associated with each.

market. This would have led to an increase in the competitive constraints being exerted on GSK, either through the process of litigation challenging GSK's patents, or through a less restrictive settlement recognising the uncertainty inherent in that litigation.

iv) *The absence of other relevant sources of competition to GSK meant that the IVAX-GSK Agreement assisted GSK in preserving its dominant position*

B.188 By entering into the IVAX-GSK Agreement, GSK materially strengthened its ability to delay the potential emergence of true generic competition, thereby assisting GSK in preserving its dominant position:

- As set out at paragraphs 4.112 to 4.115, at the time the IVAX-GSK Agreement was entered into, the only competitive constraint that GSK faced in the UK paroxetine market was provided by parallel importers of its own product. However, parallel importers faced several barriers to expansion which limited the extent to which they were capable of challenging GSK's market position (see paragraph 4.113). At the time the IVAX-GSK Agreement was entered into, there were no independent suppliers of generic paroxetine in the UK paroxetine market.
- At the time of entering into the IVAX-GSK Agreement, GUK and Tillomed were the only other potential competitors that were ready to enter the UK paroxetine market (see paragraph B.177).¹⁸⁶⁵ Shortly after the IVAX-GSK Agreement was entered into, Tillomed agreed to take supply from IVAX and transferred the Tillomed MA to IVAX (see paragraph 3.207). This meant that, having entered into the IVAX-GSK Agreement, GSK had limited the probability of its patent position being successfully challenged, and of true generic competition emerging. It also ensured that GSK would only need to reach an agreement with one further party (GUK) to ensure that the potential for generic entry was further delayed.¹⁸⁶⁶ Doing so would

¹⁸⁶⁵ During the GUK Litigation, [GSK's Finance Director A] reported that '*The generic company which has told me that it will be in a position to launch in the near future is Bioglan Laboratories Limited. I have also heard at second-hand that APS Berk (also called Approved Prescription Services) [...] is also planning to launch in the near future. I have also learned that Apotex [...] is interested in launching in the UK market*' (see [REDACTED]WS2 (GUK) Exhibit [REDACTED]5 (document 0888), paragraph 2.1). However, the CMA has not listed any of these companies as having been in a position to imminently enter because GSK had neither sent warning letters nor issued legal proceedings against them (see GSK Second Response, Part Two (document 0734), section 6C) which implies their entry preparations were not at a sufficiently advanced stage for GSK to perceive that they posed it a significant threat. In its written representations on the SO, Teva submitted that the CMA had not taken account of other generic suppliers such as Neolab or Waymade that were equally well-placed to enter the market, subject to patent infringement issues (Teva SO Written Response (document 2750), paragraph 209). As set out in this footnote, the CMA has considered this issue, but, in the absence of evidence to the contrary, did not consider Neolab or Waymade were sufficiently advanced in their entry preparations as to be '*equally well-placed*' as IVAX.

¹⁸⁶⁶ Although AlphaPharma had already applied for an MA, it was some way behind IVAX, Tillomed and GUK in its entry preparations.

mean that its patent position would remain unchallenged, and it could continue to commence litigation against (and seek to settle with) other potential competitors should any subsequently emerge. Entering into the IVAX-GSK Agreement with one of three known potential entrants therefore increased the potential for GSK to continue its strategy of securing agreements that would defer the potential emergence of true generic competition.

B.189 The anti-competitive effect of the IVAX-GSK Agreement was reinforced in view of this context: pursuant to the IVAX-GSK Agreement, GSK had agreed the Side Letter with IVAX in which it provided IVAX with some assurance in relation to its conduct of the GUK litigation (see paragraphs 3.220 to 3.222) and GSK subsequently entered into the GUK-GSK and Alharma-GSK Agreements and a settlement agreement with [REDACTED]. Together these agreements helped to make sure that each threat of potential independent generic entry was deferred, and that there was no material increase in the actual competitive constraints that GSK faced.

ANNEX C: REPRESENTATIONS ON MARKET DEFINITION AND DOMINANCE

A. Market definition

i) Representations on the CMA's approach and its key findings

C.1 GSK and Teva submitted that the relevant market should be at least as wide as SSRIs.¹⁸⁶⁷ GSK made a number of submissions concerning the approach that it considered should be adopted in this case, and the analytical significance of certain aspects of the evidence. This sub-section considers those submissions.

a) Consistency with approach taken in other recent cases in the pharmaceutical sector

C.2 GSK and Teva submitted that the CMA's approach to market definition is inconsistent with the approach taken in other recent cases in the pharmaceutical sector. In particular, they submitted that a molecule market definition has rarely been determined in the case law and decisional practice, and that where the market has been defined narrowly, this is specifically due to a lack of therapeutic substitutability. In support of this submission, GSK cited several competition cases including *AstraZeneca*,¹⁸⁶⁸ *Reckitt Benckiser*,¹⁸⁶⁹ *Genzyme* and *Napp*, as well as some of the Commission's merger cases involving antidepressants.¹⁸⁷⁰ GSK stated that in each of these

¹⁸⁶⁷ GSK SO Written Response (document 2755), paragraph 3, summary box on page 85. See also Teva SO Written Response (document 2750), paragraph 244.

¹⁸⁶⁸ GSK SO Written Response (document 2755), paragraphs 3.29 and 3.184–3.188, with reference to Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 58. GSK also submitted that the CMA's quantitative approach would have produced a narrower market definition in *AstraZeneca*. In particular, GSK submitted that lansoprazole and omeprazole would be considered to be in separate markets under the CMA's approach as generic entry in omeprazole had little effect on unit sales of Zoton (branded lansoprazole) whereas lansoprazole generic entry did have a substantial negative effect on unit sales of Zoton.

¹⁸⁶⁹ GSK SO Written Response (document 2755), paragraph 3.33, with reference to *Genzyme Limited v Office of Fair Trading* [2004] CAT 4, at [202].

¹⁸⁷⁰ GSK SO Written Response (document 2755), paragraphs 3.46–3.49. GSK cited the following merger cases: Case M.1878 *Pfizer / Warner-Lambert* (22 May 2000); Case M.5253 *Sanofi-Aventis / Zentiva* (4 February 2009); Case M.072 *Sanofi / Sterling Drug* (10 June 1991); Case M.4314 *Johnson & Johnson / Pfizer Consumer Healthcare* (11 December 2006); Case M.5295 *Teva / Barr* (19 December 2008); Case M.3354 *Sanofi-Synthelabo / Aventis* (26 April 2004); Case M.1229 *American Home Products / Monsanto* (28 September 1998); Case M.3751 *Novartis / Hexal* (27 May 2005); Case M.4402 *UCB / Schwarz Pharma* (21 November 2006); Case M.5476 *Pfizer / Wyeth* (17 July 2009); Case M.5502 *Merck / Schering-Plough* (22 October 2009); Case M.5865 *Teva / Ratiopharm* (3 August 2010). Teva SO Written Response (document 2750), paragraph 244. Teva cited the following merger cases: Case M.5253 *Sanofi-Aventis / Zentiva* (4 February 2009); Case M.5295 *Teva / Barr* (19 December 2008); Case M.3751 *Novartis / Hexal* (27 May 2005); Case M.5476 *Pfizer / Wyeth* (17 July 2009); Case M.5502 *Merck / Schering-Plough* (22 October 2009); Case M.5865 *Teva / Ratiopharm* (3 August 2010); Case M.6613 *Watson / Actavis* (5 October 2012).

cases, the approach taken focused on therapeutic substitutability which would be consistent with a market definition of at least SSRIs in the present case.¹⁸⁷¹

- C.3 The CMA considers that past cases may be a helpful starting point for defining the relevant market. The GC and the CAT have held, however, that *'the market concerned must be identified and verified according to the particular facts of the case in question.'*¹⁸⁷² That is the approach followed by the CMA in this case.
- C.4 In several of the EU merger cases relating to antidepressants, some of which GSK or Teva cited, a molecule level market was explicitly considered by the Commission,¹⁸⁷³ although the relevant product market was ultimately left open. In one case the Commission found that: *'the appropriate market definition was likely to be at the molecule level, in particular because the molecule is well-established and familiar to both patients and doctors.'*¹⁸⁷⁴
- C.5 Even if the relevant product market had not been left open in those cases, they do not preclude the existence of a molecule level product market. Market definition is a purposive exercise that can validly produce different results depending on the purpose for which it is conducted. For example, it might be appropriate to define the market widely to encompass both molecules when considering a merger between owners of two patented molecules that, while the patents last, are each other's only competitive constraints, whereas when considering whether the owner of one molecule is dominant in order to consider whether conduct intended to exclude generic competition is abusive, it might be necessary to consider whether a molecule market exists by comparing prices with and without generic entry. Consistent with this proposition, the Market Definition Notice recognises that the criteria for defining the market might lead to different results depending on the nature of the competition issue (a merger or unilateral conduct) being examined.¹⁸⁷⁵
- C.6 It may therefore be appropriate to define the relevant product market at the molecule level where, for example, there is evidence of an absence of sufficiently strong competitive constraints from medicines within higher level classifications.¹⁸⁷⁶ For example, although the ATC3 classification has often

¹⁸⁷¹ GSK SO Written Response (document 2755), paragraphs 3.23–3.53.

¹⁸⁷² *Aberdeen Journals Limited v Director General of Fair Trading* (No.1) [2002] CAT 4, at [139]. See also Judgment of 22 March 2000, *Coca-Cola v Commission*, Joined cases T-125/97 and T-127/97, ECR, EU:T:2000:84, paragraph 82.

¹⁸⁷³ M.5295 *Teva/Barr* (19 December 2008) paragraphs 10–18, 178, 188; M.5865 *Teva/Ratiopharm* (3 August 2010) paragraphs 315–320; M.6613 *Watson/Actavis* (5 October 2012) paragraphs 29–33.

¹⁸⁷⁴ M.5865 *Teva/Ratiopharm* (3 August 2010) paragraph 318.

¹⁸⁷⁵ Market Definition Notice, paragraph 12.

¹⁸⁷⁶ In this regard the CMA notes that the Commission defined the market at the molecule level in its *Servier* case, Commission Decision of 9 July 2014 in Case AT.39612 – *Servier*.

been used as a starting point for market definition, the Commission has noted that:

‘it is appropriate to carry out analyses also at other ATC levels, or a mixture thereof, if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level and there are indications that ATC3 class does not lead to a correct market definition. The Commission has previously departed from the ATC3 class in cases where the market investigation indicated that another market definition was more appropriate, for example the ATC4 class or medicines based on the same active pharmaceutical ingredient (molecule level).’¹⁸⁷⁷

C.7 In response to GSK’s other points:

- The CMA does not consider that the case law GSK cited in either *AstraZeneca* or *Genzyme* undermines its approach to market definition in this case. In particular:
 - in undertaking a quantitative analysis to consider actual consumption patterns the CMA has taken account of the weight given by doctors to the therapeutic superiority of different antidepressants; and
 - in considering antidepressants the CMA has considered medicines which treat the same condition as paroxetine, albeit that in this case the evidence has demonstrated further segmentation of the market to be appropriate based on the relative strength of competitive constraints exerted by those antidepressants on paroxetine.
- In relation to the statements that GSK quoted from the OFT’s PPRS market study,¹⁸⁷⁸ the CMA considers that its quantitative analysis has taken into account the extent to which GPs perceived the different antidepressants to be substitutable, as measured by an analysis of actual consumption patterns.
- The CMA does not accept GSK’s contention that its quantitative approach would have led to a narrower market definition in *AstraZeneca*. The focal product in *AstraZeneca* was omeprazole and not lansoprazole, so the relevant question for the analysis would have been to examine the

¹⁸⁷⁷ M.5502 *Merck/Schering-Plough*, 22 October 2009, paragraph 12.

¹⁸⁷⁸ GSK SO Written Response (document 2755), paragraph 3.54. GSK submitted that the OFT had previously recognised the importance of therapeutic considerations, for example in its 2007 PPRS study the OFT stated that if GPs consider products to be substitutable this will result in a broader market definition (*The Pharmaceutical Price Regulation Scheme, an OFT market study* (OFT885, February 2007), paragraph 2.38).

competitive constraint exerted by other medicines on omeprazole, and not whether generic entry would constrain lansoprazole as GSK's submission implies. Further, lansoprazole generic entry occurred in December 2005, which post-dated the date of the Commission's decision in *AstraZeneca* (15 June 2005); this information would not have been available to the Commission when carrying out its analysis in any case.

C.8 For the reasons set out above, the CMA is satisfied that in this case it is appropriate to place significant weight on quantitative evidence concerning the impact of true generic competition on the prices and profits that could be earned by GSK compared to those prior to generic entry and while it was the sole UK supplier of paroxetine.

b) *The relevance of evidence relating to price changes following the onset of generic price competition*

C.9 GSK submitted that the CMA is wrong to place particular emphasis on the fact that, following generic entry, paroxetine prices and profits dropped substantially. In summary, GSK submitted that:

- the fact that prices were substantially higher during the period of patent protection than they were once independent entry commenced is a normal and standard result of the patent system and '*the IP bargain*'.¹⁸⁷⁹
- the CMA's analysis implies that it would be impossible for pharmaceutical companies to realise the higher profits that justify costly R&D.¹⁸⁸⁰
- the CMA's approach would mean that every commercialised patented product is dominant.¹⁸⁸¹ Similarly, Xellia-Zoetis stated that under the CMA's reasoning all patented drugs would represent separate markets, as all patented drugs are differentiated products.¹⁸⁸²
- if patent protection is seen as connoting dominance and the competitive price viewed as the level prevailing following independent entry, '*then the IP bargain would be totally undermined*', and this would risk severely impairing R&D incentives.¹⁸⁸³

¹⁸⁷⁹ GSK SO Written Response (document 2755), paragraphs 3.7–3.8.

¹⁸⁸⁰ GSK SO Written Response (document 2755), paragraphs 3.9–3.11.

¹⁸⁸¹ GSK SO Written Response (document 2755), paragraph 3.12. GSK also referred in paragraphs 3.12 and 3.24 to the Judgment in *RTE and ITP v Commission*, Joined Cases C-241/91 P and C-242/91 P, EU:C:1995:98, and to *Chemistree Homecare Ltd v AbbVie* [2013] EWHC 264 (Ch).

¹⁸⁸² Xellia-Zoetis SO Written Response (document 2767), paragraph 296.

¹⁸⁸³ GSK SO Written Response (document 2755), paragraphs 3.13–3.14.

C.10 The CMA observes that the onset of true generic competition enables comparison of the prices and profits that GSK could sustain when faced only with competition from other molecules with those earned following generic entry. Contrary to GSK's submissions, such an analysis is of significant evidential value to an assessment of the relevant market, as it enables observation of whether a monopolist supplier of paroxetine was able to sustain a SSNIP prior to generic entry, and whether any constraint it faced was limited to other molecules only. As with the other natural events, the CMA's analysis relates to a change in the competitive constraints faced by GSK in respect of paroxetine, and the fact that the change relates to a market event such as independent generic entry following a judgment that generic entry would not infringe valid patent claims held by GSK makes it no less significant in this regard. In relation to the specific points raised by GSK:

- The CMA agrees that a feature of competition in the pharmaceutical sector is that, for many medicines, prices and profits will be higher prior to the start of true generic competition. Where a medicine supplier retains sufficient patent protection and is protected from true generic competition, the primary source of competition that such a supplier will face is from other, differentiated, medicines. However, this, of itself, does not undermine the CMA's view that, in general, where a monopolist supplier of a given medicine is able to sustain prices and profits that are sufficiently above the competitive level, this indicates that other differentiated medicines were not sufficiently close substitutes to be regarded as belonging to the same relevant market.
- The CMA does not accept that such an analysis implies that pharmaceutical suppliers would be unable to charge higher prices and earn higher profits while they benefit from patent protection. To the extent that a patent legitimately protects a patent holder from competition from products that would infringe relevant patents, it is to be expected that the patent holder should, where possible, be able to sustain higher prices prior to patent expiry than would exist following the emergence of true generic competition. There is nothing in the CMA's analysis that prevents this, as such an analysis is used to determine the parameters of the relevant market, rather than whether the observed price levels are objectionable as an abuse of a dominant position. In this regard, the CMA notes that it has not alleged that GSK was charging prices that were excessive and unfair during the period prior to independent generic entry, and only that the observed prices and profit levels are indicative of GSK having held a dominant position during that period.

- The CMA accepts that, to the extent that it can be demonstrated that a pharmaceutical supplier has been able to sustain profits that are sufficiently above the competitive level, it is possible that some pharmaceutical suppliers hold (or have held) a dominant position in relation to the supply of a particular medicine. However, the CMA does not consider such an argument, of itself, to be capable of undermining the CMA's analysis. In this regard, the CMA notes that competition law does not prohibit the holding of a dominant position, but rather the abuse of such a position. Further, the CMA does not accept that such an analysis implies that the holder of every commercialised patent is dominant by definition. As the CMA has done in this case, it is necessary to consider the extent to which other products compete with the patented product and whether the hypothetical monopolist supplier of the relevant product is able to sustain prices and profits that are sufficiently above the competitive level (see also the bullet point above).
- For the reasons set out above, the CMA does not accept that the '*IP bargain*' would be undermined, or that R&D incentives would be affected, based on its definition of the UK paroxetine market. Rather, it is GSK's analysis of this issue that would be problematic for future cases. The approach advocated by GSK is inconsistent with accepted principles of market definition, and would undermine the application of the SSNIP framework and the use of quantitative analysis in cases in the pharmaceutical sector.

ii) GSK's representations on prescribing considerations

C.11 To support its contention that SSRIs were therapeutically substitutable with paroxetine and that the market should be at least as wide as all SSRIs, GSK submitted the following:

- The CMA's statements regarding similar modes of action, therapeutic uses and efficacy according to prescribing guidelines for different antidepressants imply a market at least as wide as SSRIs.¹⁸⁸⁴ Similarly GSK stated there was significant commonality in side effect profile between different SSRIs and side effect profiles are a question of individual tolerability such that the side effect profile is not a rationale for placing paroxetine in a market of its own.¹⁸⁸⁵

¹⁸⁸⁴ GSK SO Written Response (document 2755), paragraphs 3.68–3.71.

¹⁸⁸⁵ GSK SO Written Response (document 2755), paragraphs 3.95–3.98.

- Regarding indications, the CMA had not taken account of prescribing for co-morbidity,¹⁸⁸⁶ and that doctors in any event prescribed off-label and guidelines and were not restricted by the licensed indications.¹⁸⁸⁷
- As each prescription needed to be tailored to individual patients this implies that prescribers must choose from the full set of SSRIs each time they prescribe for a new patient. According to GSK, as market definition cannot be at an individual patient level, this means that the market must be at least as wide as all SSRIs.¹⁸⁸⁸

C.12 The CMA's responses to GSK's points are as follows:

- As set out at paragraph 4.62, the CMA accepts that when prescribing, doctors faced a choice of medicines that had some similar characteristics in terms of therapeutic use, side effects and mode of action. However, the CMA considers that it is necessary to consider how prescribers behaved in practice and the extent to which different products were in reality capable of exerting a significant competitive constraint on paroxetine (see paragraph 4.63). This is particularly important given that GPs had to take a range of factors into account when prescribing, and that (as GSK noted) such factors needed to be considered on an individual patient basis.
- Although GSK submitted that prescribing off-licence was not unusual, the CMA notes that [GSK's Finance Director A] did not consider prescribing off-licence to be prevalent: *'Whilst general practitioners can prescribe "off licence" by prescribing a drug for an indication for which that drug is not approved, they are increasingly reluctant to do so as they can be personally liable if the patient suffers an adverse reaction'*.¹⁸⁸⁹ Regardless of its prevalence, and of the prevalence of prescribing for co-morbidity, the CMA considers that the possibility of prescribing off-licence is another reason to take the view that quantitative evidence on prescribing behaviour is necessary, and should be accorded due weight, to determine the extent of competitive constraints.
- The fact that prescriptions were tailored to individual patient need does not imply that the market must be at least as wide as all SSRIs. To the contrary, it implies that prescribers were less likely to consider that all SSRIs were interchangeable, and that a quantitative analysis is necessary

¹⁸⁸⁶ That is prescribing for two or more conditions occurring at the same time, such as prescribing for depression and anxiety together. GSK SO Written Response (document 2755), paragraphs 3.79–3.83.

¹⁸⁸⁷ GSK SO Written Response (document 2755), paragraphs 3.86–3.93.

¹⁸⁸⁸ GSK SO Written Response (document 2755), paragraphs 3.127–3.132.

¹⁸⁸⁹ [REDACTED]WS2 (GUK), Exhibit [REDACTED]6 (document 0887), paragraph 49.

to determine the extent to which different molecules did in practice serve to constrain paroxetine.

C.13 In the context of its representations on the CMA's quantitative analysis, GSK also submitted that marketing and detailing was primarily aimed at gaining prescriptions for new patients and those that were switching medicine when they failed to respond to the first medicine (referred to as '*new change therapy enquiries*').¹⁸⁹⁰

C.14 The fact that a number of patients fail to respond to the first antidepressant prescribed does not undermine the analysis presented by the CMA. To the contrary, it implies that substitution will be more limited in practice, as such medicines may need to be prescribed in sequence when patients fail to respond to a given medicine, and patients are more likely to continue to be prescribed a medicine that they do respond to.

iii) Representations on GSK's documents

C.15 GSK submitted that its documents demonstrate that Seroxat was competing against other antidepressants, in particular other SSRIs, and the documents therefore provide support for a market definition of at least SSRIs.¹⁸⁹¹ In support of its submission GSK made the following points:

- statements made in a witness statement by [GSK's Marketing Manager A for Seroxat] clearly demonstrate strong competition between Seroxat and Cipramil:¹⁸⁹²
 - The fact that the daily price of Seroxat and Cipramil differed by only two pence indicates that the intensity of competition had reduced prices such that they were virtually identical.
 - It is wrong to suggest that the almost 50% fall in Seroxat prices (from £33.90 to £17.76 per pack) was not meaningful competition.
 - Competition prior to 2000 had led to prices being competed down to a 'competitive level'.

¹⁸⁹⁰ GSK SO Written Response (document 2755), paragraph 3.139. See also GSK SO Written Response (document 2755), paragraphs 3.152–3.156.

¹⁸⁹¹ GSK SO Written Response (document 2755), paragraph 3.126.

¹⁸⁹² GSK SO Written Response (document 2755), paragraphs 3.104 and 3.107

- evidence in a *Lundbeck v Lilly* case heard by the Prescription Medicines Code of Practice Authority demonstrates a significant degree of active rivalry over prices between the originator companies.¹⁸⁹³
- [GSK's Finance Director A] comments (in the witness statement cited at paragraph 4.54) do not indicate that paroxetine and citalopram were not in the same relevant market, for the following reasons:¹⁸⁹⁴
 - The context is GSK countering the suggestion made by [GUK's General Manager],¹⁸⁹⁵ and, in this context, the most the CMA can infer is that [GSK's Finance Director A] believed that *'at risk entry by GUK would hurt GSK profits more than some of the existing competition in the market'*.
 - Comments made by [GSK's Finance Director A] are speculation and [X] was speaking in his capacity as the Finance Director.
 - The CMA had failed to acknowledge that the six month period [GSK's Finance Director A] was referring to was too short a period to count as concrete evidence of lack of interaction. There would be a time lag between citalopram being generically available, and GPs being aware of falling prices so as to choose to prescribe it in preference to another product.
 - Once patients are established on a particular medicine they are unlikely to be switched.
 - The context was referring to first time prescriptions, and there is a limit to the number of these to be written within a six month period, which would limit expected switching.

C.16 While GSK's documents provide a useful insight into the extent to which it considered SSRIs and other antidepressants constrained prices or sales of Seroxat, in the circumstances of this case the CMA considers that it should give greater weight to actual consumption patterns as a means of determining whether, in practice, the degree of product differentiation was such that GPs would substitute between products to an extent that would prevent a monopolist supplier of paroxetine from sustaining a SSNIP. It is in this context

¹⁸⁹³ GSK SO Written Response (document 2755), paragraph 3.108.

¹⁸⁹⁴ GSK SO Written Response (document 2755), paragraphs 3.112–3.113

¹⁸⁹⁵ The CMA notes that this is also a submission Teva made (Teva SO Written Response (document 2750), paragraph 250).

that the CMA has addressed GSK's comments on the detail of each document below:

- In relation to GSK's assessment of [GSK Marketing Manager A's] witness statement, the CMA considers that although evidence relating to the proximity of pricing for Cipramil and of previous declines in the Seroxat list price from £33.90 to £17.76 per pack between its launch and 1999¹⁸⁹⁶ may imply a degree of competitive interaction between Seroxat and other medicines in the treatment area, any constraint was not significant enough, when considered in the context of the price and profit declines that occurred following the emergence of generic paroxetine, to imply that other SSRIs should be regarded as belonging to the same relevant market. Further, given the price and profit declines observed following the emergence of true generic competition, it is evident that competition between Seroxat and Cipramil had not resulted in price and profit levels reaching their 'competitive level'.
- The CMA considers that the *Lundbeck v Lilly* case is of limited value to this assessment. In particular, the CMA notes that the case did not consider at all the extent to which paroxetine was constrained by other SSRIs. In any event, the CMA has not sought to argue that prices are not a parameter of competition between originators, or that other SSRIs did not constrain paroxetine prices to some extent (see paragraph 4.75).
- In relation to [GSK's Finance Director A's] evidence concerning the impact of the generic entry of GUK and the genericisation of citalopram, the CMA notes that [GSK's Finance Director A's] view was not restricted to speculation on the short term effects of GUK's entry, but rather that GUK's entry would *'inevitably have a long-term effect on the drug's pricing structure'*.¹⁸⁹⁷ Moreover, [GSK's Finance Director A's] expectations concerning the limited impact of generic citalopram are consistent with the evidence set out at paragraphs 4.91 to 4.93 which demonstrate the relatively limited impact of citalopram on paroxetine as compared to the impact of generic paroxetine on Seroxat sales. Further, the CMA notes that [GSK's Finance Director A's] expectations are also consistent with the

¹⁸⁹⁶ The CMA notes that this fall in the Seroxat list price can, at least in part, be explained by renegotiation of the PPRS. In the 1993 and 1999 PPRS GSK chose to modulate 19% and 14.5% of the required price decreases respectively onto Seroxat (see SmithKline Beecham Memorandum entitled 'PPRS pricing strategy' dated 15 October 1999 (document D155) and Internal memorandum from [GSK employee] to [GSK employee] and others dated 10 November 1993, entitled 'Re: Seroxat Price Reduction' (document D156)). In relation to the 1999 PPRS, GSK's strategy document indicates that the proposed price decrease was not expected to be profitable for GSK, implying that the price decrease would not have been implemented had it not been for the PPRS requirements and should therefore not be regarded as a response to competition from other antidepressants (SmithKline Beecham document entitled 'PPRS pricing strategy' (document D155)).

¹⁸⁹⁷ [redacted]WS1 (GUK) (document 0885), paragraph 6.1.

limited impact of the generic entry of fluoxetine on paroxetine, as set out at paragraph 4.86.

- In terms of the evidential value of the witness statement provided by [GSK's Finance Director A], the CMA notes that by the time of their witness statement, [GSK's Finance Director A] had acquired extensive knowledge and experience of the pharmaceutical industry, and has described himself as *'the principal commercial person responsible for negotiating the GSK Agreements'* and *'able to speak to GSK's commercial rationale for entering into the GSK Agreements'*.¹⁸⁹⁸ Further, having identified [GSK's Finance Director A] as the appropriate company representative to provide evidence in proceedings of such significance to it, it is evident that GSK considered [Finance Director A] to be well qualified to provide evidence to a court on the likely impact of generic paroxetine and generic citalopram on sales of Seroxat, and was willing to sign off and submit [Finance Director A's] witness statement as evidence on its behalf.
- The CMA does not consider the fact that [GSK's Finance Director A] was referring to first time prescriptions and that patients are unlikely to be switched once established on a particular medicine to be inconsistent with the CMA's case. On the contrary, it is supportive of the CMA's inference from [GSK's Finance Director A's] comments that switching from paroxetine to citalopram was expected to be limited (see paragraphs 4.91 to 4.93).

iv) Representations on CMA's quantitative analysis

C.17 This sub-section sets out the Parties' representations on the CMA's natural events analysis (set out at paragraphs 4.71 to 4.94) and the CMA's responses to those submissions.

a) Representations on entry of generic paroxetine

C.18 In addition to its submissions concerning the *'IP bargain'* (see paragraphs C.9 to C.10) GSK also submitted that the CMA's quantitative analysis (in relation to the entry of generic paroxetine as well as the other natural events) was flawed.¹⁸⁹⁹ In particular, GSK submitted that:

¹⁸⁹⁸ Witness statement of [GSK's Finance Director A] dated 1 August 2013 (document A 0059), paragraphs 2.1 and 2.2.

¹⁸⁹⁹ GSK SO Written Response (document 2755), page 128, sub-heading K.

- The CMA's analysis overlooks the intense non-price competition that existed between suppliers, and the CMA is wrong to infer that where a branded medicines supplier is not incentivised to cut its prices in response to a price decline for another medicine, this indicates an absence of competition.¹⁹⁰⁰
- The CMA has not given marketing sufficient attention, as manufacturers invested significant sums in promoting their products to prescribing GPs, and in particular, the CMA has not sought to compare GSK's marketing spend levels with those of competitors.¹⁹⁰¹
- Prior to true generic competition, branded pharmaceutical suppliers have no incentive to compete on price or by increasing marketing. For example, GSK stated that *'because pharmacists cannot substitute across molecules [...], and because doctors generally do not make their prescription decisions based primarily on relative prices [...], the supplier of a branded drug that does not face independent generic competition has no incentive to cut price (or increase marketing) when the price of a therapeutic substitute declines.'*¹⁹⁰²

C.19 The CMA does not accept GSK's criticisms of its approach to assessing the relevant quantitative evidence, for the following reasons:

- The CMA has recognised the relevance of non-price competition in its analysis. In analysing quantitative evidence, the CMA has considered marketing costs, which are the key non-price parameter of competition, as well as overall profit margins (see paragraph 4.75). As set out at paragraph 4.83, the CMA has found that GSK was able to sustain pricing and marketing expenditure that enabled it to persistently earn profits that

¹⁹⁰⁰ GSK SO Written Response (document 2755), paragraph 3.159. Similarly, Teva submitted that the CMA's quantitative analysis does not recognise that differentiation between medicines means that competition between them will not necessarily drive prices down to incremental costs (see Teva SO Written Response (document 2750), paragraph 247).

¹⁹⁰¹ GSK SO Written Response (document 2755), paragraphs 3.147–3.148 and 3.150–3.151. In this context GSK noted that in *AstraZeneca* the Commission found that the evidence showed 'a dominant pharmaceutical company needs to invest less in promotion and marketing' and that 'AZ's level of detailing activities for Losec...compared to its sales, always remained far below the detailing of its competitors in the two markets (Germany and the United Kingdom) where such data is available' (Commission decision of 15 June 2005 in Case COMP/A.37.507/F3 – *AstraZeneca*, paragraph 563). In this regard GSK noted that the CMA had not shown that GSK's marketing spend was below that of manufacturers of key competitor brands (see response to question 4, GSK's response to the OFT's questions of 19 November 2013 (document 3017R)).

¹⁹⁰² GSK SO Written Response (document 2755), paragraph 3.158. Similarly Teva submitted that [GSK's Finance Director A's] evidence ([§]WS2 (GUK), Exhibit [§]6 (document 0887), paragraph 49) supports GPs' relative insensitivity to price, but the CMA's analysis relies heavily on price differentials between SSRIs showing a lack of substitutability (Teva SO Written Response (document 2750), paragraph 250).

were significantly above the level it was able to earn after the emergence of true generic competition.

- The CMA does not accept that it is necessary in the circumstances to have also considered the marketing spend of other antidepressant suppliers. First, given the requirement to consider whether there were constraints of other SSRIs on paroxetine (rather than the reverse), it is appropriate to focus on the extent to which GSK was able to sustain substantially higher profits prior to true generic competition, and not necessary to consider whether the same was true of other antidepressant suppliers. Second, the events considered above provide a sufficient insight into the extent to which other medicines constrained the price and profits sustained by GSK while the sole supplier of paroxetine.
- GSK is in any case incorrect to argue that prior to true generic competition a branded supplier has *'no incentive'* to cut prices or increase marketing when the price of a therapeutic substitute declines. The CMA notes that GSK has itself made submissions that contradict this argument, having stated that price played a significant role in competition between manufacturers of different SSRIs¹⁹⁰³ and submitted materials that highlight other SSRI suppliers' strategy of using price to improve their competitive position.¹⁹⁰⁴ Further, GSK stated that price competition existed by influencing prescribers through guidelines, as evidenced by the responses to its Freedom of Information requests to primary care trusts.¹⁹⁰⁵ GSK also submitted evidence that it competed with other branded manufacturers through its expenditure on marketing.¹⁹⁰⁶
- Although pharmacies cannot substitute between molecules on receipt of a given prescription, branded suppliers will compete in seeking to persuade practitioners to prescribe their medicines, and may do this by highlighting any cost savings to the NHS. The extent of any such competition must be

¹⁹⁰³ GSK SO Written Response (document 2755), paragraphs 3.143–3.146. For example, in evidence of this, GSK cited: (i) the fact that the list prices for a daily treatment of paroxetine and citalopram were within two pence of one another at the start of the relevant period; (ii) marketing materials, such as a slide on [X]WS Exhibit [X]3 (document 0866), page 23 comparing the cost per day of Seroxat, citalopram, fluoxetine and sertraline; and (iii) prescribing guidelines. The CMA notes that Teva similarly submitted that there was contemporaneous evidence suggesting that GSK deliberately priced paroxetine relative to other SSRIs in responding to competition from other SSRIs (Teva SO Written Response (document 2750), paragraph 245). The CMA also notes that the GC in *AstraZeneca* found that the specific circumstances of the pharmaceutical sector did not undermine the use of pricing data in market definition analysis (see footnote 720).

¹⁹⁰⁴ For example, stating *'All of Seroxat's major competitors are promoting on a price platform...'*, see SmithKline Beecham document entitled 'PPRS pricing strategy' (document D155)

¹⁹⁰⁵ GSK SO Written Response (document 2755), paragraph 3.138(f).

¹⁹⁰⁶ For example, in GSK SO Written Response (document 2755), section 3J(III), paragraphs 3.147–3.151, GSK explained that investing significant sums on marketing was a competitive factor prior to generic competition.

assessed on a case by case basis. In this case, it is evident that paroxetine prices and profits were constrained to a degree by other medicines, albeit that this constraint was not sufficient to prevent GSK from maintaining prices and profits that were considerably above the level observed after independent generic entry.

- C.20 GSK also submitted that the CMA's analysis fails to identify an appropriate benchmark against which to measure the prices and profits that GSK sustained prior to independent generic paroxetine entry.¹⁹⁰⁷
- C.21 The CMA's analysis makes clear that prior to true generic competition, GSK was able to sustain prices and profits that were significantly higher than those that could be sustained thereafter. GSK's ability to sustain significantly higher profits prior to independent generic entry suggests that the constraint of competition from other molecules was far less significant than that of true generic competition. This contrast in the profits earned before and after the emergence of true generic competition is sufficient to demonstrate that GSK (as the monopolist supplier of paroxetine) was able to sustain significantly higher prices and profits prior to generic entry, such that it is not necessary to determine a 'competitive price' benchmark.
- C.22 As set out at paragraph 4.75, the CMA recognises that competition prior to generic entry is more focussed on marketing than would be the case thereafter. It is for this reason that the CMA's analysis has not focussed only on price, and has also considered whether the higher prices observed before true generic competition can be explained by significantly higher marketing expenditure. In particular, the CMA has considered whether the profits earned before and after true generic competition were at a similar level and indicative of other SSRIs preventing GSK from sustaining profits that were significantly in excess of the levels observed and sustained following generic entry. As set out above, although GSK did spend more on marketing paroxetine prior to generic entry, this did not prevent GSK from sustaining significantly higher profits and margins prior to true generic competition than it could sustain thereafter.

b) GSK's representations on entry of generic fluoxetine

- C.23 GSK submitted that there was a significant fall in paroxetine prices due to the entry of generic fluoxetine, and that a renegotiation of the PPRS was the

¹⁹⁰⁷ GSK SO Written Response (document 2755), paragraph 3.9.

mechanism by which this price fall was achieved, rather than the explanation for it, as contended by the CMA.¹⁹⁰⁸ In particular, GSK stated that:

- it chose to take a high proportion of its required PPRS price cut on paroxetine due to *'the contemporaneous genericisation of fluoxetine and the need to remain competitive given that other SSRI competitors were reducing prices for the same reason.'*¹⁹⁰⁹
- Lundbeck reducing its pricing of citalopram and, in doing so, doubling its volume of sales was a motivating factor for lowering its Seroxat price.¹⁹¹⁰

C.24 As set out at paragraph 4.86 the CMA accepts that there was a fall in paroxetine prices at the time of generic fluoxetine entry. The CMA also recognises that a manufacturer can modulate the implementation of a PPRS price cut and in doing so may apply a larger price reduction to certain medicines than the average price cut required. However, the extent of that constraint was insufficient to prevent GSK from sustaining prices and profits that were significantly above the level observed following generic entry. GSK stated that it is *'true'* that *'the constraints exerted by other medicines were insufficient during the period of patent application to compete GSK's prices and margins down to the very low levels seen following independent entry.'*¹⁹¹¹

C.25 Moreover, an internal memorandum considering the strategic rationale for changes in GSK's pricing in the 1999 PPRS noted that the price decrease was, of itself, expected to be unprofitable. This implies that, absent the 1999 PPRS, GSK would not have chosen to reduce its Seroxat price in order to compete with fluoxetine or other SSRIs, as it would have been more profitable to sustain its price at the prevailing level. The CMA further notes that this memorandum did not mention price competition with fluoxetine as being one of the motivating factors behind the Seroxat price changes effective from 1 October 1999 (albeit it did discuss price competition with Cipramil).¹⁹¹² The PPRS does therefore explain the price decrease, whereas competition from fluoxetine does not.

¹⁹⁰⁸ GSK SO Written Response (document 2755), paragraphs 3.176–3.177.

¹⁹⁰⁹ GSK SO Written Response (document 2755), paragraph 3.179.

¹⁹¹⁰ GSK SO Written Response (document 2755), paragraph 3.180.

¹⁹¹¹ GSK SO Written Response (document 2755), paragraph 3.162.

¹⁹¹² SmithKline Beecham document entitled 'PPRS pricing strategy' (document D155). As set out at paragraph 3.105, a branded supplier can choose to modulate the impact of a required PPRS price fall, by adjusting the prices of only some of the medicines covered by PPRS in order to deliver the agreed savings. In this context, the 1999 paroxetine price fall was deemed as being the most profitable means of meeting the required PPRS decrease, rather than a profitable course of action of itself (see also paragraph 4.57).

C.26 Despite the representations set out above, the CMA notes that GSK also submitted that the price of fluoxetine had no material effect on sales volumes of Seroxat because doctors make prescription decisions based on individual needs rather than on relative price comparisons, and at the time GSK was in active non-price competition with suppliers of other SSRIs.¹⁹¹³

c) Representations on the launch of Cipralex

C.27 GSK submitted that the CMA's natural events analysis relating to the launch of Cipralex is incorrect for the following reasons:

- it is incorrect to review changes in citalopram sales over the entire period between escitalopram entry and the end of 2005. The CMA should only have considered the period prior to generic paroxetine entry.¹⁹¹⁴ In particular, GSK submitted that: (i) between June 2002 and November 2003 Cipralex gained about 10 million DDDs and paroxetine lost 10 million DDDs in monthly sales, and (ii) sales of paroxetine did not fall in the first three months after Cipralex was launched, which is consistent with GSK's experience of the time delay for a new product to have an impact on sales;¹⁹¹⁵
- it is misguided to consider that the entry of Cipralex would have resulted in GSK adjusting marketing or prices, as follows:
 - marketing could not increase at the time when Cipralex was launched due to a reallocation of marketing spending following the SmithKline Beecham/Glaxo Wellcome merger;¹⁹¹⁶
 - non-price competition is the principal form of competition between branded medicines manufacturers;¹⁹¹⁷
- the CMA's analysis has not taken account of the fact that Cipralex was a successor product to Cipramil (citalopram), which meant that Cipramil volumes were declining as generic citalopram and Cipralex sales started.¹⁹¹⁸ Lundbeck may therefore simply have switched marketing spend from Cipramil to Cipralex, and so GSK's marketing spend, in order to be comparable, would not need to increase.¹⁹¹⁹

¹⁹¹³ GSK SO Written Response (document 2755), paragraph 3.181.

¹⁹¹⁴ GSK SO Written Response (document 2755), paragraph 3.172.

¹⁹¹⁵ GSK SO Written Response (document 2755), paragraphs 3.168–3.169.

¹⁹¹⁶ GSK SO Written Response (document 2755), paragraph 3.173.

¹⁹¹⁷ GSK SO Written Response (document 2755), paragraph 3.174.

¹⁹¹⁸ GSK SO Written Response (document 2755), paragraph 3.175.

¹⁹¹⁹ GSK SO Written Response (document 2755), paragraph 3.149.

C.28 The CMA does not accept the submissions made by GSK. In particular:

- The CMA disagrees with GSK's submission that the analysis should have focussed only on the period prior to the emergence of generic paroxetine, as the period following generic entry can still inform an assessment of whether the steady growth in CipraleX sales was driven by switching from paroxetine. In any case, the CMA notes that even over that period, the analysis remains that the erratic quarter to quarter sales losses of paroxetine did not correspond to the steady growth in sales of CipraleX. For example, between June 2002 and December 2003, paroxetine 20mg sales fell by 48 million DDDs¹⁹²⁰ but with erratic quarterly declines while CipraleX sales increased by 37 million DDDs¹⁹²¹ with a smoother growth rate (see Figure 4.8). This analysis again implies that the decline in paroxetine sales was not solely attributable to the growth of CipraleX. In any case, the CMA notes that the steady and consistent growth in CipraleX is not consistent with considerable switching from paroxetine to CipraleX following generic entry and the associated price declines, which further suggests that there was a limited competitive interaction between the two medicines.
- GSK's contemporaneous documents do not indicate that during the relevant period it considered that lost sales of paroxetine were primarily being diverted to CipraleX. For example, a presentation analysing growth in the SSRI sector in 2001 and 2002, states that the '*majority of Seroxat's loss is venlafaxine's gain*', and lists '[c]oncerns over withdrawal' as one of the reasons for Seroxat's underperformance, though the launch of CipraleX is not cited in this context.¹⁹²² Another document ranks several antidepressants based on the '*Competitive Position of Brand*' as perceived

¹⁹²⁰ When compared to the total sales had quarterly paroxetine sales volumes remained equal to April–June 2002 levels.

¹⁹²¹ When compared to total sales had quarterly CipraleX sales volumes remained equal to April–June 2002 levels.

¹⁹²² GSK presentation entitled 'Review of Market Position, Seroxat' (document A 0080), Slides 3 and 4. GSK stated that the CMA could not draw any inference from the absence of a mention of CipraleX when CipraleX was launched mid-way through 2002 so it would be too early to assess its impact: GSK response dated 17 September 2014 to the First Letter of Facts (document 3493). The CMA notes that even if the full impact of CipraleX had not become apparent between May 2002 and the end of 2002, a 7 month period would have been sufficient to provide an early indication of whether the constraint from CipraleX was likely to be significant and of a magnitude requiring a response from GSK (this is supported by GSK SO Written Response (document 2755), paragraphs 3.168–3.169 in which GSK stated that in its experience there would be a 3-month delay for GPs to begin prescribing a new product). GSK also submitted that the focus of the document is the review of sales of Seroxat to secondary care customers which explains the focus on venlafaxine: GSK response dated 17 September 2014 to the First Letter of Facts (document 3493), paragraph 3.28(a). The CMA notes that the quotes it has relied on are clearly made in the context of an overview of paroxetine sales overall, as confirmed by the sales values which are too large to relate only to sales to secondary care. It is only later in the presentation that the focus becomes how to use endorsement in secondary care to drive primary care prescribing, which does not undermine the CMA's reading of this document.

by GPs and places Seroxat as close to Cipramil but higher than fluoxetine, Lustral (sertraline), Effexor (venlafaxine) and CipraleX in terms of *'Relative Competitive Strength'*.¹⁹²³ From this, the CMA infers that GSK did not perceive Seroxat to be competing as closely with CipraleX as with the other antidepressants mentioned in that document.

- The CMA has acknowledged that both price and non-price competition are relevant in this sector, and it is for this reason that the CMA considered both prices and marketing spending as relevant factors for market definition (see paragraph 4.75). The CMA remains satisfied that the lack of response in relation to either parameter of competition indicates that CipraleX failed to significantly constrain sales of paroxetine. The fact that GSK's approach was part of a revised marketing strategy does not undermine this analysis, as at the time GSK continued to earn annual profits of £51 million on paroxetine¹⁹²⁴ and it was entirely open to GSK to re-focus its marketing priorities in response to the launch of CipraleX.
- To the extent that GSK's submission is that because CipraleX was a successor product to Cipramil Lundbeck's overall sales volumes and marketing expenditure did not increase, then it follows that GSK did not face an increased competitive constraint as a result of the launch of CipraleX. To that extent, the launch of CipraleX cannot account for the reduction in paroxetine sales that occurred at this time, as there was no change in the competitive constraint from Lundbeck antidepressants.
- While the CMA recognises that the launch of CipraleX may have had a limited effect on paroxetine sales, this is in the context, accepted by GSK as *'true'*, that *'the constraints exerted by other medicines were insufficient during the period of patent application to compete GSK's prices and margins down to the very low levels seen following independent entry'*.¹⁹²⁵

d) Representations on entry of generic citalopram

C.29 GSK submitted that the CMA's analysis is flawed on the basis that (i) the two events (entry of generic paroxetine and entry of generic citalopram) are too close together to be informative and (ii) the CMA's analysis is based on two observations unrelated to the event itself (the interactions between citalopram

¹⁹²³ 'Strategic Marketing Plan 2003–2005, Seroxat' (document A0079), slide 16.

¹⁹²⁴ GSK profits on 20mg and 30mg paroxetine in 2002, see Tables 4.2 and 4.3.

¹⁹²⁵ GSK SO Written Response (document 2755), paragraph 3.162.

and paroxetine prior to the entry of generic citalopram and the evidence in [GSK's Finance Director A's] witness statement).¹⁹²⁶

- C.30 The CMA accepts that a 3-month period is likely to be too short to observe a direct impact on paroxetine after the entry of generic citalopram. It is for this reason that the CMA has considered the interactions between Cipramil and Seroxat in the years prior to this event, and the expectations set out by [GSK's Finance Director A], in order to establish the extent to which citalopram provided a competitive constraint to paroxetine. As set out at paragraph 4.92, had the entry of generic citalopram resulted in the fall in paroxetine prices observed in 2003, it would have also been possible to observe effective competition between paroxetine and citalopram in the years prior to generic entry of citalopram.
- C.31 In considering the relative sizes of different competitive constraints, the CMA notes that GSK has not sought to argue that the paroxetine price fall was due to citalopram. Indeed, as set out at paragraph C.28, GSK explicitly accepted as '*true*' that the constraints exerted by other medicines were insufficient prior to generic entry to compete GSK's prices and profits down to the levels observed after generic entry.¹⁹²⁷

B. Dominance

- C.32 GSK submitted that it was not dominant during the relevant period on the basis of a market definition that is at least as wide as SSRIs.¹⁹²⁸ For the reasons outlined at paragraphs 4.17 to 4.97 the CMA has decided that the relevant market in this case is no wider than the supply of paroxetine in the UK and therefore the CMA does not accept GSK's submissions in this regard.

¹⁹²⁶ GSK SO Written Response (document 2755), paragraphs 3.164–3.166.

¹⁹²⁷ GSK SO Written Response (document 2755), paragraphs 3.162.

¹⁹²⁸ GSK SO Written Response (document 2755), paragraphs 3.190–3.207

ANNEX D: REPRESENTATIONS REGARDING ASSESSMENT OF REVERSE PAYMENT SETTLEMENT AGREEMENTS AND POTENTIAL COMPETITION

A. Representations regarding the assessment of reverse payment settlement agreements

D.1 The CMA has assessed the object of the GUK-GSK Agreement and the Alpha-GSK Agreement in light of the legal and economic context that existed at the time the Agreements were entered into.

D.2 In the course of the Investigation, both before and following the issue of the SO and SSO, several of the SO Addressees made submissions relevant to the CMA's assessment of the Infringing Agreements as a restriction of competition by 'object'.

j) The application of competition law to reverse payment settlement agreements

a) Representations on the exclusionary nature of patent rights

D.3 It was submitted that settlement agreements which do not go beyond the exclusionary scope of GSK's patents do not infringe competition law, because such agreements simply reflect the exclusionary nature that is inherent in patent rights. GSK submitted that a patent owner's right to oppose patent infringement is part of the very subject specific matter of the patent and, in this regard, stated that an infringement of competition law could only arise where there has been more than the mere enforcement of those rights.¹⁹²⁹ GSK stated that if there has been no Court finding of invalidity, the presumption of patent validity must continue to apply when assessing a patent settlement.¹⁹³⁰

D.4 The CMA does not dispute that patent holders are free to rely on their patents to oppose infringements or that GSK had the right to bring the relevant litigation, which is part of the subject specific matter of the patent.¹⁹³¹

¹⁹²⁹ GSK submitted that the GC had applied a similar principle in *Protégé International*, a case following the *ITT Promedia* precedent. GSK SO Written Response (document 2755), paragraphs 1.43–1.45).

¹⁹³⁰ GSK SO Written Response (document 2755), paragraph 1.31 (a).

¹⁹³¹ Save for vexatious litigation (see Judgment of 17 July 1998, *ITT Promedia v Commission*, T-111/96, ECR, EU:T:1998:183, paragraph 60 and Judgment of 13 September 2012, *Protégé International v Commission*, T-199/09, ECR, EU:T:2012:421, paragraph 49).

- D.5 However, the grant of a patent does not protect the patent holder from challenges to its validity, or from other firms seeking to bring a product to market without infringing valid patent claims. As such, it is not the case that the ability to exclude all potential competition is inherent in the existence of a patent right. It has been recognised by the EU Courts that competition law may apply to settlement agreements, including where the terms of the settlement agreement do not go beyond the scope of the patent in question.¹⁹³² Further, the EU Courts have consistently stated that competition law may apply to agreements which concern the use or exercise of patent rights.¹⁹³³ The right to bring litigation and oppose infringements does not extend to the right to ‘buy off’ competitive threats. Paying a potential competitor to accept entry restrictions goes beyond the exclusionary nature of the IP right and is not one of the means provided for under patent law to enforce the patent.
- D.6 In relation to GSK’s submissions concerning the presumed validity of its patents, the CMA also observes that the burden is on the patent holder to demonstrate that any patents it holds have been infringed. Moreover, the CMA observes that GSK’s submissions concerning the presumption of patent validity are in any case irrelevant to the litigation between GSK and Alpharma. By this time the majority of the patent claims in the Anhydrate Patent had been found invalid, and the anticipated litigation was to focus solely on whether Alpharma’s product infringed the remaining two patent claims. There was no presumption that Alpharma’s product infringed GSK’s remaining patent claims.

b) Representations on the adjudication of a patent’s validity

- D.7 GSK submitted that it is for the patent office and Courts to adjudicate on the merits of a patent, and it is not within the competence of competition authorities to do so.¹⁹³⁴ GSK submitted that the principle that competition authorities should not ‘*hazard a guess*’ as to the merits of a patent situation is exemplified by the facts of the paroxetine litigation, where even the competent Court found it an extremely complex issue. GSK submitted that it is the process of litigation that determines whether the parties are actual or potential

¹⁹³² Judgment in *Bayer v Sülhölfer*, 65/86, EU:C:1988:448, paragraph 15.

¹⁹³³ For example, see judgment in *Parke, Davis & Co v Probel and Others*, 24/67, EU:C:1968:11, pages 71-72: “Nevertheless, it is possible that the provisions of [Article 101] may apply if the use of one or more patents, in concert between undertakings, should lead to the creation of a situation which may come within the concepts of agreements between undertaking, decisions of associations of undertakings or concerted practices within the meaning of Article [101(1)]”.

¹⁹³⁴ GSK SO Written Response (document 2755), paragraph 1.32(b).

competitors and that the CMA is prejudging the outcome of litigation proceedings.¹⁹³⁵

- D.8 The CMA's case does not require it to adjudicate on the merits of a patent. The CMA recognises that at the time of the Agreements, the outcome of the relevant litigation was uncertain, and the Generic Companies may not have been successful in their litigation with GSK and in entering the market.
- D.9 In fact, it is the analysis submitted by the parties that would prejudice the outcome of such litigation by assuming that valid patents will always be upheld, such that there is no potential competition even in those circumstances where there are real concrete possibilities for entry. Indeed, the conduct of GSK demonstrates that the Generic Companies were perceived to be a competitive threat.
- D.10 The economic and commercial reality of the pharmaceutical sector is that generic suppliers will frequently seek to enter the market despite the existence of presumptively valid patents, and incumbents will seek to defend their interests from those threats. Patent challenges in this field can in themselves be viewed as an important aspect of the competitive process.
- D.11 The CMA's findings do not undermine the complex nature of such disputes. The CMA observes that however complex an assessment, an undertaking must form a view as to whether it is in its interests to contest litigation and on what terms it would be willing to settle the dispute (that are compatible with competition rules).

c) *The analysis of reverse payment settlement agreements as restrictions of competition by object*

- D.12 Several of the parties submitted that the settlement agreements cannot be regarded as restrictions of competition by object because the notion of infringement by object must be interpreted narrowly and confined to cases which are recognised from experience as '*inherently injurious to competition*'.¹⁹³⁶

¹⁹³⁵ GSK SO Written Response (document 2755), paragraph 1.50.

¹⁹³⁶ See Teva written response dated 21 November 2014 to the SSO (document 3645), page 8, paragraph 2.2.3, including footnote 29, referring to the Opinion of Advocate General Wahl delivered on 27 March 2014 in *Groupement des Cartes Bancaires v Commission*, C-67/13 P, EU:C:2014:1958, paragraph 56. See GSK written response dated 2 December 2014 to the SSO (document 3668), paragraphs 2.1–2.13, supporting GSK's arguments by referring to paragraph 51 of the Judgment in *Groupement des Cartes Bancaires v Commission*, C-67/13 P, EU:C:2014:2204. See Actavis written response dated 25 November 2014 to the SSO (document 3653), paragraph 2.2. See Merck written response dated 25 November 2014 to the SSO (document 3649), paragraph 2.4.

D.13 The CMA recognises that, at the time of the GUK-GSK and Alpharma-GSK Agreements, there may have been no specific case law precedent regarding reverse payment agreements between an originator and a generic undertaking. Nevertheless, the notion that agreements aimed at market exclusion in exchange for a payment are likely to constitute a restriction by object under competition law is one that is well established.

d) *Representations regarding how pay for delay agreements increase incentives to innovate and to settle litigation*

D.14 GSK submitted that:¹⁹³⁷ *'The patent system is designed to incentivise innovation by rewarding the inventor with a legal monopoly. Any undue interference with that monopoly risks undermining those incentives to innovate'*.

D.15 The CMA recognises that the patent system in the UK and EU seeks to provide research-based pharmaceutical companies, such as GSK, with incentives to invest in R&D in the knowledge that other companies will not be able to replicate products/processes that are the subject of claims in a valid patent.

D.16 The patent system was also designed to ensure that the same protections are not available where firms cannot demonstrate the level of innovation necessary to justify a patent, such that where valid patents do not apply, consumers can benefit from unrestricted competition. To facilitate that, the patent system specifically enables parties to challenge the validity of a patent to ensure that patents do not inappropriately protect patent holders from competition. Similarly, competitors are free to bring to market products which do not infringe valid patent claims.

D.17 In this case, the CMA considers that GSK was in essence 'buying off' a challenge to its patents, of the type expressly provided for under patent law. By taking action to prevent the threat of competition being 'bought-off', competition law can be used to uphold the incentives that the patent system is designed to promote.

D.18 A number of Parties submitted that an infringement finding in this case would discourage settlements in patent disputes by restricting the parties' ability to come to a compromise, including where they disagree as to the likely outcome of the relevant litigation. For example, GSK states that given the finite resources available, it is in the interests of society to encourage parties

¹⁹³⁷ GSK submission to the OFT dated 27 June 2012 (document 0746), paragraph 2.1.

to come to a compromise that might settle a dispute long before formal proceedings can be completed. In this regard, alternative dispute resolution and settlement of disputes have been encouraged as a matter of policy for many years at both a European and a UK level.¹⁹³⁸

D.19 The CMA does not accept that the potential for settlements to give rise to efficiencies should result in antitrust immunity for all settlement agreements. Rather, when conducting an assessment under EU/UK competition law, it is necessary to consider whether there is a restriction of competition, and whether such a restriction can be justified by efficiency considerations. In this case, the CMA finds that the restrictions of competition described in Part 6 were not justified by relevant efficiencies (see paragraphs 10.54 to 10.96).

ii) Representations concerning the use of value transfers to avoid risk

D.20 During the course of the Investigation, GSK submitted that the Agreements were a reasonable means of avoiding the risks and uncertainty that GSK faced at the time. For example:

- GSK submitted that *'patent litigation is extremely costly and there is an inherent binary outcome to any patent litigation. The consequences of losing are so severe for a patent owner that mitigation through settlement is prudent whatever the risk'*.¹⁹³⁹
- GSK also stated that *'[s]ince in patent litigation there will always be some risk of loss, settling on the basis of a payment to the generic supplier is likely to be worthwhile regardless of the level of risk'*.¹⁹⁴⁰
- In explaining its reasons for entering into the Agreements, GSK submitted that *'[c]ertainty is critical to any business'*,¹⁹⁴¹ and that *'[s]ettlement provided a prudent means of avoiding the uncertainty, costs and disruption of litigation'*.¹⁹⁴² In particular, GSK emphasised the need for certainty in order to:
 - *'achieve reasonable predictability of revenues and earnings'*;

¹⁹³⁸ GSK SO Written Response (document 2755), paragraphs 1.61–1.63. Actavis made similar representations: Actavis SO Written Response (document 2754), paragraphs 9.7 and 9.8.

¹⁹³⁹ GSK Second Response, Part Two (document 0734), paragraphs 1.1(b).

¹⁹⁴⁰ GSK submission to the OFT dated 27 June 2012 (document 0746), paragraph 4.3. See also GSK Second Response, Part Two (document 0734), paragraph 8.2: *'a confident patent owner may well choose to settle its disputes where reasonable terms can be reached, whatever the level of risk in pursuing litigation'*.

¹⁹⁴¹ GSK Second Response, Part Two (document 0734), paragraphs 1.1(c) and 8.1(a).

¹⁹⁴² GSK Second Response, Part Two (document 0734), paragraph 8.3(b).

- manage *'investor expectations'*; and
- *'plan [...] sales, marketing and production investment decisions going forward'*.¹⁹⁴³

D.21 The CMA accepts that, putting competition law considerations to one side, it was in GSK's interests to make the value transfers to secure entry restrictions that would defer the risk that it would lose the relevant litigation and face unrestricted generic competition. However, the fact that the Agreements may have been the more commercially lucrative and attractive option for GSK (and the Generic Companies) does not mean that they are not restrictive of competition. For example, competing undertakings may consider the formation of a cartel to be in their commercial interests, but on the basis that doing so protects them from effective competition.

D.22 In this case, the risks and costs that GSK avoided by making value transfers were those associated with the threat of true generic competition. They included the risk that its patents might be held invalid, the risk that the Generic Companies' products were found not to infringe those patents that are deemed valid, and the potential for very significant losses if widespread lawful generic entry actually occurred, and resulted in the concerns that GSK described in relation to predicting revenue, managing investor expectations and planning. GSK secured the entry restrictions by making the value transfers to induce each Generic Company to accept entry restrictions (see Part 6). By making those value transfers, GSK ensured that not only would market prices be 'predictable', but also that those prices would not be subject to any increase in the actual competitive constraints that GSK faced.

D.23 Further, the CMA observes that the Agreements did not resolve the uncertainty described by GSK, but simply deferred it. In the case of IVAX and Alpharma, for example, the initial one year duration of the Agreement was such that the Agreement succeeded in deferring any uncertainty arising from litigation for 12 months, and the value transfers that GSK made over that period enabled GSK to defer the uncertainty it faced but not to avoid it. Moreover, each of the GUK-GSK and Alpharma-GSK Agreements make explicit references to the prospect of further litigation when those Agreements terminated.¹⁹⁴⁴

¹⁹⁴³ GSK Second Response, Part Two (document 0734), paragraph 8.3. See also paragraphs 8.7–8.9 and Minutes of meeting between GSK and the OFT on 19 December 2011 (document 0688), paragraph 30, for example, where [GSK's Finance Director A] explained that *'making a deal with the generics ensured that the [GSK] management team would be able to deliver next year's numbers'*.

¹⁹⁴⁴ See paragraphs 6.90 (GUK) and 6.154 (Alpharma).

iii) Representations concerning the significance of value transfers

- D.24 GSK submitted that there is no contrast between a settlement including a value transfer and one in which entry restrictions are negotiated solely on the basis of each party's assessment of the risks and returns associated with the potential litigation outcomes, that is, of the likelihood of that patent being held by a Court to be valid and/or not infringed.¹⁹⁴⁵ GSK submitted that the Agreements under examination do reflect the parties' assessments of the risks arising from the possible litigation and that the existence of value transfers does not demonstrate otherwise. GSK stated that the CMA's finding that value transfers were in return for entry restrictions is 'fallacious' as settlements contain all sorts of benefits and losses for both sides and represent compromises. In this regard, GSK noted that because the settlements involved forbearance by GSK from continuing to proceed against the Generic Companies, there were terms regarding conduct on both sides, and that there was value to GSK in settling costly and risky litigation.
- D.25 The CMA considers there to be a clear distinction between an agreement in which an originator 'buys' entry restrictions using value transfers, and a settlement that is reached in which no such transfer can be used and the originator must instead offer more competitive entry terms to incentivise the generic suppliers to settle any anticipated or ongoing litigation. As noted above, the CMA finds that the value transfers in the GUK-GSK and Alpha-GSK Agreements were made in return for entry restrictions. In the absence of value transfers made for this purpose, any settlement would have had to involve less restrictive terms (i.e. terms that did not include 'exclusion payments', and which therefore reflected, in legitimate and pro-competitive ways, the commercial risks that were faced by the parties).
- D.26 The CMA accepts that in entering into the GUK-GSK and Alpha-GSK Agreements, GSK was agreeing not to continue with the litigation. This was an inevitable consequence of GUK and Alpha's agreement not to enter the market independently of GSK, and entirely in GSK's interests in seeking to ensure that its patents remained unchallenged and that the threat of unrestricted generic competition was delayed. However, the CMA considers that the risks that GSK made value transfers to delay were those associated with the potential emergence of true generic competition (such as those described at paragraph D.22). For the reasons set out at paragraphs 6.115 to 6.126 and 6.179 to 6.190, the CMA does not accept that the avoidance of

¹⁹⁴⁵ GSK SO Written Response (document 2755), paragraph 1.174, GUK SO Written Response (document 2752), paragraph 5.10b.

litigation cost is capable of explaining the at least £50.9 million of value transfers that GSK committed to make to the Generic Companies.

- D.27 GUK stated that the fact that it was the beneficiary of an alleged value transfer does not mean that GUK would have prevailed in litigation or otherwise entered the market.¹⁹⁴⁶ Similarly, GSK stated that the CMA has not demonstrated that the Agreements at issue involved the acceptance of terms by the Generic Companies that they had no incentive to accept based on their assessment of the potential litigation outcomes.
- D.28 The CMA has not assumed that as the beneficiary of the value transfers GUK would have prevailed in litigation or would have entered the market. The CMA accepts that at the time the Agreement was entered into, the outcome of the litigation was uncertain (see Part 6).
- D.29 The CMA is also satisfied that on the basis of evidence and analysis set out at Part 6, it is apparent that GUK and Alpharma accepted the relevant restrictions on the basis that they were compensated, through the value transfers, for doing so.

iv) *The economic models submitted by the SO Addressees*

- D.30 Several SO Addressees submitted economic papers in relation to the competitiveness of patent settlements containing value transfers. The CMA observes that none of these papers have sought to make submissions concerning the legal and economic context and facts of this case, or on the findings presented in Part 6. This Section addresses those papers for completeness only.

a) *Settlement agreements should not be characterised as object restrictions*

- D.31 Teva submitted a paper which concluded that the characterisation of settlement agreements as restrictions of competition by object is inappropriate.¹⁹⁴⁷ In particular, the paper argued that agreements that include value transfers and entry restrictions may in some circumstances have pro-competitive effects, and that sometimes reverse payments are necessary to reach pro-competitive settlements. The paper also stated that settlements with reverse payments greater than the originator's expected litigation costs

¹⁹⁴⁶ GUK SO Written Response (document 2752), paragraph 5.10b.

¹⁹⁴⁷ Teva SO Written Response (document 2750), paragraph 26. Although this Decision does not make a finding that the IVAX-GSK Agreement has the object (or effect) of restricting competition, the CMA has considered Teva's submission given its broader applicability.

need not delay entry. The paper concluded that assessing the pro-competitive or anti-competitive nature of reverse payment patent settlements is impractical as it requires knowledge of: (i) the objective strength of the patent (ii) the parties' subjective evaluation of the strength of their respective case and (iii) the parties' beliefs about their opponent's evaluation of the case.¹⁹⁴⁸

- D.32 The CMA observes that the paper submitted by Teva critiques an analysis that does not correspond to that carried out by the CMA. For example, the paper submitted by Teva proceeds on the premise that the CMA's analysis of the object of the Agreements has simply observed the existence of value transfers and entry restrictions and concluded that there has been an infringement. The reality, however, is that in assessing the GUK-GSK and Alpharma-GSK Agreements the CMA has assessed the objective aim of the value transfers in their legal and economic context. As part of that assessment, the CMA has considered (and rejected) submissions that on the facts of this case the purpose of the value transfers were not anti-competitive.
- D.33 The CMA also observes that Teva's submissions were not made by reference to the facts relevant to any of the Agreements concluded in this case, or to the legal and economic context in which they were concluded, and does not cast doubt on the specific findings made in Part 6.
- D.34 Finally, and for completeness, the CMA observes that in the models presented by Teva, the outcomes that are proposed would not be profit-maximising in a scenario in which any value transfers were considered to be permissible. The reality is that, in each of the scenarios considered, the outcomes that result in an increase in consumer welfare would, in those circumstances, not be expected to be concluded, as in each case the profit-maximising outcome would be one in which value transfers are made in return for the generic supplier's acceptance of ongoing entry restrictions.

b) GUK's model – value transfers can be necessary for settlement

- D.35 GUK presented a stylised model which sought to demonstrate that value transfers may be required to reach settlement when the originator and the generic firm have different views of their chances of prevailing in litigation.¹⁹⁴⁹
- D.36 The CMA accepts that absent value transfers from the originator some parties may choose not to settle. However, as set out at paragraph D.19, the CMA does not accept that a desirability for settlements should in all cases simply outweigh the significant competitive harm that can result from such

¹⁹⁴⁸ Teva SO Written Response Annex 1 (document 2751), paragraph 48.

¹⁹⁴⁹ Annex 1 to GUK SO Written Response (document 2753), section 4.1, page 29 and section A.2, pages 34–37.

agreements. Patent settlement agreements do not enjoy a special status that exempts them from the reach of competition law.

D.37 The CMA also notes that, in the model presented by GUK in which value transfers are paid to achieve settlement, the expected entry date is delayed relative to the expected entry date had parties instead litigated,¹⁹⁵⁰ and as such settlement in this instance cannot be said to improve consumer welfare (or even to have neutral effects on consumer welfare) as compared to a counterfactual in which the threat of independent generic entry is maintained. In the model presented by GUK, the realistic counterfactual is the continuation of the generic supplier's strategy of generic entry (through litigation), whereas under the terms of the theoretical agreement the threat of generic entry is deferred while the originator's monopoly is maintained. The agreement involving value transfers therefore improves the expected outcomes for the two companies, but results in less favourable expected outcomes for consumers (as the generic supplier's efforts to independently enter the market, and the prospect of true generic competition, is deferred).

c) GSK's Annex 4 – value transfers can increase consumer welfare

D.38 GSK submitted analysis in which it sought to demonstrate that the structure of the Agreements at issue in this case can increase expected consumer welfare even though they involve value transfers.¹⁹⁵¹ In particular:

- GSK submitted that there is no basis to conclude that expected consumer welfare would necessarily have been greater if the Agreements had been structured instead as 'authorised independent early entry agreements'¹⁹⁵² in which there was no value transfer.¹⁹⁵³
- GSK stated that its analysis shows that value transfers from the originator to the generic can be necessary to provide the generic supplier with incentives to enter into a supply agreement that increases consumer welfare relative to an authorised independent early entry agreement.¹⁹⁵⁴

D.39 The CMA observes first that GSK's analysis rebuts a case which the CMA has not advanced. In particular, the CMA has not argued that any settlement

¹⁹⁵⁰ Although the model does not specify the objective probabilities of either party prevailing in litigation (only each parties' perceptions of their chances of prevailing are specified), it is inevitable that entry is delayed relative to the expected entry date following litigation given the setup of GUK's model which is for parties to agree to a 'delayed litigation date' in settlement, rather than a delayed entry date.

¹⁹⁵¹ GSK SO Written Response (document 2755), page 68 and Annex 4 to GSK SO Written Response (CRA Report) (document 2762).

¹⁹⁵² This is a settlement agreement with an agreed entry date for the generic.

¹⁹⁵³ GSK SO Written Response (document 2755), paragraphs 2.7, 2.61–2.62.

¹⁹⁵⁴ GSK SO Written Response (document 2755), paragraphs 2.8, 2.63–2.65.

agreements involving reverse payments restrict competition. The CMA has assessed the purpose of the value transfers in this case and has established that GSK used the value transfers to induce GUK's and Alparma's acceptance of entry restrictions. In this regard, the CMA observes that GSK has not made any submission that, as per the theoretical analysis described in Annex 4 to its representations, the purpose of the Agreements' value transfers was to incentivise the Generic Companies to enter into a more competitive agreement than they would have accepted in their absence, and there is no evidence that this was the case. Furthermore, where, as in this case, the Generic Companies' paroxetine returns are generated only from value transfers rather than from meaningful competition with GSK, and where the terms on which they entered the market could not reasonably be expected to result in a meaningful increase in the competitive constraints faced by GSK, it is in any case implausible that the value transfers were made for this purpose.¹⁹⁵⁵ Furthermore, in this regard, the CMA also observes that the model constructed by GSK assumes market conditions that have little resemblance to the market conditions observed in this case or the Agreements entered into.¹⁹⁵⁶

- D.40 The CMA also observes that in a scenario in which any value transfers were permissible, contrary to GSK's submission, the profit maximising outcome within GSK's model would be the payment of value transfers in return for the potential competitor's agreement not to enter the market independently, and not the royalty rate agreement that it refers to. In that scenario, the joint profit maximising outcome in GSK's model is for the parties to select an entry date agreement and set the entry date as late as possible, that is, to the date of patent expiry, or to set a royalty rate at a high enough level to obtain the same outcome, with the generic supplier receiving value transfers to induce it to do so.

¹⁹⁵⁵ The CMA notes that in the model submitted by GSK, the value transfers provided to the generic company in order to incentivise it to enter into an agreement which increases consumer welfare make up only some proportion of the profits which the generic company makes, and the value transfer is used to incentivise the potential competitor to accept an agreement in which its returns are derived entirely from competing with the incumbent, when compared to one in which the majority of its returns are derived from competing with the incumbent but in which they are 'topped up' using a value transfer.

¹⁹⁵⁶ For example, in GSK's model, market volumes are able to increase in response to price changes, which is inconsistent with the operation of the pharmaceutical sector whereby GPs are relatively insensitive to price when prescribing and as such overall market volumes are relatively unresponsive to price changes.

B. Representations regarding potential competition

i) *Representations regarding the existence of potential competition in the context of patents and litigation*

a) *Representations regarding patents as a barrier to entry*

- D.41 The SO Addressees submitted that there can be no potential competition when there is a presumptively valid patent.¹⁹⁵⁷ In support of this submission, they referred to the cases of *E.ON Ruhrgas*¹⁹⁵⁸ and *EDP*¹⁹⁵⁹ as well as to the notion of a ‘one-way blocking position’ mentioned in the 2004 TTBE Guidelines.¹⁹⁶⁰
- D.42 The CMA rejects these submissions. For the reasons set out below, the CMA considers that a patent is neither an absolute nor an insurmountable barrier to entry and does not necessarily preclude potential competition.¹⁹⁶¹
- D.43 First, real-life experience shows that generic suppliers can and do enter pharmaceutical markets (including the paroxetine market) even though an originator undertaking may own one or more patents.¹⁹⁶² Such entry is often referred to as entry ‘at risk’ of litigation and is a common feature of the generic pharmaceutical market. Should a generic supplier enter the market ‘at risk’, the patent holder may challenge that entry by bringing patent infringement proceedings. The patent holder may also be able to prevent the generic company from entering the market before trial, by bringing injunction proceedings. There is, however, no guarantee that a patent holder will do either of these things. Its choice will depend on commercial considerations

¹⁹⁵⁷ GSK SO Written Response (document 2755), paragraphs 1.278(b), 6.18 and 7.21. GUK SO Written Response (document 2752), paragraph 4.14. Actavis SO Written Response (document 2754), paragraphs 7.7–7.11. Merck SO Written Response (document 2764), paragraphs 4.42–4.62. Xellia-Zoetis SO Written Response (document 2767), paragraph 152.

¹⁹⁵⁸ Judgment of 29 June 2012, *E.ON Ruhrgas v Commission*, T-360/09, ECR, EU:T:2012:332. GSK SO Written Response (document 2755), paragraphs 1.72–1.79 and 1.93; Merck SO Written Response (document 2764), paragraphs 3.20–3.22, 3.53–3.57 and 3.52; GUK SO Written Response (document 2752), paragraphs 4.13–4.18; Actavis SO Written Response (document 2754), paragraphs 7.1–7.12, Xellia-Zoetis SO Written Response (document 2767), paragraphs 243–255.

¹⁹⁵⁹ Judgment of 21 September 2005, *EDP v Commission*, T-87/05, ECR, EU:T:2005:333.

¹⁹⁶⁰ GSK SO Written Response (document 2755), paragraphs 1.82–1.89; Teva SO Written Response (document 2750), paragraphs 58–64; GUK SO Written Response (document 2752), paragraphs 4.13–4.18; Merck SO Written Response (document 2764), paragraphs 3.12–3.46. Commission Notice: Guidelines on the application of Article 81 of the EC Treaty (now Article 101 TFEU) to technology transfer agreements, OJ C 101/2, 27.4.2004 (‘2004 TTBE Guidelines’) state, at paragraph 32, that a ‘one-way blocking position exists when a technology [right] cannot be exploited without infringing upon another technology [right]’. Further, the related definition of potential competitor includes the phrase ‘without infringing the intellectual property rights of the other party’ (2004 TTBE Guidelines, paragraph 29).

¹⁹⁶¹ Further, the CMA notes that 2004 TTBE Guidelines not in force at the time the Agreements were entered into.

¹⁹⁶² There is no requirement, for example, in deciding whether to grant an MA to a generic supplier, for the MHRA to consider the patent status of the relevant product.

such as the costs of litigation, the prospects of success, and the extent of any sales and profitability decreases resulting from such market entry.

- D.44 Second, it is an integral part of the patent system that the validity of patents can be (and often are) challenged.¹⁹⁶³ Generic companies can challenge the validity of patents in a stand-alone action for revocation or as part of a counterclaim to an infringement action brought by an originator. In the case of paroxetine, for example, the validity of GSK's Anhydrate Patent was challenged by BASF in July 2001¹⁹⁶⁴ by the Apotex Parties in October 2002;¹⁹⁶⁵ and by GUK in its counterclaims to the infringement action brought by GSK.¹⁹⁶⁶ The fact that it is possible to challenge the validity of a patent, and that such challenges regularly result in invalidation of all or parts of a patent,¹⁹⁶⁷ clearly indicates that a patent is not an absolute barrier to entry.
- D.45 Third, the presumptive validity of patents does not, or not necessarily, create a blocking position. A generic undertaking is entitled to challenge the validity of any patent invoked against it. Even if a patent is held to be valid, it is possible for a generic product to be found to be non-infringing, such that the generic is able to enter the market. Whilst the burden of proof in patent validity proceedings rests on the party claiming invalidity, in the case of infringement proceedings the burden of proof is on the originator undertaking to prove that the generic product infringes the relevant patent.
- D.46 Fourth, the nature of the paroxetine market in the UK at the time of the Agreements is fundamentally different to the nature of the markets in the cases cited by the SO Addressees. There is a distinction between the national legislation in *E.ON Ruhrgas* and *EDP*, which precluded entry and were not readily challengeable, and GSK's patents in this case, which were challengeable and were not insurmountable barriers to entry.¹⁹⁶⁸

¹⁹⁶³ See for example the CJ's statements in *Windsurfing International v Commission*: "...the specific subject-matter of [a] patent...cannot be interpreted as affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error." – see Judgment in *Windsurfing International v Commission*, 193/83, EU:C:1986:75, paragraph 92.

¹⁹⁶⁴ *BASF AG v SmithKline Beecham Plc* [2002] EWHC 1373 (Ch).

¹⁹⁶⁵ *SmithKline Beecham Plc and Others v Apotex Europe Ltd and Others* [2002] EWHC 2556 (Ch).

¹⁹⁶⁶ *SmithKline Beecham Plc v Generics (UK) Ltd*, 23 October 2001, (2002) 25(1) I.P.D. 25005.

¹⁹⁶⁷ For instance, in the period from 2000 to 2007, the European Commission's Pharmaceutical Sector Inquiry of July 2009 found that, across the EU, although the originator companies initiated the majority of the relevant patent litigation against generic companies, those generic companies won 62% of the cases in which the courts rendered final judgments. In addition, generic companies won nearly three quarters of all patent cases which they initiated (71%). See Sector Inquiry Final Report, section 2.2.2.6. - Outcome of the Main Action on the Merits, paragraphs 621–624, page 224.

¹⁹⁶⁸ Judgment of 21 September 2005, *EDP v Commission*, T-87/05, ECR,EU:T:2005:333, paragraphs 114–116.

D.47 Fifth, even when a presumptively valid patent exists, there are several routes to market available for a generic supplier. This can be particularly apparent where a primary patent has expired and what remains are secondary or process patents relating to various production processes and formulations, as was the case in respect of paroxetine. The situation may be marked by reciprocal uncertainty – the originator lacking certainty that the remaining patent protection will be sufficient to keep generics legally at bay; generic suppliers running the risk that they may fail to circumvent valid patents, and/or fail in infringement or invalidity litigation and incur the risk of having to pay damages.

D.48 Whilst potential competition may therefore emerge several years before the expiry of a compound or ‘primary’ patent,¹⁹⁶⁹ the scope for potential competition is even greater once the compound patent has expired, given the number of routes to market which then exist. In the case of paroxetine, a number of options existed for a generic supplier that wished to launch a generic paroxetine product, for example:

- Launch ‘at risk’ and face a patent challenge from GSK.
- Make efforts to ‘clear the way’ with GSK, before entering the market.
- Request a declaration of non-infringement from the relevant Court.
- Claim patent invalidity before the relevant Courts.
- Oppose the patent before the IPO or EPO with a request to revoke or narrow the patent.
- Change the process by which the product (either the API or the compound) is manufactured to eliminate or reduce the risk of infringement.¹⁹⁷⁰
- Switch to another API supplier to eliminate or reduce the risk of patent infringement.

D.49 Given the range of options that were open to the Generic Companies, it is clear that the potential for generic competition was not eliminated by the existence of GSK’s secondary patents. Provided that, from an objective examination of the facts, there were ‘real concrete possibilities’ for a generic

¹⁹⁶⁹ See D.64.

¹⁹⁷⁰ While a change in the manufacturing process may engender some extra regulatory delays, this may be a viable alternative route to the market.

supplier to enter the market and compete with GSK, the existence of GSK's secondary patents would not, on its own, preclude a finding of potential competition.

D.50 Sixth, the CMA notes that the SO Addressees' submissions effectively ignore the competitive constraints that the presence of potential generic entrants evidently creates. Indeed, in this case, it was GSK's expectation that their entry would cause substantial price and profit declines that motivated its decision to enter into the Agreements and to make the value transfers to the Generic Companies. Furthermore, the CMA notes that were it to accept the submissions that a generic supplier cannot be a potential competitor until a court rules that a patent is invalid or not infringed the following would result:

- Should a patent holder decide not to challenge generic entry, the generic entrant would, under the SO Addressees' reasoning, still not constitute a potential competitor, despite being an actual competitor on the market;¹⁹⁷¹ and
- Patent settlement agreements of this nature would effectively be deprived of competition law scrutiny. This would run counter to the judgment in *Bayer v Süllhöfer*,¹⁹⁷² in which the CJ held that '[i]n its prohibition of certain "agreements" between undertakings, Article [101(1) of the TFEU] makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind.'

b) Relevance of uncertainty of litigation

D.51 A number of the SO Addressees stated that the outcome of any litigation was uncertain, and that they may not have ultimately won against GSK, such that the Generic Companies cannot have been potential competitors.¹⁹⁷³

D.52 The CMA does not dispute the fact that there was uncertainty regarding the outcome of the litigation. In this context, the fact that there was genuine uncertainty as to the outcome of litigation did not remove the threat posed by the generic undertakings – rather, this uncertainty was one of the factors contributing to the Generic Companies' decisions to invest in the development

¹⁹⁷¹ Indeed, on the basis that there were concerns that the GUK and Alphantra products may infringe the hemihydrate and/or dry tableting patents, on GSK's analysis both companies would not have constituted potential competitors even after their market entry in March and August 2004, when they were actually competing with GSK, as there remained apparently plausible claims that both products infringed presumptively valid patents.

¹⁹⁷² Judgment in *Bayer v Süllhöfer*, 65/86, EU:C:1988:448, paragraph 15.

¹⁹⁷³ Teva SO Written Response (document 2750), paragraphs 69–73, Merck SO Written Response (document 2764), paragraphs 3.68 and 3.85, Actavis SO Written Response (document 2754) paragraphs 3.11–3.26, GUK SO Written Response (document 2752) paragraphs 3.3–3.10, Xellia-Zoetis SO Written Response (document 2767), paragraphs 97–188.

of generic paroxetine and the competitive pressure exerted on GSK. This conclusion is supported by GSK's actions, in that it was willing to transfer significant value to the Generic Companies in order to remove that uncertainty by way of the Agreements.

D.53 If the SO Addressees' submissions were accepted, this would mean that wherever there is uncertainty about whether an undertaking would in fact overcome a barrier to entry, potential competition would be excluded. However, the analysis of potential competition by definition looks at potential developments, not at the certainty that entry would in fact occur.

c) *Representations that a generic company must clear the way or have a manifestly non-infringing product to be a potential competitor*

D.54 GSK stated that, given the uncertainty of the litigation outcomes, in order to be considered a potential competitor a generic supplier must first clear the way, or have a manifestly non-infringing product.¹⁹⁷⁴

D.55 As set out in paragraph D.48, even in the face of a presumptively valid patent, there are several routes to market open to a generic supplier, such that the potential for entry still exists. Clearing the way may result in a party becoming an actual competitor, but it cannot be said that the potential for entry does not exist until such time as this has happened.

D.56 The recent case of *Cephalon Inc v Orchid Europe Limited* has made clear that there was never any legal obligation¹⁹⁷⁵ on generic suppliers to 'clear the way'; it was simply one of a number of factors to be taken into account in considering the balance of convenience.¹⁹⁷⁶ Whether a party has 'cleared the way' would have no bearing on the final outcome in validity or infringement proceedings.

D.57 GSK's submission that a party must have a '*manifestly non infringing product*' in order to be a potential competitor has no legal basis. As set out above, a generic supplier does not have to prove that it is non-infringing in order to enter the market. The burden of proof is on the patent holder to demonstrate that a product infringes the claims of one of its patents.

¹⁹⁷⁴ GSK SO Written Response (document 2755), paragraphs 1.46, 1.87, 1.96–1.101; 6.3–6.64; 7.3–7.56; Actavis SO Written Response (document 2754), paragraphs 3.2, 3.7–3.10.

¹⁹⁷⁵ As a matter of domestic civil procedure and patent law.

¹⁹⁷⁶ *Cephalon Inc v Orchid Europe Limited*, [2010] EWHC 2945 (Pat), paragraphs 50–51; see also paragraph 72.

d) Representations relating to the timing of potential entry

- D.58 A number of SO Addressees have stated that, in order to be a potential competitor, entry must be possible within a short period of time, often with reference to the time periods set out in Commission Guidelines.¹⁹⁷⁷ The SO Addressees also stated that the Court process which they would have to go through in order to enter the market would have taken too long for the Generic Companies to be considered potential competitors.¹⁹⁷⁸
- D.59 The CMA has addressed the timing of each Party's potential entry in paragraphs 6.49 to 6.51 (GUK), 6.67 to 6.69 (Alpharma) and B.4 to B.45 (IVAX). However, as a general point, the CMA notes that in *Visa*, the GC held that a finding of potential competition was not 'invalidated' by the fact that the Commission had provided no estimate of the time required for entry. The GC noted that, *'the essential factor is the need for the potential entry to take place with sufficient speed to form a constraint on market participants...'*¹⁹⁷⁹ The GC also held that the period mentioned in Commission Guidelines was *'illustrative only'*.¹⁹⁸⁰
- D.60 As to the SO Addressees' representations regarding delays arising from potential litigation,¹⁹⁸¹ the CMA's view is that these are not sufficient to prevent the Generic Companies being considered potential competitors.

¹⁹⁷⁷ For instance, the 2004 TTBE Guidelines state, at paragraph 29, that '[i]n order to constitute a realistic competitive constraint entry has to be likely to occur within a short period. Normally a period of one to two years is appropriate. However, in individual cases longer periods can be taken into account.' Commission Notice: Guidelines on Vertical Restraints, OJ C 130, 19.5.2010 states, at paragraph 27, that 'A company is treated as a potential competitor of another company if, absent the agreement, in case of a small but permanent increase in relative prices it is likely that this first company, within a short period of time normally not longer than one year, would undertake the necessary additional investments or other necessary switching costs to enter the relevant market on which the other company is active.'. The Horizontal Guidelines state, at paragraph 10, that 'A company is treated as a potential competitor of another company if, in the absence of the agreement, in case of a small but permanent increase in relative prices it is likely that the former, within a short period of time, would undertake the necessary additional investments or other necessary switching costs to enter the relevant market on which the latter is active. This assessment has to be based on realistic grounds, the mere theoretical possibility to enter a market is not sufficient [...]'. Footnote 6 explains that "What constitutes a 'short period of time' depends on the facts of the case at hand, its legal and economic context, and, in particular, on whether the company in question is a party to the agreement or a third party."

¹⁹⁷⁸ Teva SO Written Response (document 2750), paragraphs 60 and 69; GSK SO Written Response (document 2755), paragraph 7.51; GUK SO Written Response (document 2752), paragraph 4.11; Merck SO Written Response (document 2764), paragraphs 3.86–3.100; and Xellia-Zoetis SO Written Response (document 2767), paragraph 119.

¹⁹⁷⁹ Judgment of 14 April 2011, *Visa Europe v Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 189.

¹⁹⁸⁰ Judgment of 14 April 2011, *Visa Europe v Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 189. In this case the relevant guidelines were the Horizontal Guidelines, which stated at footnote 9 that the '*Guidelines on Vertical Restraints* [...] consider a period of maximum 1 year [...]. However, in individual cases longer time periods can be taken into account. The time period needed by companies already active on the market to adjust their capacities can be used as a yardstick to determine this period.'

¹⁹⁸¹ See, for example, Teva SO Written Response (document 2750), paragraphs 72–73.

- D.61 First, the CMA considers that the SO Addressees' representations overstate the chances that Generic Companies would be excluded from the market for the timeframes they suggest. For example, the SO Addressees overstate the chances that the Generic Company would necessarily remain enjoined following a first instance judgment in the Generic Company's favour and pending an appeal.¹⁹⁸² This point is considered further in paragraph D.72.
- D.62 Second, in view of the likely duration of the relevant court proceedings, the CMA does not consider the likely delays caused by litigation to be sufficiently long for the Generic Company not to exert competitive pressure on GSK. The GUK-GSK Agreement and Alpharma-GSK Agreement were signed shortly before trials which could have resulted in findings of invalidity or non-infringement. Given the likely length of a first instance trial was around 6 – 12 months¹⁹⁸³ and that there was no guarantee that an injunction/undertaking would remain in place throughout any appeal proceedings, there was a potential for entry to take place in a relatively short timeframe. GUK itself noted in the GUK Litigation that '[p]reparations for launch [were] at an advanced stage' and if no injunction was granted, it was 'in a position to sell the product very shortly thereafter'.¹⁹⁸⁴
- D.63 However, even in the event that there was a risk of a longer delay from litigation, including appeal proceedings, that does not mean that the Generic Companies did not exert competitive pressure on GSK and that they therefore did not constitute potential competitors. As the GC noted in *BaByliss*, '[t]he mere fact it takes longer than planned to enter the market does not mean that such entry will not take place, particularly since ... the cost and time necessary for entering a new product market may be considerable'.¹⁹⁸⁵ The potential for entry still existed, following the relevant litigation process. Indeed, at the time GSK entered into the Agreements with each of the Generic Companies, it is evident that it considered that there was a real risk that they would enter the market with a speed that was sufficient to justify entering into

¹⁹⁸² For example, GUK state that, even if GUK had won the first instance litigation, had GSK sought a further injunction pending appeal, GSK was 'likely' to have been successful (GUK SO Written Response (document 2752), paragraph 3.34); Actavis states that 'The Alpharma Undertaking would not have been lifted before the outcome of final litigation' (Actavis SO Written Response (document 2754), paragraphs 7.33–7.34); See also transcript of Xellia-Zoetis SSO Oral Hearing dated 10 December 2014 (document 3878), page 18 lines 11 to 19.

¹⁹⁸³ Consistent with the timeframe from the trial to the first instance judgment in *SmithKline Beecham Plc and Others v Apotex Europe Ltd and Others* [2003] EWHC 2939 (Ch).

¹⁹⁸⁴ [X]WS (document 0901), paragraph 16. See OFT SO paragraph 7.114, footnote 1001.

¹⁹⁸⁵ Judgment of 3 April 2003, *BaByliss SA v Commission*, T-114/02, ECR, EU:T:2003:100, paragraph 102. See also Judgment of 14 April 2011, *Visa Europe v Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 189, where the GC held that "...the essential factor is the need for the potential entry to take place with sufficient speed to form a constraint on market participants...".

those Agreements and to committing to make substantial value transfers to those companies.

- D.64 While delays may reflect the difficulty of entering in terms of cost, time and complexities in development, they do not necessarily call into question the ability to enter or indicate that there is no competitive pressure exercised. Rather, it may suggest that the time-frame over which competitive pressure may be exercised by a potential entrant is longer. Indeed, the CMA notes that in the pharmaceutical sector, potential competition in respect of originator medicines can emerge a number of years before relevant patents are due to expire.¹⁹⁸⁶
- D.65 In pharmaceutical markets, potential generic competitors can act to constrain an originator's expected returns in the relevant market, as the originator would be aware that, if such entry is successful, it is liable to result in significant declines in the prices and profits that they can sustain. For example, in this case, GSK would have been aware that, even if litigation proceedings were to continue for some years, any true generic entry prior to patent expiry would be expected to result in lower returns that GSK would otherwise have expected to realise over the remaining period of the Anhydrate Patent (which expired in January 2013) (see paragraphs 6.34 to 6.39 and B.61 to B.62). As noted further in paragraphs 6.56 to 6.60 (GUK), 6.75 to 6.78 (Alpharma) and B.46 to B.48 (IVAX), the fact that GSK was willing to make significant value transfers to the Generic Companies, despite the possible delay to independent entry that may arise from litigation proceedings, is a strong indication of the competitive pressure exerted by the Generic Companies.

e) *Representations on the relevance of the GUK Interim Injunction and the Alpharma Undertaking to the assessment of potential competition*

- D.66 The Parties submitted that the GUK Interim Injunction and Alpharma Undertaking constituted a complete bar to entry, such that GUK and Alpharma cannot be considered potential competitors.¹⁹⁸⁷ GSK, GUK and Merck

¹⁹⁸⁶ Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 108.

¹⁹⁸⁷ GSK SO Written Response (document 2755), paragraphs 1.86 and 7.10; GUK SO Written Response (document 2752), paragraph 4.12 and Merck SO Written Response (document 2764), paragraph 3.50; Merck SO Written Response (document 2764), paragraph 3.72–3.80; Actavis SO Written Response (document 2754), paragraph 7.13–7.18 and 7.33–7.41; Xellia-Zoetis SO Written Response (document 2767), paragraph 102 and 108.

submitted, by reference to the 2004 TTBE Guidelines, that an injunction is particularly convincing evidence that a '*one-way blocking position*' exists.¹⁹⁸⁸

- D.67 GUK submitted that the CMA has erred in assessing the GUK Interim Injunction as temporary, because the CMA has failed to establish that GUK would have pursued the GUK Litigation or indeed prevailed in the GUK Litigation.¹⁹⁸⁹ Actavis submitted that the CMA has erred in assessing the significance of the Alparma Undertaking, and specifically that there was no basis upon which to allege the Alparma Undertaking would have been lifted (as a result of Alparma being successful in the Alparma Litigation) or that Alparma would have entered the market in a sufficiently timely manner to be considered a potential competitor.¹⁹⁹⁰
- D.68 GSK, GUK and Merck submitted that, even if GUK had been successful at first instance, the GUK Interim Injunction may have remained in place pending an appeal by GSK and that this would prevent entry by GUK for a sufficient timeframe such that GUK should not be considered a potential competitor.¹⁹⁹¹ Actavis made similar representations with respect to the Alparma Litigation.¹⁹⁹²
- D.69 The CMA does not accept these submissions. Neither the GUK Interim Injunction nor the Alparma Undertaking created an insurmountable barrier to entry. As explained in more detail below: an interim injunction is, by definition, a temporary measure; and the grant of an interim injunction is not based on a determination of the merits of the case. These points are addressed further below.

An interim injunction is, by definition, a temporary measure

- D.70 The GUK Interim Injunction and the Alparma Undertaking were each, by definition, a temporary measure and no more than a holding position until the main proceedings have been decided.
- D.71 In this case, the GUK-GSK Agreement was signed the day before the substantive hearing was due to commence, and the Alparma-GSK Agreement was signed shortly before the trial was due to commence. The

¹⁹⁸⁸ Merck SO Written Response (document 2764), paragraph 3.13 and footnote 32; GSK SO Written Response (document 2755), paragraph 1.86; GUK SO Written Response (document 2752), paragraph 4.14.

¹⁹⁸⁹ GUK SO Written Response (document 2752), paragraphs 3.11–3.37. GSK SO Written Response (document 2755), paragraphs 7.10–7.11.

¹⁹⁹⁰ Actavis SO Written Response (document 2754), paragraph 7.17.

¹⁹⁹¹ GSK SO Written Response (document 2755), paragraph 1.86 and 1.99; Merck SO Written Response (document 2764), paragraph 3.79–3.80; GUK SO Written Response (document 2764), paragraphs 1.1–1.6 and 3.4–3.5.

¹⁹⁹² Actavis SO Written Response (document 2754), paragraph 7.34.

trials in the GUK Litigation and Alparma Litigation would have determined the case on its merits (and therefore determined whether the GUK Interim Injunction and Alparma Undertaking would remain in place or be lifted). All Parties have stressed how uncertain the outcome of the litigation was.

D.72 The CMA notes that:

- Whilst it may have been likely that GSK would appeal any first instance judgment in GUK's or Alparma's favour, this was not inevitable.
- Similarly, were GSK to appeal, there is no guarantee that an injunction or undertaking would have remained in place for the appeal period. This would depend on whether GSK sought to maintain the injunction/undertaking and, if so, where the balance of convenience lay at the relevant time.¹⁹⁹³ Following the first instance judgment in the *Apotex* case, for example, GSK decided not to seek to maintain an interim injunction while the appeal was pending.
- Furthermore, even if an interim injunction/undertaking had remained in place pending an appeal, this would not affect the inherently temporary nature of the injunction/undertaking or the fact that there was the potential for GUK or Alparma to enter the market independently following the appeal Court's judgment.

D.73 The potential for independent generic entry would therefore have remained. As set out in further detail in paragraph D.63, even in the event that there was a risk of a longer delay from litigation, including appeal proceedings, that does not mean that the Generic Companies did not exert competitive pressure on GSK and that they therefore did not constitute potential competitors. It should also be recalled that, in *Hitachi*, evidence showing that entry may have been

¹⁹⁹³ Note that the considerations in the balance of convenience pending an appeal may be different from those at first instance. For example, in *SmithKline Beecham v. Apotex*, on 8 December 2003 the judge considered the fact that the potential entry of other generics, following the first instance judgment in Apotex's favour, could deprive Apotex of a 'small and no doubt significant' first mover advantage. Pumfrey J stated in paragraph 17 that: 'However, the real problem in the present case is that if I am to ensure that justice is done to the defendants as well as to the claimants, I have to consider the position of third parties. The reason is the one that I outlined at the beginning of this judgment, which is that in this trade generic suppliers can move quickly. The fact that I have handed down a judgment invalidating the patent will no doubt in the fullness of time, which may be a short period, become known to those manufacturers. What, then, were I to grant an injunction now, is the position of Apotex if tomorrow or the day after other generic manufacturers enter the market with non-SKB supplied material, substantially undercutting SKB and thereby doing all the damage which SKB fear the entry of Apotex into the market will do, and at the same time depriving Apotex of what would otherwise have been a small and no doubt significant head start over those other manufacturers? I have found this an extremely difficult balance to strike.' *SmithKline Beecham v. Apotex* [2003] EWHC 3383 (Ch).

difficult, but not impossible, would not prevent a party from being considered a potential competitor.¹⁹⁹⁴

The grant of an interim injunction is not based on a determination of the merits of the case

D.74 When deciding whether to grant an interim injunction, the court must decide whether there is a *'serious question to be tried'*,¹⁹⁹⁵ which is not a determination of the merits of the case. If there is a serious question to be tried, the court must consider whether the *'balance of convenience'* lies in favour of an interim injunction at the time of the application.¹⁹⁹⁶ With regard to the GUK injunction hearing, for example, it is clear from the High Court's judgment that the judge came to no conclusion on the relative merits of the parties' cases:¹⁹⁹⁷

'I have come to the clear conclusion that I am quite unable to decide the relative strengths of the parties' contentions.

Take the issue of infringement. ... I cannot resolve it one way or the other.

...

As to the attack on validity, ... I really cannot decide one way or the other on the information I have. So I think this is a classic Cyanamid case.'

D.75 An interim injunction does not therefore remove (or even impact upon) the possibility that an undertaking will be able to launch its product after the determination of the main proceedings. This is equally applicable to the Alparma Undertaking.

D.76 It is also relevant that the GUK Interim Injunction and the Alparma Undertaking did not alter the period over which GUK or Alparma could generate returns from entering the market, and as such should not of itself materially alter the viability of entry for GUK or Alparma respectively. For example, although the GUK Interim Injunction and Alparma Undertaking prevented GUK and Alparma from entering until the conclusion of the GUK

¹⁹⁹⁴ Judgment of 12 July 2011, *Hitachi v Commission*, T-112/07, ECR, EU:T:2011:342, paragraphs 110–111.

¹⁹⁹⁵ *American Cyanamid Co (No 1) v Ethicon Ltd* [1975] UKHL 1.

¹⁹⁹⁶ *American Cyanamid Co (No 1) v Ethicon Ltd* [1975] UKHL 1.

¹⁹⁹⁷ *SmithKline Beecham v Generics UK Ltd* (2002) 25(1) I.P.D. 25005; Official Transcript; Ch D (Patents Ct); 23 October 2001.

Litigation and Alpharma Litigation respectively,¹⁹⁹⁸ GUK or Alpharma would have been able to claim for damages had they been successful before the Courts. The GUK Interim Injunction and Alpharma Undertaking also ensured that GUK and Alpharma would not face a potentially significant damages claim from GSK (in the event that they had entered the market prior to GSK succeeding in its litigation), such that the substantial potential losses associated with 'at risk' entry were avoided.

- D.77 The CMA has concluded that the existence of the GUK Interim Injunction and Alpharma Undertaking does not undermine a finding that GUK and Alpharma respectively were potential competitors to GSK. It is not necessary to demonstrate that GUK or Alpharma would have pursued the GUK Litigation or Alpharma Litigation to a final judgment, or that GUK or Alpharma were certain to win the GUK Litigation or Alpharma Litigation, in order to reach this conclusion. The Parties could, for example, have agreed to settle (on competitive terms) and to discharge the GUK Interim Injunction or Alpharma Undertaking as part of that settlement.¹⁹⁹⁹
- D.78 As to the 2004 TTBE Guidelines to which the Parties refer, the CMA notes that: (i) technology was not transferred by the Agreements in this case; and (ii) in any event, the relevant sections of the 2004 TTBE Guidelines relate to final injunctions, not to interim injunctions granted on the basis of the balance of convenience such as was the case here.²⁰⁰⁰

f) Representations on risk aversion

Alpharma's claimed strategy of relying on BASF to clear the way

- D.79 Actavis, Xellia-Zoetis and GSK submitted that Alpharma expected the BASF Litigation to result in the Anhydrate Patent being invalidated and that its strategy was based on BASF clearing the way. Following the first instance judgment in the BASF Litigation, it was submitted that Alpharma could no longer rely on that strategy, and that the issue changed from validity to

¹⁹⁹⁸ Or whilst the GUK Interim Injunction or Alpharma Undertaking were still in place (see paragraph 0).

¹⁹⁹⁹ It is also relevant to note that the GUK Interim Injunction and Alpharma Undertaking were granted or made in favour of a party to litigation, in this case the patentee. Therefore, the patentee (GSK) had the power to effect the variation, or even the lifting, of the GUK Interim Injunction and Alpharma Undertaking.

²⁰⁰⁰ It is also relevant to note that the revised (and current) version of the 2004 TTBE Guidelines (namely, Commission Communication: Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, OJ C 89/3, 28.3.2014, does not refer specifically to injunctions in its discussion of blocking positions.

infringement.²⁰⁰¹ Actavis submitted that it did not intend to engage in patent litigation.²⁰⁰² Actavis submitted that, following the GUK Litigation, the obligation was on the generic company to clear the way, and that this had not been achieved by the BASF Litigation.²⁰⁰³

- D.80 GSK stated that Alparma would not have been aware of the degree of likelihood of being injuncted when it first began preparations, and that the Alparma Undertaking may have influenced its risk appetite.²⁰⁰⁴ It was submitted that Alparma was not prepared to launch until the risks of potential patent infringement were significantly reduced (and therefore, even if the Alparma Undertaking had been removed, it did not have the ability to enter the market).²⁰⁰⁵ Xellia-Zoetis submitted that Alparma was a risk averse company, having testified in court that it had no intent to infringe upon valid intellectual property, which was subject to the Alparma Undertaking.²⁰⁰⁶ Xellia-Zoetis referred to an Alparma internal document which referred to the potential financial ramifications (i.e. damages) associated with launching 'at risk' and concerns regarding the Dry Tableting Patent.²⁰⁰⁷
- D.81 First, the CMA notes that a finding of potential competition does not depend on the willingness of a party to enter the market 'at risk'. In the case of paroxetine, a number of options existed for a generic supplier that wished to launch a generic paroxetine product (see paragraph D.48). Whilst entry 'at risk' was one option for Alparma, it could also have entered the market following determination of the Alparma Litigation, if successful.
- D.82 Second, while the CMA accepts that the outcome of the BASF Litigation was relevant to (and potentially beneficial for) Alparma's preparations to launch its paroxetine product (see paragraph 3.319), the outcome of that litigation did not, however, determine its ability to enter the market independently. That fact emerges clearly from Alparma's actions after BASF had failed to 'clear the way' in July 2002. Later that month, Alparma [ApS]'s patent attorney remained of the view that the Anhydrate Patent was invalid (see paragraph 3.334). Alparma proceeded with internal analysis of anticipated sales and profits for its paroxetine (see, for example, paragraph 3.349). Even after GSK's modified claim 11 of the Anhydrate Patent, Alparma continued to fight

²⁰⁰¹ Actavis SO Written Response (document 2754), paragraphs 2.7–2.9 and 7.24; GSK SO Written Response (2755), paragraphs 7.13 and 7.101(c); Xellia-Zoetis SO Written Response (document 2767), paragraphs 50–51 and 172.

²⁰⁰² Actavis SO Written Response (document 2754), paragraph 2.9 and 7.24–7.27. Slides for Actavis SO Oral Hearing dated 23 October 2013 (document 2936), slide 7.

²⁰⁰³ Actavis SO Written Response (document 2754), paragraph 3.8.

²⁰⁰⁴ GSK SO Written Response (document 2755), paragraph 7.22.

²⁰⁰⁵ Actavis SO Written Response (document 2754), paragraphs 7.35–7.45.

²⁰⁰⁶ Xellia-Zoetis SO Written Response (document 2767), paragraph 102.

²⁰⁰⁷ Xellia-Zoetis SO Written Response (document 2767), paragraphs 103–104.

the Alparma Litigation and maintained its position that it had not infringed (see paragraphs 3.333 to 3.338 and 3.347). GSK served its statement of case in November 2002, but this did not alter Alparma's stance (see paragraphs 3.353 to 3.354).

- D.83 Third, once the Alparma Undertaking had been given, it is clear that Alparma's ability to enter following a successful first instance judgment remained. The CMA notes that, following the Alparma Undertaking, Alparma continued to contest the Alparma Litigation for over three months and until it entered into the Alparma-GSK Agreement (see paragraph 6.74). Furthermore, even if it was accepted that Alparma's entry would not have occurred until following an appeal, or even following generic entry by another party, and on a later timescale, the CMA does not consider that entry on this basis would preclude a finding that Alparma was a potential competitor (see paragraphs D.58 to D.65-D.65).
- D.84 Fourth, the CMA notes that the claimed implications of the GUK Litigation relate to entry 'at risk' and not more generally to Alparma's potential to enter the market.
- D.85 Fifth, submissions that Alparma testified in court that it had no intent to infringe are irrelevant to the CMA's conclusions because Alparma did not accept that the Anhydrate Patent was valid and, moreover, submitted that its product did not infringe. Further, whilst the internal document referred to by Xellia-Zoetis shows Alparma considering the financial implications of launch, the CMA notes that the document concludes with '*the present summary indicates we may launch by now...*' (see paragraph 3.347).
- D.86 Sixth, the CMA observes that Alparma's decision on entering 'at risk' would in practice have been influenced by the actions of other generic suppliers. This is because a decision in favour of Alparma in the first instance in the Alparma Litigation would have had an impact on other suppliers' strategies, and the potential entry of other suppliers would have had a significant impact on Alparma's perception of the risk and returns associated with entering 'at risk' or staying out of the market while other generic suppliers gained market share. For example, following the Apotex first instance judgment²⁰⁰⁸ in relation to the Anhydrate Patent, a number of parties, including Alparma, entered the market 'at risk' of further litigation or an appeal from GSK. These parties will

²⁰⁰⁸ *SmithKline Beecham Plc and others v Apotex Europe Ltd and others* [2003] EWHC 2939.

have observed that their exposure to damages was more limited as other entrants also entered the market.²⁰⁰⁹

GUK's representation that it was not prepared to launch 'at risk'

- D.87 Similarly, GUK submitted that it was not prepared to launch its product 'at risk' (even if the GUK Interim Injunction had been lifted before the end of the proceedings).²⁰¹⁰
- D.88 First, and as set out above, the CMA notes that a finding of potential competition does not depend on the willingness of a party to enter the market 'at risk' (see paragraph D.48).
- D.89 Second, the evidence demonstrates that there was uncertainty as to whether GUK would have ultimately chosen not to enter 'at risk' after a judgment at first instance in GUK's favour (and before any appeal by GSK):
- As GUK itself notes, views and risk appetite varied over time.²⁰¹¹ GUK had been willing to enter 'at risk' prior to being enjoined, when it had no legal judgments in its favour. The CMA therefore considers it possible that GUK would have taken the decision to enter following a positive first instance judgment.
 - In relation to the documents on which GUK relies to support its assertion that it would not have entered 'at risk' (in which [the Chief Executive of Merck Generics Group] sets out a position that he would not, or would not have, launched 'at risk'), these need to be considered in their proper context. The emails consider how best to approach negotiations with Sumika regarding the compensation GUK should pay to Sumika as a result of the fact that GUK no longer intended to purchase Sumika's

²⁰⁰⁹ Actavis acknowledged this in the context of Alpharma's entry following the Apotex Litigation: '*...it was only after the judgment in the Apotex proceedings in December 2003 that Alpharma's risk position changed because:...(d) Apotex had launched at risk pending the appeal; and (e) accordingly, the fact there was at least one other independent generic product on the market meant that Alpharma's exposure to damages had significantly diminished.*' Letter from [external law firm] to the OFT dated 12 November 2013 (document 3087), paragraph 2.4 (emphasis as original).

²⁰¹⁰ GUK SO Written Response (document 2752), paragraph 3.38 and paragraphs 3.42–3.46. See also GSK SO Written Response (document 2755), paragraph 6.39. Merck also submitted that '*...none of the evidence referred to in paragraphs 2.313 to 2.320 of the SO could even remotely support a conclusion that GUK was prepared to enter at risk... [i]f anything, therefore, the evidence cited by the OFT would suggest the opposite conclusion – that GUK very clearly concluded that entry was only possible following success in the litigation.*' Merck SO Written Response (document 2764), paragraph 3.49.

²⁰¹¹ GUK SO Written Response (document 2752), paragraph 3.25: '*The evolving nature of GUK's risk assessment was confirmed by both [Merck's Head of Patents and Raw Material Support Group] and [the Chief Executive of Merck Generics Group] to the OFT.*'

API.²⁰¹² In considering the level of payment that GUK should make, [the Chief Executive of Merck Generics Group] states that GUK need to determine a *'notional launch date'*. It is in this context that [the Chief Executive of Merck Generics Group] states *'and this one I would not launch at risk'*. Clearly, the later GUK's *'notional launch date'* the less compensation that GUK would be required to pay to Sumika.

Understandably, therefore, in that negotiation, GUK would have wanted to present a position to Sumika that best benefited GUK, i.e. suggesting that the period over which GUK would have been likely to purchase API would have been shorter, such that the period for which GUK needed to compensate Sumika was shorter.²⁰¹³ The CMA considers that these documents cannot be relied upon to show that GUK would not have considered entering the market following a successful first instance judgment in the GUK Litigation.

- In this regard, the CMA observes that GUK's decision on entering 'at risk' would in practice have been influenced by the actions of other generic suppliers. This is because, a decision in favour of GUK would have had an impact on other entrants' strategies, and the potential entry of other suppliers would have had a significant impact on GUK's perception of the risk and returns associated with entering 'at risk' or staying off the market while other generic suppliers gained market share (see paragraph D.86).

g) *Relevance of GSK's views and actions to the potential competitor analysis*

D.90 A number of the SO Addressees stated that GSK's views and actions are not relevant to the assessment of whether the Generic Companies were potential competitors.²⁰¹⁴ It was submitted that GSK's beliefs are of limited probative value as they were not based on a full understanding of the Generic Companies' positions²⁰¹⁵ and that it was in the Generic Companies' interest to create the impression that they had a commercially viable product.²⁰¹⁶

²⁰¹² In this regard, the CMA notes that [the Chief Executive of Merck Generics Group's] comments were provided in the context of GUK needing *'to think about Sumika'* and were prefaced as *'the following to consider with them [Sumika]'*. Email chain between [the Chief Executive of Merck Generics Group], [GUK's Commercial Director] and others dated 12 April 2002 (document 1040).

²⁰¹³ This is further supported by [the Chief Executive of Merck Generics Group's] statement in the same email, in which he explained that *'[...] Sumika need to understand this very clearly. If we [GUK] did not prevail, then we would not be buyoing [sic] any API in the short term.'* Email from [the Chief Executive of Merck Generics Group] to [GUK's General Manager] dated 12 March 2002 (document 0990).

²⁰¹⁴ GUK SO Written Response (document 2752), paragraph 4.19. Teva SO Written Response (document 2750), paragraph 93.

²⁰¹⁵ Teva SO Written Response (document 2750), paragraph 77 and paragraphs 93–94.

²⁰¹⁶ Teva SO Written Response (document 2750), paragraph 45.

- D.91 The CMA considers that it is the actions of the market incumbent that are relevant to the assessment of whether potential competition existed. If the undertaking perceives the competitive threat from generic undertakings to be credible, and its response indicates that the generic undertaking is exerting competitive pressure on its behaviour on the market, this is relevant to the analysis of potential competition.²⁰¹⁷
- D.92 The CMA accepts that bluff may play a certain role in negotiations, in that parties may aim to present their situations in the best possible light. However, in this case, given the routes to market open to each of the Generic Companies, claims that the Generic Companies were simply ‘bluffing’ are not credible in light of the evidence. GSK had significant expertise and experience on which to base its judgment and would be well aware of the potential for bluff. In this case, GSK had considerable information on which to base its assessments, for example, GSK was aware: (i) that IVAX had acquired an MA in Ireland in September 2001;²⁰¹⁸ (ii) that GUK was imminently due to be granted an MA in the UK in September 2001 prior to its application for an injunction;²⁰¹⁹ (iii) that GUK belonged to a corporate group that had launched generic paroxetine in Australia and had acquired an MA in Denmark;²⁰²⁰ and (iv) that Alpharma had been granted an MA in the UK and was taking customer orders for paroxetine.²⁰²¹ GSK was not likely to part with such substantial sums lightly, or without giving serious consideration to the ability of the Generic Companies to enter the market.
- D.93 The fact that GSK was willing to make such substantial value transfers is a strong indication that GSK perceived the Generic Companies as a credible threat to the returns that it would otherwise have expected to make over the life time of its remaining paroxetine patents, and that the Generic Companies exerted competitive pressure on GSK.

²⁰¹⁷ See paragraph 6.16.

²⁰¹⁸ See paragraph 3.157.

²⁰¹⁹ See [REDACTED]WS1 (GUK), paragraph 5.2. See also the Witness Statement of [GSK's Patent Attorney] dated 27 September 2001 (document 0162), paragraphs 9–11. GUK was subsequently granted its MA on 29 October 2001 (see paragraph 3.254).

²⁰²⁰ See [REDACTED]WS1 (GUK), paragraph 5.2. See also the Witness Statement of [GSK's Patent Attorney] dated 27 September 2001 (document 0162), paragraphs 9–11.

²⁰²¹ See paragraphs 3.325.

ANNEX E: GUK AND GSK'S INTERNAL ASSESSMENTS ON THEIR PROSPECTS IN THE GUK LITIGATION AND OF GUK ENTERING THE UK PAROXETINE MARKET INDEPENDENTLY OF GSK

- E.1 As set out at 6.61 to 6.64, the CMA considers that the evidence set out in this Decision (see paragraphs 6.47 to 6.60) is sufficient to show that GUK constituted a potential competitor to GSK in the UK paroxetine market at the time the GUK-GSK Agreement was entered into.
- E.2 However, the Parties submitted that internal documents and witness evidence demonstrate that GUK was not confident that it would prevail in the GUK Litigation and that there was no realistic possibility of GUK entering the UK paroxetine market independently of GSK, such that GUK cannot therefore be considered a potential competitor of GSK. The CMA has therefore examined the internal documents of GUK and GSK, in order to assess their views on the prospects of GUK entering the UK paroxetine market independently of GSK.
- E.3 As set out below, the Parties' internal documents are consistent with the CMA's finding that GUK was a potential competitor to GSK at the time the GUK-GSK Agreement was entered into. They demonstrate that there was genuine uncertainty on both sides as to their prospects in the GUK Litigation and of GUK entering the UK paroxetine market independently of GSK at the time that the GUK-GSK Agreement was entered into. The contemporaneous evidence indicates that GUK was not ready to walk away from the GUK Litigation, and would not have been willing to abandon its efforts to enter the market independently, without sufficient compensation.

A. GUK's documents

i) Internal documents prior to the GUK Interim Injunction

- E.4 Before the GUK Interim Injunction was granted (on 23 October 2001), views expressed internally within GUK and in the GUK Litigation indicated that GUK considered that its generic paroxetine product did not infringe relevant patent claims in GSK's paroxetine patents or that GSK's patent claims were not valid. This evidence supports the CMA's case that GUK was prepared to enter the market independently of GSK and to defend patent litigation with GSK (see paragraphs 6.47 to 6.60). For example:

- In an internal GUK email on 23 April 2001, [Merck's Head of Patents and Raw Material Support Group] explained that '*We do not believe that we infringe valid patents but litigation is likely*'.²⁰²²
- In an internal GUK email on 29 May 2001, [the Chief Executive of Merck Generics Group] wrote that '*I have taken the decision to proceed with launch in Australia and Europe - working on the basis that **GSK has an invalid patent and we do not infringe***' (emphasis added).²⁰²³
- In the context of discussing a possible settlement between GSK and Alphapharm, [the Chief Executive of Merck Generics Group] explained that GSK's offer to GUK '*was simply an offer to license GUK to give a reasonable returnbut not good enough for us to avoid the patent risks and launch*'.²⁰²⁴ [The Chief Executive of Merck Generics Group's] view that GSK's offer was '*not good enough*' for GUK not to enter the UK paroxetine market independently of GSK ('*launch*'), indicates that GUK's view at that time was that such a '*launch*' was expected, notwithstanding the 'patent risks', and that it would only not do so if a 'good enough' offer was provided by GSK.
- In his witness statement in the GUK Litigation, [GUK's General Manager] said that GSK's decision to enter into a supply agreement with IVAX a full five years before patent expiry was, in his experience, highly unusual and was most likely to be explained by GSK's view that generic suppliers would be able to bring to market a product which did not infringe valid claims in GSK's patents:²⁰²⁵

*'In my experience of the generics market, **no pharmaceutical company has ever attempted** to join forces with a generics company to supply a version of its product 5 years prior to the [Hemihydrate] patent on the branded product expiring. Yet that is precisely the position here, which begs the question why is SB doing this? There are only two possible reasons that I can think of. **The first and most likely is that it is a reflection of SB's views on the strength of its anhydrate patent**, which was granted as recent as 1997. That is to say, the reason that SB is going to start selling generic paroxetine is*

²⁰²² Email from [Merck's Head of Patents and Raw Material Support Group] to [a GUK-Merck Senior Registration Officer] and others dated 23 April 2001 (document 0843).

²⁰²³ Email from [the Chief Executive of Merck Generics Group] to [Merck's Chairman of the Executive Board] dated 29 May 2001 (document 0850).

²⁰²⁴ Email chain between [the Chief Executive of Merck Generics Group] and [the Head of Merck Operation in Australia] dated 27 July 2001 (document 0859).

²⁰²⁵ [redacted]WS (document 0901), paragraph 37.

that it can see that generic competitors will shortly be entering the market in any event, either because the anhydrate patent is invalid or because the competitors have a non-infringing product. The only other possible reason I can think of is the impending genericisation of Cipramil [...]' (emphasis added).²⁰²⁶

ii) Internal documents following the GUK Interim Injunction

E.5 In its representations GUK submitted that the GUK Interim Injunction changed its perception of the strength of its case, such that it was more risk averse following the granting of the GUK Interim Injunction. GUK submitted that, whatever views were expressed within GUK before the GUK Interim Injunction (or in its aftermath), these no longer represented GUK's own internal assessment of success at the time of the settlement.²⁰²⁷

E.6 GUK made reference to [the Chief Executive of Merck Generics Group] and [Merck's Head of Patents and Raw Material Support Group's] witness interviews with the OFT. For example, GUK highlighted that:

- [Merck's Head of Patents and Raw Material Support Group] stated that the GUK Interim Injunction came as a big shock:

'it was a landmark injunction. There'd never been an injunction in the United Kingdom for the previous ten years. It was the first pharmaceutical injunction I think that had happened. I did not expect to be injuncted'.²⁰²⁸

- [The Chief Executive of Merck Generics Group] confirmed that the GUK Interim Injunction impacted on his risk assessment:

'The minute you get an injunction it does sort of make you think, hold on a second, maybe we don't have such a strong case. It probably did, it probably did have some effect on it (...) when we got the injunction. The whole litigation process, as I've said before, is a fragile process. This would have been ... although this wasn't directly involved in that, it was part of the whole and so it's ... so an injunction definitely would

²⁰²⁶ Additionally, in an interview with the CMA [Merck's Head of Patents and Raw Material Support Group] explained '*... if an innovator is willing to settle then they must have to a certain extent a feeling ... as much as we had, you know, not necessarily a hundred percent of winning, they would have the same viewpoint, they may not have a hundred percent chance of winning, so there's a certain amount of 'leverage', so they must feel as insecure as we feel insecure, so having got to that position where there's an insecurity on the other side, let's lever it for as much as possible*', [REDACTED]1 (document 2330), pages 41–42.

²⁰²⁷ GUK SO Written Response (document 2752), paragraphs 3.24–3.27

²⁰²⁸ [REDACTED]1 (document 2330), pages 28–29.

*have had a negative consequence and made us ... made me more risk averse.*²⁰²⁹

- [The Chief Executive of Merck Generics Group] recorded his concerns in an email to [GUK's General Manager] on 12 March 2002, shortly prior to entering into the GUK-GSK Agreement, stating: *'the only reason we are contemplating a distribution agreement with GSK is because there is a real chance we may not prevail in the courts'*.²⁰³⁰
- Similarly, shortly after entering into the GUK-GSK Agreement, in an email on 12 April 2002, [the Chief Executive of Merck Generics Group] stated the following as a reason for GUK's decision to enter into the GUK-GSK Agreement: *'We were injuncted - and may never have prevailed i.e. there was a risk that we might never have launched in the UK [hence the settlement]'*.²⁰³¹

E.7 The CMA refers to paragraphs 3.269 to 3.279 in relation to the GUK Interim Injunction. Further, the CMA observes that:

- Even if the GUK Interim Injunction may have made GUK more cautious than it was earlier in the GUK Litigation, the documents and witness evidence simply reflect the fact that GUK may have been less bullish than it was previously about its chances of success. The documentary evidence does not indicate that GUK was ready to walk away from the GUK Litigation, or would have been willing to abandon its efforts to enter the market independently, had it not received sufficient compensation. Rather, and consistent with GUK's decision to continue to contest the GUK Litigation for some five months following the granting of the GUK Interim Injunction, the internal documents in fact show that there was genuine uncertainty on both sides as to GUK's and GSK's prospects in the GUK Litigation, and of GUK entering the UK paroxetine market independently of GSK at the time that the GUK-GSK Agreement was entered into, such that there remained the potential for GUK to enter the market independently. In addition, as explained at paragraphs D.74 to D.77, the granting of the GUK Interim Injunction said nothing about the judge's views as to the merits of either side's case. Indeed, Mr Justice

²⁰²⁹ [REDACTED]1 (document 2335), page 20.

²⁰³⁰ GUK SO Written Response (document 2752), paragraph 3.18 referring to the email from [the Chief Executive of Merck Generics Group] to [the Head of Merck Operation in Australia] and the email from [the Chief Executive of Merck Generics Group] to [GUK's General Manager] dated 12 March 2002 (document 0990).

²⁰³¹ Email chain between [the Chief Executive of Merck Generics Group], [GUK's Commercial Director] and others dated 12 April 2002 (document 1040).

Jacob explained that he had '*come to the clear conclusion that I am quite unable to decide the relative strengths of the parties' contentions'* (see paragraph 3.273).²⁰³²

- A number of the documents and witness statements to which the Parties refer need to be considered in the context in which they were written or given. For example, GUK relies heavily on witness interviews given to the OFT in the context of GUK's defence to the Investigation.²⁰³³ The CMA considers that the contemporaneous documentation (with the exception of certain emails referred to below) do not reflect the level of pessimism suggested by [the Chief Executive of Merck Generics Group] and [Merck's Head of Patents and Raw Material Support Group] in their respective interviews and in [the Chief Executive of Merck Generics Group's] subsequent witness statement.²⁰³⁴ The CMA notes that contemporaneous documents are likely to be more credible than later explanations given by GUK employees.²⁰³⁵
- As regards [the Chief Executive of Merck Generics Group's] emails referred to at paragraph E.6, the CMA observes that his comments indicate that there was uncertainty as to the outcome of the GUK Litigation, but not that he considered that pursuing independent generic entry was no longer an economically viable strategy. Furthermore, [the Chief Executive of Merck Generics Group's] comments need to be considered in their proper context: a situation in which GUK was considering how best to approach an upcoming negotiation with Sumika regarding how much GUK should pay Sumika to compensate it for no longer requiring its API.²⁰³⁶ Understandably, in that negotiation, GUK would have wanted to present a position to Sumika that best benefited GUK – overemphasising the risk that GUK would not have won the GUK

²⁰³² In a similar vein, Mr Justice Jacob also observed at page 5 that '[t]here is nothing to tip the balance of probability one way or the other' and at page 6 that '*I really cannot decide one way or the other on the information I have*': see *SmithKline Beecham Plc v Generics (UK) Limited*, transcript of hearing before Jacob J, dated 23 October 2001 (document 0911), pages 4–5.

²⁰³³ See GUK SO Written Response (document 2752), paragraphs 3.18–3.20. For example, GUK refer to a witness statement produced by [the Chief Executive of Merck Generics Group] in response to the SO in July 2013, in which [the Chief Executive of Merck Generics Group] states that he had a '*real concern*' that GUK would not prevail in the GUK Litigation and had decided '*to settle on the best possible terms with GSK*' see email chain between [the Chief Executive of Merck Generics Group], [GUK's Commercial Director] and others dated 12 April 2002 (document 1040).

²⁰³⁴ See Annex 2 to GUK SO Written Response - [the Chief Executive of Merck Generics Group] witness statement dated 25 July 2013 (document A 0041).

²⁰³⁵ *JJB Sports v OFT*, [2004] CAT 17, [287].

²⁰³⁶ In this regard, the CMA notes that [the Chief Executive of Merck Generics Group's] comments were provided in the context of GUK needing '*to think about Sumika*' and were prefaced as '*the following to consider with them [Sumika]*'.

Litigation would have benefited GUK in discussions with Sumika by increasing Sumika's willingness to accept a lower payment.²⁰³⁷

- The CMA notes that other internal documents relevant to the period following the GUK Interim Injunction suggest a more confident position than the Parties put forward in their written representations or witness interviews.²⁰³⁸ For example:
 - An email from [GUK's Managing Director] to various GUK employees on 24 October 2001 shows that GUK continued to be 'confident' of its position:²⁰³⁹

*'We are confident that we do not infringe and will therefore be able to launch next year AND claim substantial damages from GSK.'*²⁰⁴⁰
 - In an email on 26 October 2001, [a GUK Sales and Marketing employee], when discussing stock requirements and the impending GUK Litigation, explained that 'obviously there is an inherent risk' but that the prospect of a loss before the Courts was 'unlikely'. [A GUK Sales and Marketing employee] therefore concluded that 'given our confidence that we have a non-infringing product it would seem prudent to have our full stock requirement for launch'.²⁰⁴¹
 - In a letter which was sent to all of GUK's wholesalers on 29 October 2001, [GUK's General Manager] stated:²⁰⁴²

²⁰³⁷ This is further supported in an earlier email from [the Chief Executive of Merck Generics Group] to [GUK's General Manager] dated 12 March 2002 (document 0990) in which he explained that '[...] Sumika need to understand this very clearly. If we [GUK] did not prevail, then we would not be buyoing [sic] any API in the short term.'

²⁰³⁸ This was despite the fact that GSK had sought to amend its claim against GUK, to include a claim for infringement of the Hemihydrate Patent, and therefore understood that this issue would arise in the future (see paragraph 3.128).

²⁰³⁹ Email from [GUK's Managing Director] to [GUK's Sales and Marketing Director] and others dated 24 October 2001 (document 0913). See also email from [a GUK Sales and Marketing employee] to [GUK's General Manager] dated 26 October 2001 (document 0917).

²⁰⁴⁰ In an interview with the CMA on 25 May 2012, [the Chief Executive of Merck Generics Group] [the Chief Executive of Merck Generics Group] suggested that [GUK's Managing Director's] email was a 'typical salesman letter to the troops', that [GUK's Managing Director] was not 'that close to the litigation' and that 'his optimism would have been also slightly third hand' ([§]1 (document 2335), page 19). While this may suggest that [GUK's Managing Director] may have overstated GUK's position, it is, as demonstrated throughout the other evidence in this paragraph, far from the only internal correspondence following the GUK Interim Injunction where such confidence was expressed.

²⁰⁴¹ Email from [a GUK Sales and Marketing employee] to [GUK's General Manager] dated 26 October 2001 (document 0917).

²⁰⁴² Letter from [GUK's General Manager] to GUK wholesaler dated 29 October 2001 (document 0921).

'We are confident that we have a non-infringing product and will win our legal case.'

- In an email on 2 January 2002 to [GUK's General Manager], [GUK's Head of Research and Development] commented that:²⁰⁴³

*'court cases are a bit of lottery.....I am 110 % confident that we will present the best case....there is always a **small chance** that despite the evidence the court decides against us'* (emphasis added).

- In an email on 2 January 2002 to [the Chief Executive of Merck Generics Group], [Merck's Head of Patents and Raw Material Support Group] stated, after a positive consideration of GUK's position, that *'[w]hilst I am confident of winning in the long run...that is the operative word...long [...] ultimately we will win'*.^{2044, 2045}
- In an email on 12 March 2002 (the day before the GUK-GSK Agreement was entered into) to [the Chief Executive of Merck Generics Group] and [GUK's Managing Director], [GUK's Head of Research and Development] confirmed what he had discussed with [the Chief Executive of Merck Generics Group] and [GUK's Managing Director], including that on the Anhydrate Patent *'we [GUK] have a good case and will argue for non infringement and invalidity'*.²⁰⁴⁶
- In an email on 13 March 2002 (the date on which the GUK-GSK Agreement was entered into) [GUK's Head of Research and

²⁰⁴³ Email from [GUK's Head of Research and Development] to [GUK's General Manager] dated 2 January 2002 (document 0959).

²⁰⁴⁴ Email from [Merck's Head of Patents and Raw Material Support Group] to [the Chief Executive of Merck Generics Group] dated 2 January 2002 (document 0958). [Merck's Head of Patents and Raw Material Support Group's] reasons for this view were:

'a) the anhydrate patent is invalid, we can prove that now

b) the tablet patent is invalid or could be restricted to hemihydrate only.

c) the hemihydrate patent is more difficult to knock out, but possible'.

²⁰⁴⁵ Moreover, in an interview with the CMA on 25 May 2012 (see [§]1 (document 2330), page 27, [Merck's Head of Patents and Raw Material Support Group] stated *'my expertise and knowledge in those days for litigation was somewhat limited... It may be slightly naive perhaps, but at the time I felt scientifically I was right, but then scientifically as I said beforehand when you get into court it's not straightforward'*. Although [Merck's Head of Patents and Raw Material Support Group] notes his litigation experience was somewhat limited, during the Relevant Period, he considered that he was right (that is, that GUK's product did not infringe valid claims in GSK's paroxetine patents or that the relevant claims in GSK's paroxetine patents were not valid).

²⁰⁴⁶ Email from [GUK's Head of Research and Development] to [the Chief Executive of Merck Generics Group] and others dated 12 March 2002 (document 0994).

Development] provided 'a few ponderous thoughts' to [the Chief Executive of Merck Generics Group]:²⁰⁴⁷

'- the first strage [sic] of the case is no issue.....ie anhydrate.....think we can win this part.....'

- hemihydrate is a bit more tricky because we know that under certain circumstances or [sic] product can contain hemihydrate.....think it is winnable but it is a bit more uncertain....'

E.8 GUK made a number of submissions in relation to these documents. GUK submitted that: (i) the CMA cannot rely on the views of [Merck's Head of Patents and Raw Material Support Group] because he stated to the OFT that, whilst he may have been confident from a scientific viewpoint, this did not mean he was equally confident GUK would prevail in court; (ii) others within GUK treated [Merck's Head of Patents and Raw Material Support Group's] views with scepticism;²⁰⁴⁸ (iii) the CMA cannot attach undue weight to statements made by members of GUK's commercial team (such as [GUK's General Manager] and [GUK's Managing Director]) to demonstrate GUK's confidence because these individuals had no patent law knowledge and their statements sought to provide reassurance to both customers and employees of GUK;²⁰⁴⁹ and (iv) the decision of whether or not to launch 'at risk' was not one for [GUK's Head of Research and Development], GUK's Head of R&D, to make and so his views were incapable of substantiating that GUK was prepared to launch 'at risk'.²⁰⁵⁰

E.9 The CMA rejects GUK's submissions in relation to this evidence:

- First, the CMA has not considered any of the contemporaneous documents in isolation and it has also had due regard to all documents put forward by GUK. The CMA has considered the evidence as a whole, and concluded that both GSK and GUK regarded the outcome of the GUK Litigation as uncertain. The evidence does not suggest that GUK regarded GSK's patents, or the prospect of litigation, as an insurmountable barrier to entry, or that GUK was willing to abandon or defer its efforts to enter the market independently of GSK without sufficient compensation.

²⁰⁴⁷ Email from [GUK's Head of Research and Development] to [the Chief Executive of Merck Generics Group] and [GUK's Managing Director] dated 13 March 2002 (document 0997).

²⁰⁴⁸ GUK SO Written Response (document 2752), paragraphs 3.26(a) and 3.26(b).

²⁰⁴⁹ GUK SO Written Response (document 2752), paragraph 3.27.

²⁰⁵⁰ GUK SO Written Response (document 2752), paragraph 3.46.

- Second, [Merck's Head of Patents and Raw Material Support Group] was GUK's patent expert,²⁰⁵¹ who had extensive professional experience in the evaluation of patents at the time. Whilst the CMA accepts that his viewpoint was a scientific one, the science in question was the pertinent point in the GUK Litigation, so a '*scientific viewpoint*' would be highly relevant. In his position as Head of Patents at Merck, [X] was a key advisor to [the Chief Executive of Merck Generics Group] on this subject and also provided a witness statement in the GUK Litigation providing his views on the issues of non-infringement and invalidity of the Anhydrate Patent.²⁰⁵² The CMA notes that [Merck's Head of Patents and Raw Material Support Group's] views were sufficiently important at the time for [the Chief Executive of Merck Generics Group] to consult him on the prospects of winning the GUK Litigation. Finally, the CMA observes that in the email cited above, [Merck's Head of Patents and Raw Material Support Group] was in fact expressing a view that he was confident of GUK '*winning*' in court, and was not therefore commenting only on the scientific considerations in isolation.
- Third, as regards [GUK's General Manager] and [GUK's Managing Director], these were senior and experienced members of staff at GUK who were in close contact with [the Chief Executive of Merck Generics Group] regarding the paroxetine case. [X] was the General Manager/ Sales and Marketing Director of GUK. [X] was the Managing Director of GUK and the Regional European Director of Merck Generics Group. The CMA therefore considers that their evidence is also relevant as part of an examination of the evidence as a whole. The CMA acknowledges that, for the purposes of communications to staff and customers in the aftermath of the GUK Interim Injunction, [GUK's General Manager] and [GUK's Managing Director] may have had cause to emphasise a positive viewpoint. However, had GUK's confidence deteriorated as significantly as GUK suggests, it would have been unusual (and indeed risky for GUK's reputation and commercial relationships) for such senior staff to make claims such as these to their customers and staff. Further, it is not necessary for GUK's commercial representatives to have knowledge of patent law. As above, the CMA has not considered these statements in

²⁰⁵¹ Transcript of first interview with [IVAX's Head of New Business Development] on 28 June 2012, dated 14 September 2012 (document 2231), page 15.

²⁰⁵² Witness statement of [Merck's Head of Patents and Raw Material Support Group] in the GUK Litigation, dated 15 October 2001 (document 0900).

isolation. However, they are relevant as part of an examination of an assessment of internal documents as a whole.

- Fourth, [GUK's Head of Research and Development] had worked on GUK's paroxetine project for five years.²⁰⁵³ The CMA notes [GUK's Head of Research and Development's] scientific background and considers, as set out above, that the science in question was the pertinent point in the GUK Litigation, so a '*scientific viewpoint*' would be highly relevant. In his position as Head of R&D, [X] was an important advisor to [the Chief Executive of Merck Generics Group] on issues relating to the GUK Product, including sharing his views on the questions of invalidity and non-infringement of the Anhydrate Patent and Hemihydrate Patent (see paragraph E.7). The CMA observes that, in his email to [the Chief Executive of Merck Generics Group] the day before the GUK-GSK Agreement was entered into (see paragraph E.7), [GUK's Head of Research and Development] expressed views as to GUK's position under the Anhydrate Patent and Hemihydrate Patent.

- E.10 GUK also submitted that, whatever the claims made by others at GUK, the views of the Chief Executive of Merck Generics, [X], carry significant weight (as the final decision on whether to settle rested with him) and his views therefore take precedence over the views which others at GUK may have had. GUK submits that [the Chief Executive of Merck Generics Group] had a real concern that GUK would not prevail in the GUK Litigation.²⁰⁵⁴
- E.11 The CMA acknowledges that [the Chief Executive of Merck Generics Group] was the ultimate decision-maker regarding GUK's entry into the UK paroxetine market, and that he did on certain occasions highlight that there was some risk that GUK would not prevail in the GUK Litigation.
- E.12 However, there is in any case no documentary evidence that suggests [the Chief Executive of Merck Generics Group] regarded GSK's patents, or the GUK Litigation, as an insurmountable barrier to entry, or that GUK would have been willing to abandon its efforts to enter the market independently of GSK without sufficient compensation from GSK. Rather, the documentary evidence shows that [the Chief Executive of Merck Generics Group] regarded GUK's entry to be sufficiently realistic and valuable to GUK such that he would only contemplate a settlement with GSK (which included a restriction on GUK's

²⁰⁵³ Email from [GUK's Head of Research and Development] to [GUK's Managing Director] and [the Chief Executive of Merck Generics Group] dated 12 March 2002 (document 1002).

²⁰⁵⁴ GUK SO Written Response (document 2752), 3.29(a).

independent entry into the UK paroxetine market) if GSK offered sufficiently high value transfers to compensate GUK for doing so. For example:

- In an email to [Merck's Head of Patents and Raw Material Support Group] on 31 December 2001 [the Chief Executive of Merck Generics Group] explained that GSK's *'final offer was still not acceptable'* and stated that²⁰⁵⁵ *'as long as you remain confident of winning [although there are no guarantees] we must push for the best deal we can and that means [under scenario 2 - which is the option under discussion] that we need the API covered - plus a decent profit - otherwise we should puch [sic] on with the case for ultimate launch'* (emphasis added).
- In the email of 12 March 2002, which GUK highlight in their written representations, [the Chief Executive of Merck Generics Group] explained that GUK had *'a real concern that we may not prevail in the patent case'* but added that *'a settlement and local distribution agreement seem to be the best way to go - provided the numbers are right'* (emphasis added).²⁰⁵⁶
- Further, as outlined at paragraphs 3.281 to 3.304, [the Chief Executive of Merck Generics Group] was prepared to reject a series of lucrative settlement offers from GSK before finally agreeing to restrict GUK's independent entry in return for value transfers of at least £21.3 million, despite [the Chief Executive of Merck Generics Group's] apparent risk aversion, and the uncertainty that would have existed as to whether GSK would make further settlement offers to GUK at that time.²⁰⁵⁷

E.13 GUK submitted that the fact that [the Chief Executive of Merck Generics Group] wanted to obtain the best possible commercial terms from GSK does

²⁰⁵⁵ Email from [the Chief Executive of Merck Generics Group] to [Merck's Head of Patents and Raw Material Support Group] and others dated 31 December 2001 (document 0954).

²⁰⁵⁶ [The Chief Executive of Merck Generics Group] has explained that, given his aversion to risk, only a limited element of doubt in GUK's position would be necessary to encourage him to consider alternative options, such as settlement. In particular, in an interview with the OFT, [the Chief Executive of Merck Generics Group] explained that the chances of GUK losing *'wouldn't even have to be 25'* per cent in order for him to have concerns. Email chain between [GUK's Head of Research and Development], [GUK's Managing Director], [the Chief Executive of Merck Generics Group], [GUK's General Manager], [Merck's Head of Patents and Raw Material Support Group], [Commercial Director of Merck Generics] and [the Head of Merck Operation in Australia] dated 12 March 2002 (document 0990). See GUK SO Written Response (document 2752), paragraphs 3.18 and 3.20.

²⁰⁵⁷ [redacted]1 (document 2335), page 33. This is consistent with the interview with [Merck's Head of Patents and Raw Material Support Group] on 25 May 2012, [redacted]1 (document 2330), page 35, in which [Merck's Head of Patents and Raw Material Support Group] explained that [the Chief Executive of Merck Generics Group] *'was very, very conservative'* and *'[f]or [the Chief Executive of Merck Generics Group] it almost was it [sic] had to be a hundred percent safe because he was very, very conservative. He doesn't like risk. [...] if I couldn't give him a hundred percent guarantee...or ninety-five, no, for him maybe ninety-five or a hundred per cent guarantee – he would worry about it.'*

not establish that he was confident that they would prevail in the GUK Litigation.²⁰⁵⁸ The CMA does not consider that it is necessary to show that [the Chief Executive of Merck Generics Group] was ‘*confident*’ that GUK would prevail in the GUK Litigation. However, as noted above, the CMA considers that the documentary evidence shows that the potential for GUK’s entry was sufficiently realistic and valuable to [the Chief Executive of Merck Generics Group] that he would only contemplate settling with GSK (and restricting GUK’s independent entry into the UK paroxetine market) if GSK offered sufficiently high value transfers to compensate GUK for doing so. This is further supported by the fact that [the Chief Executive of Merck Generics Group] considered he had sufficient bargaining power to turn down a number of multimillion pound settlement offers and extract ‘*additional concessions*’ from GSK. [The Chief Executive of Merck Generics Group]’s approach to the settlement negotiations suggests that he considered that GUK could (and would) enter the market independently of GSK.

iii) ***The Hemihydrate Patent***

E.14 GUK submitted that the evidence demonstrates that it had real concerns in relation to the alleged infringement of GSK’s Hemihydrate Patent.²⁰⁵⁹ GUK made reference to the following contemporaneous documentation:

- An email dated 13 March 2002 by [X] (GUK’s Head of Research and Development) to [the Chief Executive of Merck Generics Group] and others stated that ‘*hemihydrate is a bit more tricky because we know that under certain circumstances or [sic] product can contain hemihydrate ... think it is winnable but it is a bit more uncertain.*’²⁰⁶⁰
- An email dated 2 January 2001 in which [Merck’s Head of Patents and Raw Material Support Group] stated that the Hemihydrate Patent was ‘*more difficult to knock out*’.²⁰⁶¹
- GUK also referred to the following witness interviews:
 - In an interview with the OFT [Merck’s Head of Patents and Raw Material Support Group] explained to the OFT that his primary objective

²⁰⁵⁸ GUK SO Written Response (document 2752), Section B.2.1

²⁰⁵⁹ GUK SO Written Response (document 2752), paragraphs 3.26(c) and 3.37.

²⁰⁶⁰ Email from [GUK’s Head of Research and Development] to [the Chief Executive of Merck Generics Group] and [GUK’s Managing Director] dated 13 March 2002 (document 0997). See GUK SO Written Response (document 2752), paragraph 3.29(a).

²⁰⁶¹ Email from [Merck’s Head of Patents and Raw Material Support Group] to [the Chief Executive of Merck Generics Group] dated 2 January 2002 (document 0958). See GUK SO Written Response (document 2752), paragraph 3.29(b).

was to ensure that GUK's product did not infringe the Hemihydrate patent: *'we did not want to get involved with ... when I say we didn't want to get involved with litigation on the hemihydrate patents, that was the plan'*²⁰⁶² and that he considered that GSK's Hemihydrate Patent was a strong patent: *'We could have arguments about it, but they may not be particularly strong arguments'*.²⁰⁶³

- In an interview with the OFT, in response to being shown an email in which [Merck's Head of Patents and Raw Material Support Group] states that the *'hemihydrate patent is more difficult to knock out'*, [the Chief Executive of Merck Generics Group] stated: *'That would be a real problem for me. Again, I'm an accountant, I'm conservative, I'm looking at the interests of the group, your scientist comes along and says, you possibly may not win this. That's like a red rag for me. Because when a scientist starts saying you might lose it, then your chances of the lawyers winning it for the other side are huge, I think. That would have been my response to that. We have a chance of losing'*.²⁰⁶⁴
- In the same interview, [the Chief Executive of Merck Generics Group] also stated that his *'level of scepticism increased a little bit probably, once I realised, or it was explained to me, that we weren't just looking at one patent, which needed to be overcome. But there were perhaps two or three and often multiples of them. So my level of scepticism was always there. I suppose I was allowed to be optimistic to a point where, hold on a second, if the product isn't completely stable and it could contain infringing product, that was for me a much different set of circumstances than if it was just a simple open and closed patent case'*.²⁰⁶⁵

E.15 As with the GUK Interim Injunction, the CMA observes that the prospect of litigation on the Hemihydrate Patent may have made GUK more cautious than it was earlier in the GUK Litigation. However, there is no suggestion from the documentary evidence that, a result of the potential litigation on the Hemihydrate Patent, GUK would have been willing to abandon its efforts to enter the market independently, had it not received sufficient compensation. Rather, the documentation suggests that the ultimate outcome of litigation, whether in relation to the Anhydrate or Hemihydrate Patents, remained uncertain, such that there remained the potential for GUK to enter the market

²⁰⁶² [REDACTED] 1 (document 2330), page 13. See GUK SO Written Response (document 2752), paragraph 3.37(b).

²⁰⁶³ [REDACTED] 1 (document 2330), page 22. See GUK SO Written Response (document 2752), paragraph 3.37(b).

²⁰⁶⁴ [REDACTED] 1 (document 2335), page 22. See GUK SO Written Response (document 2752), paragraph 3.29(c).

²⁰⁶⁵ [REDACTED] 1 (document 2335), page 18. See GUK SO Written Response (document 2752), paragraph 3.29(c).

independently. These documents therefore do not alter the CMA's assessment that GUK was a potential competitor to GSK.

- E.16 In these documents, the authors suggest that they think GUK will win the relevant litigation but note that the litigation might be more *'tricky'*²⁰⁶⁶ or take a long time. [Merck's Head of Patents and Raw Material Support Group] email of January 2002 is prefaced: *'[w]hilst I am confident of winning in the long run...that is the operative word...long [...] ultimately we will win'*.²⁰⁶⁷
- E.17 Similarly, in relation to the prospect of being injuncted in relation to the Hemihydrate Patent, the internal documentation suggests that GUK by no means considered this to be inevitable. In an internal GUK email on 12 March 2002 (the day before the hearing in the GUK Litigation was scheduled to start), [GUK's Head of Research and Development] wrote to *'confirm what I have discussed'* with [the Chief Executive of Merck Generics Group] and [GUK's Managing Director]. [GUK's Head of Research and Development] explained that if GUK won the GUK Litigation it could *'then launch at risk,.....they [GSK] will try to injunct on the basis of the hemihydrate patent.....we think they will not succeed as we will argue that they should have gone fro [sic] this action long before May.....ie when they are likely to try for an injunction based upon loosing [sic] the anhydrate case'*.²⁰⁶⁸
- E.18 Finally, the CMA observes that, if the Parties' submissions as to potential infringement of the Hemihydrate Patent and the prospect of future litigation were to be accepted, this would mean that GUK would not have been a potential competitor even after they had entered the market in 2004, as GSK could have claimed at that stage that its Hemihydrate Patent was infringed.

B. GSK's Documents

- E.19 Internal GSK documents also indicate genuine uncertainty within GSK as to its prospects of preventing GUK from entering the UK paroxetine market independently of GSK. For example:
- In July 2000, an internal GSK email from [the Marketing Director for Seroxat],²⁰⁶⁹ refers to an opinion from Counsel on the validity of its

²⁰⁶⁶ For example, see email from [GUK's Head of Research and Development] to [the Chief Executive of Merck Generics Group] and others dated 12 March 2002 (document 0994).

²⁰⁶⁷ Email from [Merck's Head of Patents and Raw Material Support Group] to [the Chief Executive of Merck Generics Group] dated 2 January 2002 (document 0958).

²⁰⁶⁸ Email from [GUK's Head of Research and Development] to [the Chief Executive of Merck Generics Group] and others dated 12 March 2002 (document 0994).

²⁰⁶⁹ Email from GSK's [Marketing Director for Seroxat] to [GSK's Vice President – R&D Legal Operations] and others dated 21 July 2000 (document 0121), entitled 'Paroxetine anhydrate telecon – 28th July'.

Anhydrate Patent in the light of the '*potential anhydrate threat*' from Norton (or IVAX). That email specifically linked GSK's consideration of the patent position with '*engagement in third party discussions*'. The fact that GSK subsequently went on to engage in such third party discussions, and negotiated various settlement agreements in countries across Europe, including with GUK in the UK, demonstrates GSK's uncertainty regarding its patent position.

- In an internal GSK presentation dated 5 February 2001 and co-authored by [Finance Director A], GSK considered the threat posed by the paroxetine anhydrate product being developed by IVAX.²⁰⁷⁰ In that presentation GSK noted that various product approvals were expected in Ireland and Denmark, and stated that a test is '*required to ensure no patent infringement*'. It then proceeded to '[r]ecommend establishment of [a] supply agreement' as a means of protecting sales and maintaining market share. The fact that a decision had been taken to make such a recommendation, before any such tests had been conducted on any generic products, also suggests GSK's uncertainty regarding its patent position.
- As part of Project Dyke (see paragraphs 3.144 to 3.154) GSK was closely monitoring the situation across various different jurisdictions to inform its patent position. In this light, it is to be expected that prior to entering into the GUK-GSK Agreement, GSK's assessment of the likely outcome of patent litigation would have been informed by its experiences in those other jurisdictions which it was so closely monitoring. In April 2001, the German appeal court found that the 'Form A' claim, one of the anhydrate forms referenced in the Anhydrate Patent, was invalid. GSK noted that it was '*[n]ot yet known whether other jurisdictions will follow the German decision*', suggesting concern that it was possible that other jurisdictions may come to the same conclusion. This uncertainty is likely to have influenced GSK's decision to '*[e]xplore agreement with third parties [generic suppliers]*' in various countries, including the UK.²⁰⁷¹
- Finally, in a subsequent internal GSK presentation entitled 'Seroxat Patent', GSK stated that it should '*[a]ssume generic competition everywhere in Europe from anhydrate*' although it should nevertheless continue to attempt to enforce its anhydrate patents in those countries in which patents had been obtained. Such an assumption would be

²⁰⁷⁰ GSK presentation entitled 'Seroxat Patent Challenge' dated 5 February 2001 (document 0123), page 4.

²⁰⁷¹ GSK presentation entitled 'Seroxat Patent' (document 0082), pages 3–4.

unreasonable if GSK was not uncertain of its patent position such that it sought to settle litigation subsequently with generic suppliers.²⁰⁷²

- In a document likely to have been based on a briefing that took place ‘a few weeks or months’ after August 2003,²⁰⁷³ [GSK’s Finance Director B] referred to her understanding of the patent position relevant to the Agreements with the Generic Companies (including the GUK-GSK Agreement) as a ‘Wk. patent’. [GSK’s Finance Director B] later said she believed ‘Wk. patent’ to refer to ‘Weak’ patent and confirmed that these comments were notes that she made as she ‘got up to speed on the historic patent disputes, litigation, settlement and supply agreements’.²⁰⁷⁴ This is particularly relevant given that [GSK’s Finance Director B] considered that this note was likely to be reflective of a discussion with [GSK’s Associate General Counsel for Europe], who was directly involved in the negotiation of the Agreements with the Generic Companies.²⁰⁷⁵ [GSK’s Finance Director B] then noted, specifically regarding GUK, that ‘had we lost GUK would have gone in 02’ which she believes meant that ‘had GSK lost in the litigation with GUK then GUK (and other generics) would have entered the market in 2002’.²⁰⁷⁶

- E.20 GSK submitted that these documents do not support a finding that GUK was a potential competitor to GSK because, for example, they do not constitute probative evidence that GSK regarded GUK as a potential competitor, and they say nothing about the level of the risk of losing the litigation.²⁰⁷⁷
- E.21 The CMA considers that these documents demonstrate GSK’s overall views in relation to its prospects in any litigation surrounding its paroxetine patents (in particular in relation to the Anhydrate Patent).

²⁰⁷² GSK document entitled ‘Seroxat patent’ dated 11 May 2001 (document 0133), slide 2.

²⁰⁷³ GSK Third Response (document 0750), paragraph 12.8. See [REDACTED]WS2 (document 3180) at paragraph 4.2: ‘I recall that page 3 of the Handwritten Notes was written within a few weeks or months of becoming GSK Finance Director in [August] 2003, so fairly soon into the new role.’

²⁰⁷⁴ GSK Third Response (document 0750), paragraph 12.5.

²⁰⁷⁵ As outlined at paragraph F.17, GSK submitted that the [GSK’s Finance Director B’s] note is of limited evidential value. For the reasons outlined at paragraphs F.17–F.20, the CMA does not accept GSK’s submissions in this regard.

²⁰⁷⁶ GSK Third Response (document 0750), paragraph 12.19.

²⁰⁷⁷ See SO Written Response (document 2755), paragraphs 4.53, 6.29. See also paragraphs 3.240, 6.135 and F.17–F.20.

ANNEX F: REPRESENTATIONS ON WHETHER THE GUK-GSK AGREEMENT RESTRICTS COMPETITION BY OBJECT

A. Representations on entry restrictions in the GUK-GSK Agreement

- F.1 GSK submits that the CMA is incorrect to state that the GUK-GSK Agreement deferred rather than settled their dispute. In this regard, GSK states that the GUK-GSK Agreement did not restrict GUK from entering the market independently of GSK following the expiry of the GUK-GSK Agreement.²⁰⁷⁸ Similarly, Merck submitted that the Agreement did amount to a settlement of the dispute, and that a settlement that preserves the parties' rights in this way is a standard means of resolving such disputes.²⁰⁷⁹
- F.2 The CMA does not dispute that an agreement that preserves each parties' rights may be a common outcome in the settlement of a dispute, and the CMA does not object to such terms in and of themselves. However, the CMA observes that it was self-evident from the GUK-GSK Agreement that GUK and GSK did not resolve the substantive issues that were the subject of the litigation between them, and observes that neither GUK nor GSK have disputed this. The issues were not therefore resolved and, under the terms of the GUK-GSK Agreement, were deferred until the GUK-GSK Agreement expired, or until the relevant issues were resolved as a consequence of a dispute between GSK and another generic supplier.

i) Representations on value transfers in the GUK-GSK Agreement

a) Representations on the stock purchase

- F.3 GSK submitted that the purpose of the stock purchase was to ensure that the terms of settlement were not evaded, and that payment for stock was a reasonable solution.²⁰⁸⁰ GSK stated that GUK made the arrangement a condition of settlement, and that the relevant sum was a matter of negotiation.²⁰⁸¹ GSK submitted that its objective was to secure the position it would have been in had it obtained the remedy it was seeking before the court

²⁰⁷⁸ GSK SO Written Response (document 2755), paragraph 6.113.

²⁰⁷⁹ Merck SO Written Response (document 2764) (document 2764), paragraph 4.31.

²⁰⁸⁰ GSK SO Written Response (document 2755), paragraph 6.152.

²⁰⁸¹ GSK SO Written Response (document 2755), paragraphs 6.154–6.158.

and that, in that sense, it should be seen as one aspect of the overall settlement.²⁰⁸²

- F.4 The CMA considers that GSK's submission does not undermine the analysis set out in paragraphs 6.99 to 6.102. To the contrary, the CMA considers that GSK has set out a clear articulation of a value transfer being used to secure entry restrictions that GSK could otherwise have secured only if it had prevailed before the courts, and that GUK would have been unwilling to accept those entry restrictions absent the value transfers. The fact that GUK wanted to maximise its returns in relation to stock is irrelevant to an assessment of GSK's rationale for making the payments to GUK. GUK's determination to '*extract the best it could*' is consistent with it requiring adequate compensation in return for its acceptance of entry restrictions.
- F.5 In practice, it is clear from GSK's representations (and response to a Section 26 Notice)²⁰⁸³ and the evidence (see paragraphs 6.99 to 6.102) that it was GUK's requirement for compensation that drove the transfer of stock to GSK and the associated value transfer from GSK. Consistent with this, it is noted that GSK did not require product from Alpharma, presumably on the basis that had Alpharma sought to enter the market and terminate the Alpharma-GSK Agreement, it would have been in a position to source additional product in order to do so. The same was also true of GUK who could, as required, have purchased further product from its supplier Alphapharm, who at the time continued to supply paroxetine in other countries.²⁰⁸⁴ It is apparent therefore that the cash payments attributed to the purchase of stock were a means of compensating GUK for its wider acceptance of the entry restrictions.
- F.6 GUK submitted that the payments made by GSK to GUK for the purchase of stock should not be termed a value transfer where they reflect a fair payment in return for a tangible asset, and should therefore be revised down by £3.7 million to reflect the value of the stock that GSK acquired from GUK.²⁰⁸⁵

²⁰⁸² GSK SO Written Response (document 2755), paragraph 6.161.

²⁰⁸³ GSK Second Response, Part Two (document 0734), paragraph 10.12.

²⁰⁸⁴ See, for example, the Witness Statement of [GSK's Patent Attorney] dated 27 September 2001 (document 0162), paragraph 5. See also documents [§]WS (document 0901), Second Witness Statement of [GSK's Patent Attorney] dated 20 October 2001 (document 0905) and Exhibit [§]3 referred to in the Witness Statement of [GUK's external lawyer] dated (document 0985). In fact, in determining how much product it should supply to GSK under the terms of the GUK-GSK Agreement, GUK was considering the benefits of retaining as much as possible for supply to other markets. For example an internal GUK email from [GUK's General Manager] to [the Chief Executive of Merck Generics Group], dated 12 March 2002, states '*[w]hat are your thoughts on what we want to sell to GSK. They are expecting to get something for their £. I would suggest that we try to get away with the stock below and leave any remaining bulk/active for use in other markets*'. See [The Chief Executive of Merck Generics Group's] response to [GUK's General Manager] dated 12 March 2002 (document 0992).

²⁰⁸⁵ Annex 1 to GUK SO Written Response (document 2753), section 3.1.2.

F.7 The CMA considers that, in the context of the analysis described above, there is no reason to make the adjustments suggested by GUK. Given that GSK purchased product with a view to destroying it, it is evident that the stock was of no value to GSK (other than the value associated with deferring the threat of true generic competition). The value that GUK seeks to attribute to the stock is therefore of no relevance to an assessment of the value of the stock to GSK, and does not therefore provide any explanation for GSK's decision to make the relevant value transfers to GUK. From GUK's perspective, the payments were a part of the value transfers that GUK received in return for its acceptance of the value transfers.

b) *Representations on the transfer of a restricted volume of paroxetine*

F.8 GSK submitted that, even if the volume restriction operated as alleged by the CMA, the GUK-GSK Agreement provided for competition on the basis that it allowed for a reasonable profit margin and a substantial volume of product.²⁰⁸⁶

F.9 Although the GUK-GSK Agreement provided for what GSK considers to be a reasonable profit margin and a material product volume, the CMA does not accept that the GUK-GSK Agreement provided for a meaningful increase in the competitive constraints faced by GSK. As explained above, the CMA considers that as a consequence of the volume restrictions, GUK was not incentivised to price materially below prevailing market levels. Consistent with this, the CMA notes that the introduction of the GUK-GSK Agreement (and the subsequent Alpharma-GSK Agreement) had no material impact on prices in the relevant market (see paragraph 3.387).

F.10 GSK submitted that GUK was not constrained by volume provisions because (i) GSK provided IVAX with more volume to accommodate sales to GUK; (ii) the Agreements enabled GUK to vary its orders from one month to the next, provided that it provided GSK with sufficient notice; and (iii) the CMA has not pointed to evidence that GUK approached GSK or IVAX for additional volume once the GUK-GSK Agreement was entered into.²⁰⁸⁷

F.11 The CMA does not accept these submissions, and observes that:

- The fact that GSK increased the quantities of paroxetine it supplied to IVAX does not mean that supplies of GSK's paroxetine to GUK were unconstrained. Rather, it simply reflected the fact that, under the GUK-

²⁰⁸⁶ GSK SO Written Response (document 2755), paragraph 6.171.

²⁰⁸⁷ GSK SO Written Response, paragraph 6.172.

GSK Agreement, IVAX was responsible for supplying a fixed amount of GSK's paroxetine to GUK.

- The CMA does not dispute that GUK retained an ability to vary its month to month orders. However, as outlined above (see paragraphs 3.309 and 6.103), it is evident that the total volumes that GUK could receive over the contract year were restricted.
- The CMA observes that, having tried and failed to secure higher volumes from GSK at the time the GUK-GSK Agreement was entered into, it is unsurprising that GUK did not have any expectation that GSK would provide further volume to it such that it did not make any such requests. In particular, GUK would have been aware that having secured its acceptance of the entry restrictions over the three year term of the GUK-GSK Agreement, GSK had no incentive to provide additional volumes to GUK.

F.12 GSK stated that the profit guarantee clause (see paragraph 6.105) should be considered in a legal and economic context in which there was *'deep set rivalry between IVAX and GUK and considerable mutual distrust'*.²⁰⁸⁸ GSK submitted that since IVAX set the input price for GUK, GUK would otherwise be at a competitive disadvantage in terms of discounting to customers absent some other means of price discounting. In support of its claims, GSK refers to the [the Chief Executive of Merck Generics Group] interview transcript in which [the Chief Executive of Merck Generics Group] speculated that the profit guarantee clause would have allowed it to be more competitive in the market.²⁰⁸⁹

F.13 The CMA observes that the volume restriction ensured that there was no meaningful competition or 'rivalry' between those Parties. Further, the CMA observes that there was no potential for IVAX to increase the supply price of £8.45, as this was fixed over the three year term of the GSK-GUK Agreement. That price, stipulated within the IVAX-GSK Agreement, was itself a condition precedent to the GUK-GSK Agreement (see paragraph 6.85). In this context, it is evident that the profit guarantee clause acted to provide GUK with further insurance that it would receive the value transfers envisaged under the terms of the GUK-GSK Agreement (see paragraph 6.105).

F.14 The CMA notes that, contrary to [the Chief Executive of Merck Generics Group's] speculation, the volume restriction ensured that the profit guarantee

²⁰⁸⁸ GSK SO Written Response (document 2755), paragraph 6.173.

²⁰⁸⁹ GSK SO Written Response (document 2755), paragraphs 6.173–6.176.

clause could not reasonably have been expected to be used to fund material discounts to the prevailing price levels. Had GUK done so, the resulting demand would have caused it to reach the volume restriction very early in the relevant contract year, and GUK would have been unable to supply its customers for long periods. Instead, the profit guarantee clause acted to formalise the value transfer that was envisaged on providing GUK with a limited volume of paroxetine. This is presumably why GUK did not choose to discount its product to £8.45 (or close to that level) and instead to adopt a pricing strategy that provided for sales throughout the relevant contract,²⁰⁹⁰ and why when appraising GSK's settlement offers GUK assumed that it would sell its restricted product volume at prevailing market prices throughout the period of the GUK-GSK Agreement (see paragraph 6.108).

c) Representations on the Parties' intentions

- F.15 GSK submitted that GUK had various rationales for accepting the entry terms of the GUK-GSK Agreement, and that the restrictions were not therefore accepted as a consequence of the value transfers from GSK.²⁰⁹¹ In this regard, GSK stated that (i) GUK initiated the relevant discussions, having observed that it was incumbent upon it to seek supply from GSK as a means of limiting any damages that could be suffered while its independent entry was prevented as a consequence of the injunction;²⁰⁹² (ii) GUK became less confident of its case and, when considered in this context,²⁰⁹³ it is evident that GUK's references to '*compensation*' referred to discussion by GUK concerning ways to mitigate the losses it had suffered in relation to its '*project which had essentially failed*';²⁰⁹⁴ and (iii) GUK weighed up the risks, and considered that the GUK-GSK Agreement was preferable to pursuing litigation in which its chances of success were 'far from certain'.²⁰⁹⁵
- F.16 The CMA does not consider that GSK's representations undermine a finding that GUK's intention was to accept the entry restrictions provided that it

²⁰⁹⁰ The CMA notes that GUK ordered a consistent monthly volume of paroxetine from IVAX. For example, between May 2002 and March 2004 GUK ordered between 59,670 and 66,655 packs each month from IVAX (part two of the response dated 4 May 2012 to the Teva Second Section 26 Notice, and Annexes 1–3 (documents 2049 and 2050)).

²⁰⁹¹ GSK SO Written Response (document 2755), paragraph 6.126.

²⁰⁹² See GSK SO Written Response (document 2755), paragraphs 6.127–6.130, which refers to an email chain between [Merck's Head of Patents and Raw Material Support Group], [GUK's Managing Director], [the Chief Executive of Merck Generics Group], [GUK's General Manager], [GUK's Head of Research and Development], [GUK's Senior Patents Manager] dated 31 October 2001 (document 0926).

²⁰⁹³ See GSK SO Written Response (document 2755), paragraphs 6.131–6.132, which refers to an email chain between [GUK's Head of Research and Development], [GUK's Managing Director], [the Chief Executive of Merck Generics Group], [GUK's General Manager], [Merck's Head of Patents and Raw Material Support Group], [Commercial Director of Merck Generics] and [the Head of Merck Operation in Australia] dated 12 March 2002 (document 0990), regarding paroxetine.

²⁰⁹⁴ GSK SO Written Response (document 2755), paragraph 6.134.

²⁰⁹⁵ GSK SO Written Response (document 2755), paragraph 6.135.

received adequate compensation, through the payment of value transfers, from GSK. In response to point (i) above, the CMA observes that the question of who initiated discussion does not affect this analysis or the nature of the GUK-GSK Agreement. In response to point (ii), the CMA finds that the evidence set out at paragraphs 6.47 to 6.64 does not support GSK's claim that GUK's strategy had *'failed'*. To the contrary, the evidence demonstrates that, had GUK not received sufficient returns through value transfers from GSK, it would have continued to contest its litigation with GSK and with its strategy of seeking to launch generic paroxetine independently of GSK (see paragraphs 6.47 to 6.64). As regards point (iii), the CMA notes that the fact that GUK preferred the acceptance of the value transfers to the uncertainty of litigation does not undermine a finding that GUK accepted entry restrictions on the basis that it would receive compensation through the value transfers.

- F.17 GSK submitted that the [GSK's Finance Director B's] note cited at paragraph 6.134 is of limited evidential value as regards its reasons for making value transfers to GUK (and the other Generic Companies) because: (i) it is a note of a telephone call that took place two years after the relevant Agreements were entered into; (ii) [the GSK Finance Director B] was not herself involved with negotiations; (iii) although [GSK's Finance Director B] believes that the conversation was with [GSK's Associate General Counsel for Europe], [GSK's Associate General Counsel for Europe] does not recall the conversation and does not recognise the views reflected in the note; (iv) [the GSK Finance Director B] did not need to understand the rationale for the Agreement to perform her role in implementing the Agreements; and (v) [GSK's Finance Director B] has stated that her notes were *'impressionistic'*.²⁰⁹⁶
- F.18 The CMA observes that [GSK's Finance Director B's] notes are entirely consistent with the facts of the GUK-GSK Agreement which, over its three year period, included various *'mechanisms'* through which to make payments to GUK, and that did in fact induce entry restrictions that *'stopped'* GUK *'entering the market'* (see paragraphs 6.88 to 6.90). The CMA also observes that [GSK's Finance Director B's] note that GSK's patent position was apparently considered to be *'weak'* is also consistent with GSK's willingness to commit to make value transfers of at least £50.9 million and that were commercially rational only as a means of deferring the threat of GUK's independent generic entry (see paragraphs 6.91 to 6.141).

²⁰⁹⁶ GSK SO Written Response (document 2755), paragraph 4.53.

- F.19 In relation to GSK's submissions concerning the timing of the note, the CMA observes that in her role as GSK's new Finance Director [B], it remained very important that [X] was clear as to the basis for the substantial payments made under the Agreements, and that she correctly understood the views of GSK's Associate General Counsel in this regard.²⁰⁹⁷ In particular, although the notes were written some time after the initial negotiations, the purpose of the Agreements remained relevant to decisions as to whether or not to renew each of the Agreements. For example, at the time of the note, GSK was considering whether to extend the Alparma-GSK Agreement (including the associated value transfers and restrictions) and GSK opted to do so on 14 November 2003, shortly after [GSK's Finance Director B's] note was written (see paragraphs 3.373 to 3.374).
- F.20 The CMA observes therefore that the document records a briefing provided to GSK's new Finance Director at a time when it was important for [the Finance Director B] to understand the commercial value of the multimillion pound payments and restricted product transfers that GSK was making to other companies, and in which the views expressed are both internally consistent and consistent with the terms of the relevant Agreements. The CMA does therefore consider [GSK's Finance Director B's] note to be of evidential value.

²⁰⁹⁷ [X]WS2 (document 3180), paragraph 2.2 at which [GSK's Finance Director B] states that: '*My main role in this regard was to administer the payments which had been agreed by GSK under the Paroxetine Agreements and to anticipate what the financial impact might be for the organisation, for financial planning purposes.*'

ANNEX G: ALPHARMA AND GSK'S INTERNAL ASSESSMENTS ON THEIR PROSPECTS IN THE ALPHARMA LITIGATION AND OF ALPHARMA ENTERING THE UK PAROXETINE MARKET INDEPENDENTLY OF GSK

- G.1 As set out at paragraphs 6.79 to 6.82, the CMA considers that the evidence set out in the Decision (see paragraphs 6.65 to 6.78) is sufficient to show that Alpharma constituted a potential competitor to GSK in the UK paroxetine market at the time the Alpharma-GSK Agreement was entered into.
- G.2 However, the Parties submitted that internal documents and witness evidence demonstrate that Alpharma was not confident that it would prevail in the Alpharma Litigation and that there was no realistic possibility of Alpharma entering the UK paroxetine market independently of GSK, such that Alpharma cannot therefore be considered a potential competitor of GSK. The CMA has therefore examined the internal documents of Alpharma and GSK, in order to assess their views on the prospects of Alpharma entering the UK paroxetine market independently of GSK.
- G.3 As set out below, the Parties' internal documents are consistent with the CMA's finding that Alpharma was a potential competitor to GSK at the time the Alpharma-GSK Agreement was entered into. They demonstrate that there was genuine uncertainty on both sides as to their prospects in the Alpharma Litigation and of Alpharma entering the UK paroxetine market independently of GSK at the time that the Alpharma-GSK Agreement was entered into. The contemporaneous evidence indicates that Alpharma was not ready to walk away from the Alpharma Litigation, and would not have been willing to abandon its efforts to enter the market independently, without sufficient compensation.

A. Alpharma's documents

i) Internal documents prior to the Alpharma Undertaking

- G.4 Before the Alpharma Undertaking, views expressed internally within Alpharma indicated that Alpharma considered that the Alpharma Product did not infringe relevant patent claims in GSK's paroxetine patents or that GSK's patent claims were not valid. This evidence supports the CMA's case that Alpharma was prepared to enter the market independently of GSK and to defend patent litigation with GSK (see paragraphs 6.65 to 6.78). For example:

- [Alpharma ApS's Director of Intellectual Property and Technology Affairs], in an internal Alpharma email on 29 April 2002, reported that [GSK's] *strongest weapon will be their Hemihydrate patent. The API in our product is the Anhydrate, and there will initially not be any (significant) Hemihydrate in the product. GSK should therefore not be able to stop us, at launch*'.²⁰⁹⁸
- In an email in April 2002, [Alpharma ApS's Director of Intellectual Property and Technology Affairs], in full awareness of likely litigation with GSK, agreed that Alpharma should order around 500,000 packs of paroxetine from Medis, at a cost of some £3.5 million.²⁰⁹⁹ [Alpharma Ltd's Marketing Manager] confirmed that expenditure of that magnitude was '*a significant amount for Alpharma to pay for stock, given that Alpharma had total annual revenues of £80 million*'.²¹⁰⁰
- [Alpharma ApS's Director of Intellectual Property and Technology Affairs], in an internal Alpharma email on 7 June 2002, reported that '*Everybody is still confident that the GSK patent on paroxetine anhydrate will become invalidated, even though GSK is intensifying their daily harassment*'.²¹⁰¹

G.5 The CMA also notes that these documents were written after the GUK Interim Injunction was granted and, therefore, that Alpharma appears to have remained confident on its prospects of success in the Alpharma Litigation even after the GUK Interim Injunction was granted.

ii) Internal documents following the Alpharma Undertaking

G.6 The Parties cited documents which they claim demonstrate that GSK had confidence in its patents,²¹⁰² that Alpharma had been over-optimistic in terms of its initial strategy to enter 'at risk' and that, after the Alpharma Undertaking had been given, Alpharma was less confident of its position.²¹⁰³ Actavis referred to an internal document showing that, on 2 September 2002,

²⁰⁹⁸ Email chain between [Alpharma Ltd's Marketing Manager], [Alpharma ApS's Director of Intellectual Property and Technology Affairs] and others dated 29 April 2002 (document 1309).

²⁰⁹⁹ Email from [Alpharma ApS's Director of Intellectual Property and Technology Affairs] to [Alpharma Ltd's Marketing Manager] and others dated 29 April 2002 (document 1309).

²¹⁰⁰ [X]WS (document 1587), paragraph 3.9.

²¹⁰¹ Email chain between [Alpharma ApS's Director of Intellectual Property and Technology Affairs], [Alpharma Inc's President (Human Generics)], [VP New Products – FP at Alpharma ApS], [Alpharma Ltd's Director of Sales and Marketing], [Alpharma ApS's Sales and Marketing Director], [Alpharma Inc's Vice President of Intellectual Property] and [Alpharma Ltd's Marketing Manager] dated 7 June 2002 (document 1314).

²¹⁰² Actavis SO Written Response (document 2754), paragraphs 7.28–7.32. GSK SO Written Response (document 2754), paragraphs 7.23–7.36.

²¹⁰³ For example, see Actavis SO Written Response (document 2754), paragraphs 7.20–7.27 and 7.39. GSK SO Written Response (document 2755), paragraph 7.46–7.47.

Alpharma considered whether it was possible to halt production of the orders that had been placed from Delta.²¹⁰⁴ Actavis stated that there was a real concern within Alpharma that Delta used a displacement step covered by the remaining claims of GSK's Anhydrate Patent and Alpharma's external lawyers had identified this was a real risk for Alpharma²¹⁰⁵ and therefore the situation was becoming increasingly complicated for Alpharma. For example:

- GSK referred to a document from June 2002, following the hearing in the BASF case, in which [Alpharma ApS's Director of Intellectual Property and Technology Affairs] states that *'I still think we are in a good position, but it is no "walk over". GSK is a significant opponent, and we will spend a considerable amount of money on this endeavour'*.²¹⁰⁶
- GSK referred to an email from [Alpharma Inc's Vice President of Intellectual Property] on 1 August 2002 which reports on the results of the interim injunction hearings and stated that the Alpharma Undertaking was *'disappointing news'*²¹⁰⁷ for Alpharma.
- Actavis referred to a document on 2 September 2002, in which Alpharma considered whether it was possible to halt production of the orders that had been placed from Delta.²¹⁰⁸
- Actavis referred²¹⁰⁹ to the email from [Alpharma ApS's Sales and Marketing Director] to [Alpharma's Quality Operations Manager] on 3 October 2002 which stated: *'With all the current litigation problems I*

²¹⁰⁴ Actavis SO Written Response (document 2754), paragraphs 3.17(a) and (c): Email chain between [Alpharma Ltd's Marketing Manager] and [Alpharma Ltd's Director of Sales and Marketing] dated 4 September 2002 (document A 0056), entitled 'Paroxetine – production to continue?'. See also Email from [Alpharma ApS's Sales and Marketing Director] to [Alpharma's Quality Operations Manager] and others dated 3 October 2002 (document A 0057). Email chain from [Alpharma ApS's Sales and Marketing Director] to [Alpharma's Quality Operations Manager] dated 4 October 2002 (document A 0053).

²¹⁰⁵ See email from [Alpharma's external lawyer] of [external law firm] to [Alpharma Ltd's Director of Sales and Marketing] dated 2 September 2002 (document A 0048).

²¹⁰⁶ GSK SO Written Response (document 2755), paragraph 7.45.

²¹⁰⁷ Email chain between [Alpharma ApS's Sales and Marketing Director], [Patent Specialist and Patent Manager at Alpharma ApS], [Alpharma ApS's patent attorney], [Alpharma Inc's Vice President of Intellectual Property], [Alpharma's Head of Purchasing], [Alpharma Ltd's Director of Sales and Marketing], [Alpharma Inc's President (Human Generics)], [VP New Products – FP at Alpharma ApS], [Alpharma Inc's Chief Legal Officer], [Alpharma's external lawyer] of [external law firm] dated 1 August 2002 (document 1331), entitled 'Disappointing Paroxetine hearing'.

²¹⁰⁸ Actavis SO Written Response (document 2754), paragraphs 3.17(a) and (c): Email chain between [Alpharma Ltd's Marketing Manager] and [Alpharma Ltd's Director of Sales and Marketing], dated 4 September 2002 (document A 0056), entitled 'Paroxetine – production to continue?'

²¹⁰⁹ Actavis SO Written Response (document 2754), paragraph 3.17(c).

*suggest we cancel all orders we can cancel as of now. This thing [the litigation] will draw on for a very long time.*²¹¹⁰

- Actavis referred to an email dated 4 October 2002 in which [Alpharma ApS's Sales and Marketing Director] stated: *'It is unlikely that we can launch Paroxetine in the UK in the near future. I will ask you to investigate whether some of the UK stock held in Iceland can be repacked to meet demand in other markets who will launch before the UK. Otherwise, I'm concerned that we will end up with some serious scrapping during 2003'*.²¹¹¹

G.7 GSK also submitted that it was conceivable that Alpharma did not necessarily have all the relevant material concerning the Alpharma Product from the outset of litigation or from the start of its preparations, which is likely to be a *'further reason why its views as to infringement wavered'*.²¹¹²

G.8 The CMA refers to paragraphs 3.326 to 3.354 in relation to the Alpharma Undertaking. Further, the CMA observes that:

- Even if the Alpharma Undertaking may have made Alpharma more cautious than it was earlier in the Alpharma Litigation, the documents and witness evidence simply reflect the fact that Alpharma may have been less bullish than it was previously about its chances of success. There is no suggestion from the documentary evidence that Alpharma was ready to walk away from the Alpharma Litigation, or would have been willing to abandon its efforts to enter the market independently, had it not received sufficient compensation. Rather, and consistent with Alpharma's decision to continue to contest the Alpharma Litigation for a period of five months from the start of the Alpharma Litigation (and more than three months after the Alpharma Undertaking), the internal documents in fact show that there was genuine uncertainty on both sides as to Alpharma's and GSK's prospects in the Alpharma Litigation, and of Alpharma entering the UK paroxetine market independently of GSK at the time that the Alpharma-GSK Agreement was entered into, such that there remained the potential for Alpharma to enter the market independently. Indeed, GSK states that

²¹¹⁰ Email from [Alpharma ApS's Sales and Marketing Director] to [Alpharma's Quality Operations Manager] and others dated 3 October 2002 (document A 0057).

²¹¹¹ Email chain from [Alpharma ApS's Sales and Marketing Director] to [Alpharma's Quality Operations Manager] dated 4 October 2002 (document A 0053).

²¹¹² GSK SO Written Response (document 2755), paragraph 7.53. Alpharma internal report by [Alpharma ApS's patent attorney] entitled 'Status summary Paroxetine' dated 17 July 2002 (document 1323).

'[b]oth parties were clearly prepared to continue litigation' and 'neither party could be confident regarding the final outcome'.²¹¹³

- Internal Alparma documents demonstrate that, notwithstanding certain concerns with respect to the patent position, Alparma continued to consider, as the Alparma Litigation developed, that it could have entered the UK paroxetine market with a non-infringing product. In particular:
 - In respect of the Anhydrate Patent, [Alparma Inc's Vice President of Intellectual Property] reported:²¹¹⁴ *'[Our external patent lawyer] is optimistic that as soon as the independent expert sees the process, and presumably agrees with us, we can strongly urge SKB to drop the case'*.
 - By 19 August 2002, [Alparma ApS's patent attorney] prepared a note which reflected Alparma's view that GSK's patents did not mean that it would not be able to enter the UK paroxetine market:²¹¹⁵

*'Alparma was originally accused by SKB of infringing **GB 2 297 550** (the "anhydrate patent") and **EP 0 223 403** (the "hemihydrate patent").*

*For **EP B 0 223 403** experiments conducted in connection with the present trial showed that no hemihydrate was found in the tablets. Stability studies conducted by Delta indicate the tablets are stable over time, but this may become an issue again. Presently, Alparma is not accused of infringing the hemihydrate patent.*

*A large part of the anhydrate patent claims have been declared invalid. The only unamended claim of **GB 2 297 550** is (old) claim 11, which claims the use of a displacement agent in order to displace solvated solvent. BASF claims not to use this step, and are willing to allow an inspection, given the right confidentiality assurance. [...] An inspection is likely to resolve the matter in the beginning of September 2002.*

²¹¹³ GSK SO Written Response (document 2755), paragraph 7.26(q).

²¹¹⁴ Email chain between [Alparma ApS's Sales and Marketing Director], [Patent Specialist and Patent Manager at Alparma ApS], [Alparma ApS's patent attorney], [Alparma Inc's Vice President of Intellectual Property], [Alparma's Head of Purchasing], [Alparma Ltd's Director of Sales and Marketing], [Alparma Inc's President (Human Generics)], [VP New Products – FP at Alparma ApS], [Alparma Inc's Chief Legal Officer], [Alparma's external lawyer] of [external law firm] dated 1 August 2002 (document 1331), entitled 'Disappointing Paroxetine hearing'.

²¹¹⁵ Alparma internal report by [Alparma ApS's patent attorney] entitled 'Paroxetine hydrochloride anhydride patent situation in Germany, Copenhagen' dated 19 August 2002 (document 1335).

The patent EP B 0 734 260 is currently under opposition in the EPO. The claims on file indicate the anhydrate form will not be covered.' (emphasis as in original)

- In late August 2002, Alparma was still considering that it may be possible to launch in September 2002. Alparma's 'New Product Team Report' dated 30 August 2002, shows that all steps had been completed for the Alparma Product launch (for example, artwork proofs returned, PIP code obtained). This report, dated 30 August 2002, stated that for paroxetine:²¹¹⁶

[Alparma ApS's Sales and Marketing Director] confirmed we may still launch Sept if the judge removes the injunction. Await further info. Product packed at Delta ready for release. 20mg – 44.5K packs, 30mg – 10.5K packs.'

- In an update on the status of the Alparma Litigation, prepared by [Alparma ApS's patent attorney] on 12 September 2002, Alparma considered that a judgment in the Alparma Litigation would be possible towards the end of 2002, and that aspects of the proceeding had benefited Alparma. In particular, there is no evidence to suggest that Alparma considered doing anything other than proceeding with the Alparma Litigation. Extracts from that status report are as follows:²¹¹⁷

'It resulted from the hearing Monday that BASF and Delta are not joined in our proceedings. However, BASF and Delta has agreed to give disclosure of their processes, which should work to our benefit.

...

Lately, the judge seems not to be sympathetic to our [anhydrate] cause; maybe he compares our business to counterfeiting.

...

At present our solicitors are struggling to keep our trial date of 22 October 2002. The trial should take 3 to 4 days, and we may expect a verdict in a few days, extending to possibly as long as a month. This will bring us to November or early December 2002.'

²¹¹⁶ Document entitled 'New Product Team Report' dated 30 August 2002 (document 1337).

²¹¹⁷ Alparma internal report by [Alparma ApS's patent attorney] entitled 'Paroxetine update' dated 12 September 2002 (document 1346).

- In an internal e-mail dated 6 November 2002, shortly before entering into the Alharma-GSK Agreement, [Alharma ApS's patent attorney] reported that there was no *'terribly disturbing news'* to report following a GSK statement of case in the Alharma Litigation:²¹¹⁸

'While GSK was expected to make a statement of case last monday [sic], 4 November 2002, this statement was very limited. Either [GSK] do not have a very strong case, or they are going to surprise us all just before the trial.'

...

In short, there are [sic] no terribly disturbing news from the trial.'

G.9 Further, in their written representations, the Parties acknowledged the uncertainty of the Alharma Litigation and that GSK and Alharma had differing views of their respective positions in the Alharma Litigation.²¹¹⁹

G.10 Consistent with this, the later evidence following the commencement of the Alharma-GSK Agreement (including when Alharma was considering the extension of the Alharma-GSK Agreement) demonstrates that Alharma continued to consider that the Alharma Product was non-infringing. For example:

- In an email from [Alharma Inc's Vice President of Intellectual Property], summarising discussions that took place on 4 September 2003, [Alharma Inc's Vice President of Intellectual Property] stated that Alharma was *'comfortable'* it would win any patent challenge from GSK if it were to

²¹¹⁸ Email from [Alharma ApS's patent attorney] to [Alharma Inc's President (Human Generics)], [Alharma ApS's Sales and Marketing Director], [VP New Products – FP at Alharma ApS], [Alharma Ltd's Director of Sales and Marketing], [Alharma Inc's Vice President of Intellectual Property] dated 6 November 2002 (document 1388).

²¹¹⁹ Each of GSK, Alharma and Xellia-Zoetis acknowledged this in their written representations. GSK SO Written Response (document 2755), chapter 7 stated that *'[t]he parties had strong but opposing views regarding the patent position but neither party could be certain of the outcome of litigation.'* Actavis SO Written Response (document 2754), paragraph 7.11: *'...patent litigation is subject to considerable uncertainty: there is a certain probability that a court would have found GSK's patents valid and infringed and vice versa. These probabilities are unknown and hard to estimate with any reliable precision (and indeed...were unknown and hard to estimate at the time of settlement).'* Xellia-Zoetis SO Written Response (document 2767), paragraph 174 *'...Alharma merely exchanged the uncertainty of litigation and certainty of exclusion pending invalidation of the dry tableting patent for immediate entry and the option to change to an independent supplier immediately after that became available.'*

launch independently rather than renew the GSK-Alpharma Agreement.²¹²⁰

- In a further document considering the termination or extension of the Alpharma-IVAX Agreement, it is stated that it would be *'tough'* for GSK to prevail in a challenge relating to the Anhydrate Patent.²¹²¹

' - API supplier does not use this step [a displacement step which could infringe the Anhydrate Patent]

- [...] GSK may argue that displacement steps occurs during tablet process at Delta

- Tough argument for GSK to win, likely no infringement.' (emphasis in original)

iii) The Hemihydrate Patent

G.11 The Parties submitted that Alpharma considered the Hemihydrate Patent to be *'quite strong'*, and recognised that the Hemihydrate Patent could be raised again by GSK at a later stage.²¹²² Actavis referred to an internal document dated 4 September 2002 in which [Alpharma ApS's patent attorney] noted, in relation to the Hemihydrate Patent that: *'[s]tability studies conducted by Delta indicate that the tablets are stable over time, but this may become an issue again'*.²¹²³

G.12 However, the CMA notes that the evidence presented in relation to the risk of potential conversion of the Alpharma Product (from anhydrate to hemihydrate) was no longer a contested issue at the time the Alpharma-GSK Agreement was entered into, given that testing by GSK had found that the Alpharma

²¹²⁰ Email from [Alpharma Inc's Vice President of Intellectual Property] to [Alpharma Inc's CEO] and [Alpharma Inc's Chief Financial Officer] dated 4 September 2003 (document 1434).

²¹²¹ Alpharma internal presentation entitled 'Paroxetine UK Patent Situation' (document 1295), slide 1. This document was submitted by Actavis and was described as having been prepared in connection with the decision whether to terminate or extend the supply arrangements with GSK or to launch Alpharma's own product.

²¹²² Actavis SO Written Response (document 2754), paragraphs 3.21–3.22. Xellia-Zoetis SO Written Response (document 2767), paragraph 115. GSK SO Written Response (document 2755), paragraphs 6.21 (i) and 6.29(b) with respect to the GUK Litigation and paragraph 7.44 with respect to Alpharma. Email chain between [Alpharma Ltd's Marketing Manager], [Alpharma ApS's Director of Intellectual Property and Technology Affairs] and others dated 29 April 2002 (document 1309). [X]WS (document 1315), paragraph 11. Alpharma report entitled 'Paroxetine hydrochloride anhydride patent situation in the European Alpharma markets, Copenhagen 4 September 2002' by [Alpharma ApS's patent attorney] dated 4 September 2002 (document 1344).

²¹²³ Alpharma internal report by [Alpharma ApS's patent attorney] entitled 'Paroxetine hydrochloride anhydride patent situation in Germany, Copenhagen' dated 19 August 2002 (document 1335).

Product did not infringe the Hemihydrate Patent by that stage.²¹²⁴ The main issue that remained to be decided was whether the Alparma Product infringed claim 11 of GSK's Anhydrate Patent and this was due to be heard in a trial dated 9 December 2002.²¹²⁵

G.13 In any event, as with the Alparma Undertaking, the CMA observes that even if the prospect of litigation on the Hemihydrate Patent may have made Alparma more cautious, there is no suggestion from the documentary evidence that, as a result of potential litigation on the Hemihydrate Patent, Alparma would have been willing to abandon its efforts to enter the market independently without sufficient compensation. Rather, the documentation indicates that the ultimate outcome of litigation, whether in relation to the Anhydrate or Hemihydrate Patents, remained uncertain, such that there remained the potential for GUK to enter the market independently of GSK. These documents therefore do not alter the CMA's assessment that GUK was a potential competitor to GSK.

iv) *Dry Tableting Patent*

G.14 In relation to the Dry Tableting Patent, GSK and Actavis submitted that internal documents indicate that Alparma considered that the Alparma Product infringed the Dry Tableting Patent and therefore its only option was to seek the invalidation of this patent.²¹²⁶ For example, the Parties referred to the following evidence:

²¹²⁴ This was confirmed following a GSK inspection of the production facility of Delta, Alparma's supplier of paroxetine, in October 2002, see GSK Second Response, Part Two (document 0734), paragraph 7.3. See SO paragraph 7.230.

²¹²⁵ A Court Order dated 9 September 2002 permitted GSK to carry out an inspection of the Iceland plant of Delta (Alparma's supplier). This took place in October 2002. GSK state that this test confirmed that the product was an anhydrate (Form A) (see GSK SO Written Response (document 2755), paragraph 7.26).

²¹²⁶ GSK SO Written Response (document 2755), paragraph 7.50. Actavis SO Written Response (document 2754), paragraphs 3.233.26. Xellia-Zoetis SO Written Response (document 2767), paragraphs 63 and 104. Alparma internal document entitled 'Alparma/SKB Tableting Patent' (document 1287). Email chain between [Alparma ApS's Sales and Marketing Director], [Patent Specialist and Patent Manager at Alparma ApS], [Alparma ApS's patent attorney], [Alparma Inc's Vice President of Intellectual Property], [Alparma's Head of Purchasing], [Alparma Ltd's Director of Sales and Marketing], [Alparma Inc's President (Human Generics)], [VP New Products – FP at Alparma ApS], [Alparma Inc's Chief Legal Officer], [Alparma's external lawyer] of [external law firm] dated 1 August 2002 (document 1331), entitled 'Disappointing Paroxetine hearing'. Email chain between [Alparma ApS's Sales and Marketing Director], [Alparma Inc's President (Human Generics)] and others dated 11 October 2002 (document 1360). Alparma internal document entitled 'Alparma Possible action on the SKB tableting patent' (document 1288). Actavis SO Written Response (document 2754), paragraphs 3.23–3.26. Xellia-Zoetis SO Written Response (document 2767), paragraph 115. [X]WS (document 1315), paragraph 11. Report by [Alparma ApS's patent attorney] entitled 'Paroxetine hydrochloride anhydride patent situation in the European Alparma markets, Copenhagen' dated 4 September 2002 (document 1344). Xellia-Zoetis SO Written Response (document 2767), paragraphs 112–113. Instructions to counsel in the Alparma Litigation dated 13 June 2002 (document A 006), pages 3 and 5. Email from [Alparma ApS's patent attorney] to [Alparma ApS's Sales and Marketing Director] and others dated 15 October 2002 (document 1363).

- A passage of the Alharma report on the Dry Tableting Patent (undated) which stated: *'The patent covers the dry tableting of paroxetine in any form, and tablets containing paroxetine made by a dry tableting process. It would appear that Delta infringe this patent and that the tablets to be marketed by Alharma will accordingly also infringe in those jurisdictions where the patent is in force'*.²¹²⁷
- A report dated 4 September 2002 stated: *'If [the Dry Tableting Patent] is upheld in its present form, it may impede the activities of Alharma for the designated states DE, DK, GB, NL, PT and SE.'*²¹²⁸
- An internal email from [Alharma ApS's patent attorney] dated 4 October 2002 referred to a range of possible outcomes and noted that invalidation proceedings in respect of the Dry Tableting Patent *'might be over somewhere between december [sic] 2002 and may [sic] 2003.'*²¹²⁹ (see paragraph 3.350).
- An email dated 11 October 2002 stated that it would be *'impossible to launch before well into 2003 due to that patent'*.²¹³⁰

G.15 Xellia-Zoetis states that the only reason the Dry Tableting Patent had not yet been asserted by GSK was because GSK had not received a sample of the Alharma Product and could therefore not test whether the relevant process step had been used.²¹³¹

G.16 However, the CMA notes that:

- GSK had not taken any steps to legally enforce this patent at the time of the GSK-Alharma Agreement.²¹³² Xellia-Zoetis' submission as to the reasons for this supports the fact that there was genuine uncertainty as to the position under the Dry Tableting Patent.

²¹²⁷ Alharma internal document entitled 'Alharma/SKB Tableting Patent' (document 1287).

²¹²⁸ Report by [Alharma ApS's patent attorney] entitled 'Paroxetine hydrochloride anhydride patent situation in the European Alharma markets, Copenhagen' dated 4 September 2002 (document 1344).

²¹²⁹ Email from [Alharma ApS's patent attorney] to [Alharma ApS's Sales and Marketing Director] and others dated 15 October 2002 (document 1363).

²¹³⁰ Email chain entitled 'UK settlement negotiations for Paroxetine – meeting October 11, 2002' dated 14 October 2002 (document 1361).

²¹³¹ Xellia-Zoetis SO Written Response (document 2767), paragraph 112.

²¹³² The CMA notes, for example, that the Dry Tableting Patent was not mentioned in GSK's warning letter dated 27 May 2002 (documents D185, D186 and D187).

- An internal Alharma document (undated²¹³³) set out Alharma's view that the opposition of the Dry Tableting Patent in the EPO *'is likely to succeed'* (albeit that *'the final outcome could take several years'*).²¹³⁴
- Whilst, during September and October 2002, there was some concern²¹³⁵ within Alharma in relation to the Dry Tableting Patent, Alharma continued to consider that it was unlikely to survive the pending opposition procedure before the EPO and that a reasonably swift decision on the matter would be possible from the UK High Court.²¹³⁶ An internal Alharma report dated 2 September 2002 stated that:²¹³⁷

'we may launch by now, as the granted patents and pending applications should not be valid to the extend [sic] they cover Paroxetine hydrochloride anhydrate in Form A and the tablets comprising this API.

While it is unlikely the dry tablet process patent is going to survive the opposition, at least to the extend [sic] it covers the anhydrate form of Paroxetine, it is prudent to estimate any economical risk associated with launch in the face of the presently valid patent.

[...]

UK is special because in a worst case scenario damages may be exceedingly high.'

²¹³³ The CMA infers from the manuscript comments (see document 1287) and the other documents created during that period (see, for example, document 1335) that the document (document 1287) was dated during September 2002.

²¹³⁴ Alharma internal document entitled 'Alharma/SKB Tableting Patent' (document 1287). The CMA notes that, at the time of the GSK-Alharma Agreement, GSK had not brought any action against Alharma in relation to the Dry Tableting Patent.

²¹³⁵ See, for example, email chain between [Alharma Ltd's Director of Sales and Marketing], [Alharma ApS's Sales and Marketing Director], [Alharma Inc's Vice President of Intellectual Property], [Alharma Inc's President (Human Generics)], [Alharma ApS's patent attorney], [Alharma employee], [Alharma Inc's Chief Financial Officer], [Alharma Inc's Chief Legal Officer] dated 14 October 2002 (document 1361), entitled 'UK settlement negotiations for Paroxetine – meeting October 11, 2002'.

²¹³⁶ Alharma internal document entitled 'Alharma/SKB Tableting Patent' (document 1287). See email from [Alharma ApS's patent attorney] to [Alharma ApS's Sales and Marketing Director] and others dated 15 October 2002 (document 1363).

²¹³⁷ Alharma report entitled 'Paroxetine hydrochloride anhydride patent situation in the European Alharma markets, Copenhagen 4 September 2002' by [Alharma ApS's patent attorney] dated 4 September 2002 (document 1344).

- In October 2002, Alparma's patent advisers continued to consider there to be '*a strong case for complete anticipation*' for the Dry Tableting Patent, such that the patent would be invalidated.²¹³⁸

- G.17 With respect to timing, internal Alparma documents refer to the options and timing of an invalidation case in respect of the Dry Tableting Patent. Alparma's patent advisers considered that such a case would be decided between December 2002 at the earliest and May 2003 at the latest.²¹³⁹ Further, the documents cited by the Parties relate to delays to the timing of Alparma's entry to the UK paroxetine market,²¹⁴⁰ rather than indicating that Alparma considered entry would not take place at all. Even in the event of a delay as a result of invalidation proceedings on the Dry Tableting Patent, this does not undermine the CMA's finding that Alparma was a potential competitor to GSK.²¹⁴¹
- G.18 Finally, the CMA observes that, if the Parties' submissions as to potential infringement of the Hemihydrate Patent and/or Dry Tableting Patent and the prospect of future litigation were to be accepted, this would mean that Alparma would not have been a potential competitor even after they had entered the market in 2004, as GSK could have claimed at that stage that its Hemihydrate Patent and/or Dry Tableting Patent were infringed.

B. GSK's documents

- G.19 Internal GSK documents also indicate genuine uncertainty within GSK as to its prospects of preventing Alparma from entering the UK paroxetine market independently of GSK. See Annex E Section B which equally applies in the case of the Alparma-GSK Agreement.
- G.20 GSK submitted that these documents: (i) are not specific to Alparma; (ii) underscore GSK's submissions that the CMA does not have any probative evidence that GSK regarded Alparma as a potential competitor; and (iii) show that the CMA has not addressed itself to the underlying reality of infringement litigation.²¹⁴²

²¹³⁸ Email from [Alparma ApS's patent attorney] to [Alparma ApS's Sales and Marketing Director] and others dated 15 October 2002 (document 1363).

²¹³⁹ Email from [Alparma ApS's patent attorney] to [Alparma ApS's Sales and Marketing Director] and others dated 15 October 2002 (document 1363).

²¹⁴⁰ For example, the Alparma internal document entitled 'Alparma/SKB Tableting Patent' (document 1287).

²¹⁴¹ See, for example, judgment of 3 April 2003 in *BaByliss SA v Commission*, T-114/02, ECR,EU:T:2003:100, paragraph 102.

²¹⁴² GSK SO Written Response (document 2755), paragraphs 7.33–7.35.

G.21 The CMA considers that these documents demonstrate GSK's overall views in relation to its prospects in any litigation surrounding its paroxetine patents.

ANNEX H: REPRESENTATIONS ON WHETHER THE ALPHARMA-GSK AGREEMENT RESTRICTS COMPETITION BY OBJECT

A. Representations on the entry restrictions in the Alpharma-GSK Agreement

- H.1 Actavis submitted that because the terms of the Alpharma-GSK Agreement had a limited initial duration of 12 months and Alpharma had a right to terminate on one month's notice,²¹⁴³ the terms preserved the ability for Alpharma to determine its own degree of commercial risk and also if and when it was prepared to launch.²¹⁴⁴
- H.2 The CMA observes that the reality is that Alpharma entered into and maintained the Alpharma-GSK Agreement over a period of one year and three months. Moreover, Alpharma's right to terminate on one month's notice was limited to circumstances in which generic entry led to average market prices falling below £8.45, or upon the '*demise*' of claim 11 of the Anhydrate Patent (see paragraph 3.368). As such, Alpharma preserved its ability to launch only in those circumstances where GSK had failed in its strategy of seeking to defer the threat of true generic competition. Alpharma accepted entry restrictions that ensured that, for as long as no other party was successful in entering the market independently of GSK, it would not seek to do so.
- H.3 GSK submitted that the CMA is incorrect to state that the Alpharma-GSK Agreement deferred rather than settled their dispute. In this regard, GSK stated that the Alpharma-GSK Agreement did not restrict Alpharma from entering the market independently of GSK following the expiry of the Alpharma-GSK Agreement, and it did not prevent Alpharma from challenging the validity of GSK's patents.²¹⁴⁵
- H.4 The CMA observes that under the terms of the Alpharma-GSK Agreement the Parties did not resolve the substantive issues that were the subject of the litigation between them (see paragraph 6.154). The issues being contested by the Alpharma Litigation (which was focussed on whether Alpharma's generic product infringed claim 11 in the Anhydrate Patent rather than on its validity) were not therefore resolved and, under the terms of the Alpharma-GSK

²¹⁴³ Actavis written response dated 25 November 2014 to the SSO (document 3653), paragraphs 3.27–3.28.

²¹⁴⁴ Actavis written response dated 25 November 2014 to the SSO (document 3653), paragraph 3.25.

²¹⁴⁵ GSK SO Written Response (document 2755), paragraph 6.113.

Agreement, were deferred until the Alparma-GSK Agreement expired, or until the relevant issues were resolved as a consequence of a dispute between GSK and another generic supplier. Consistent with this, the Alparma-GSK Agreement expressly recognised the prospect of subsequent litigation in relation to paroxetine hydrochloride in the UK between Alparma and GSK after the Alparma-IVAX Agreement had ended and reserved all prospective rights and causes of action for GSK and Alparma in respect of that litigation.²¹⁴⁶

i) Representations on value transfers in the Alparma-GSK Agreement

a) Representations on the volume restriction

H.5 GSK submitted that, even if the volume restriction operated as alleged by the CMA, the Alparma-GSK Agreement provided for competition on the basis that it allowed for a reasonable profit margin and a substantial volume of product.²¹⁴⁷

H.6 Although the Alparma-GSK Agreement provided for what GSK considers to be a reasonable profit margin and a material product volume, the CMA does not accept that the Alparma-GSK Agreement provided for a meaningful increase in the competitive constraints faced by GSK. As explained above, the CMA considers that as a consequence of the volume restrictions, Alparma was not incentivised to price materially below prevailing market levels. Consistent with this, the CMA notes that the introduction of the Alparma-GSK Agreement (and the earlier Agreements with IVAX and GUK) had no material impact on prices in the relevant market (see paragraph 3.387). The ‘reasonable’ profit margin represented a value transfer, and did not provide for effective price competition.

H.7 GSK submitted that Alparma was not constrained by volume provisions because: (i) the 500,000 packs that GSK provided Alparma with was a reasonable forecast for sales in a market with two existing sellers of generic product; (ii) volumes agreed with Alparma were very close to the volumes of independent product that Alparma proposed to supply; and (iii) when the Agreement was renewed GSK increased volumes to 620,000 packs per year, an amount which was effectively agreed as part of the original settlement.²¹⁴⁸

²¹⁴⁶ Alparma-GSK Settlement Agreement (document 0356), clause 9.

²¹⁴⁷ GSK SO Written Response (document 2755), paragraph 6.171.

²¹⁴⁸ GSK SO Written Response (document 2755), paragraph 7.126.

H.8 The CMA does not accept these submissions and observes that:

- Alparma's forecast sales through independent entry totalled 728,000 packs²¹⁴⁹ (of 20mg and 30mg packs) in the first year after entry, which is substantially higher than the volume allowance of 500,000 pack included in the first year of the Alparma-GSK Agreement.
- In any case, it remains that GSK would only supply product up to agreed levels and Alparma could not supply more than this quantity. Alparma ordered the maximum available prior to independent entry taking place (data on the volume of product that IVAX supplied to Alparma shows that, during the Alparma-GSK Agreement, Alparma received 416,666 packs in the first contract year which equates to 100% of the restricted volume available to Alparma in that year).²¹⁵⁰
- The CMA considers that the increase in the volume allowance demonstrates that the level of the restriction changed, but not that there was no constraint on the volumes that Alparma could purchase. As discussed at paragraph 6.165, GSK only granted such an increase in return for extinguishing a debt from GSK to Alparma of £500,000. For completeness, the CMA also notes that the evidence does not support GSK's claim that the changes to the volume allowance had been pre-agreed at the time of the original settlement (see for example, paragraphs 3.360, 3.361, 3.367 and 3.374).

H.9 In relation to Alparma's reasons for entering into the Alparma-GSK Agreement, Actavis submitted that the offer of product enabled Alparma to gain immediate access to the market and prior to the date on which it could have entered independently of GSK.²¹⁵¹

H.10 The CMA observes that the early entry that the Alparma-GSK Agreement provided for was by means of a value transfer, and that Alparma's entry with a limited volume of paroxetine could not reasonably have been expected to increase the competitive constraints faced by GSK. In any case, the CMA does not consider that the existence of other benefits undermines the finding that Alparma accepted value transfers as compensation for its acceptance of the entry restrictions included within the Alparma-GSK Agreement.

²¹⁴⁹ Alparma spreadsheet entitled 'Opening order quantities of Paroxetine' (document 1348).

²¹⁵⁰ See paragraph 7.80 for details of calculations.

²¹⁵¹ Actavis SO Written Response (document 2754), paragraph 4.14 (b).

b) Representations on production and preparation costs

- H.11 Actavis and Xellia-Zoetis submitted that these payments (and other value transfers) are reasonable when considered in the context of the cross-undertaking in damages that existed in relation to the litigation between GSK and Alpharma (see paragraphs 6.191 to 6.192).
- H.12 For the reasons set out in paragraphs 6.193 to 6.196, the CMA does not consider that the existence of the cross-undertaking undermines its finding that, in the circumstances of this case, the payments in respect of Alpharma's legal, production and presentation costs represented value transfers that were made in return for Alpharma's acceptance of entry restrictions.

c) Representations on the Parties' intentions

- H.13 Actavis submitted that the value transfer did not alter Alpharma's paroxetine strategy or its evaluation of the risks associated with entry, because (i) Alpharma had a low appetite for risk such that it would not enter the market 'at risk' pending an appeal; and (ii) that its paroxetine patent strategy had failed.²¹⁵²
- H.14 The CMA observes that Alpharma's alleged unwillingness to enter 'at risk' is not relevant to the analysis presented above, as its willingness to do so does not alter the conclusion that Alpharma regarded the value transfers as compensation that it required in return for its acceptance of the entry restrictions. The CMA observes that because the restrictions Alpharma accepted deferred the judicial process that would have determined whether Alpharma's product infringed claim 11 of the Anhydrate Patent, the restrictions evidently impacted upon Alpharma's entry strategy by deferring its potential market entry.²¹⁵³ Alpharma therefore accepted restrictions that deferred the earliest date on which it could enter, whether 'at risk' or otherwise.
- H.15 As established at paragraph 6.79, at the time it entered into the Alpharma-GSK Agreement, Alpharma was a potential competitor to GSK. The evidence does not support Alpharma's assertion that its strategy had 'failed' in the sense that it was not a potential competitor to GSK at the time it entered into the Alpharma-GSK Agreement. To the contrary, at the time the Alpharma-

²¹⁵² Actavis written response dated 25 November 2014 to the SSO (document 3653), paragraphs 3.13 and 3.14.

²¹⁵³ For example, on the basis of the initial one year term of the Alpharma-GSK Agreement (which the CMA notes was then extended), Alpharma's proposed entry would (other things being equal) have been delayed by at least a year, as any such entry following the expiry of the Alpharma-GSK Agreement would have been subject to renewed litigation.

GSK Agreement was entered into, Alparma had developed its product and was continuing to contest the litigation with GSK, which GSK had launched in response to Alparma's proposed market entry (see paragraph 6.79).

- H.16 Xellia-Zoetis submits that the Alparma-GSK Agreement represented a commercially rational agreement that was '*perfectly in line with what the court deemed to be an appropriate balancing of risk between the parties*'.²¹⁵⁴ In this regard, Xellia-Zoetis noted that: (i) the settlement '*perfectly mirrored the balance in the court-approved undertaking*' as Alparma would not enter independently while GSK would pay Alparma's damages; and (ii) the Agreement enabled GSK to avoid litigation costs and the lost profits of independent entry, and Alparma to avoid the threat of a significant damages claim from GSK and the possibility that its litigation undermine that being pursued by BASF.²¹⁵⁵
- H.17 The CMA considers that the terms described by Xellia-Zoetis are consistent with an anti-competitive agreement in which GSK has paid Alparma to accept entry restrictions. Although the Alparma-GSK Agreement mirrored the cross-undertaking insofar as Alparma was provided with compensation for being prevented from entering the market independently of GSK, the CMA observes that Xellia-Zoetis has described a situation in which GSK has compensated Alparma for agreeing to defer the relevant litigation and its potential independent generic entry, and as a means of delaying the '*lost profits of independent entry*'.
- H.18 The CMA observes that the existence of other considerations does not alter the finding that the Alparma-GSK Agreement included value transfers from GSK which were made in return for Alparma's acceptance of entry restrictions. In any case, the CMA observes that Alparma could have avoided damages exposure even if it had continued with the litigation (by not entering 'at risk'), or had it settled on terms that did not involve value transfers made in return for entry restrictions.
- H.19 In relation to the BASF litigation, the CMA observes that the evidence indicates that in the absence of a settlement agreement with GSK, Alparma would have continued to contest its litigation with GSK, and there is no evidence that it had decided not to so on the basis of concerns relating to the impact on the BASF case (see Part 6 Section 6.141). Furthermore, the CMA does not in any case consider that the questions of patent infringement that

²¹⁵⁴ Xellia-Zoetis submission on points raised at the oral hearing dated 15 December 2014 (document 3715), paragraph 6.

²¹⁵⁵ Xellia-Zoetis submission on points raised at the oral hearing dated 15 December 2014 (document 3715), paragraph 6.

were to be addressed by the Alparma Litigation could have been expected to undermine the position of BASF at that time. The appeal that GSK had brought concerned the validity of the many claims in the Anhydrate Patent that had been held invalid, whereas the Alparma Litigation was considering whether the Alparma Product infringed one of two claims that was held valid (claim 11) following the BASF Litigation (see paragraph 3.337).

- H.20 Actavis submitted that Alparma sought to negotiate as competitive terms as was possible in the circumstances.²¹⁵⁶
- H.21 The CMA notes that while Alparma may have initially sought a settlement that provided for its independent entry by April 2003, the evidence demonstrates that it was ultimately willing to accept the value transfers from GSK in return for Alparma's commitment not to enter the market independently of GSK (see paragraphs 6.199 to 6.203). Just as GSK was apparently unwilling to accept the terms proposed by Alparma, it was open to Alparma to refuse the entry restrictions and the value transfers which were made in return for its acceptance of them.

²¹⁵⁶ Actavis SO Written Response (document 2754), paragraph 8.11.

ANNEX I: REPRESENTATIONS ON EFFECTS

I.1 The SO Addressees made representations regarding the effects of the Agreements that are relevant to each Agreement. This Section sets out the key submissions and the CMA's responses to them.

A. Appropriate measure of prices

I.2 In considering developments in prices before, during and after the Agreements, the CMA used data provided by relevant parties on the prices at which branded and generic paroxetine was sold to pharmacies.²¹⁵⁷

I.3 However, GSK,²¹⁵⁸ GUK²¹⁵⁹ and Teva²¹⁶⁰ submitted that the Agreements resulted in a positive welfare effect and a reduction in the Drug Tariff price of paroxetine 20mg for the NHS, in particular due to the Drug Tariff category change of paroxetine from C to A following entry of the Generic Companies. GSK submitted that by focussing on prices at which paroxetine was sold to pharmacies, the CMA's analysis has the wrong focus and has ignored effects on the NHS.²¹⁶¹

I.4 The CMA does not agree that the Drug Tariff reimbursement price is the appropriate measure of price for the purpose of assessing the competitive effects of the Agreements:

²¹⁵⁷ Prices are a weighted average net price per DDD and represent the price charged to pharmacies (where a wholesale price was supplied, the CMA applied a mark-up to adjust for the mark-up a wholesaler would have applied in selling to pharmacies). See footnote 611 for a fuller description of the data.

²¹⁵⁸ GSK SO Written Response (document 2755), summary box pages 68 and 257, paragraphs 2.10-2.41, 2.54-2.55 and 8.8. GSK considered that the Agreements led to a 15% reduction in the price paid by the NHS on generic prescriptions of paroxetine 20mg by December 2003 (GSK SO Written Response (document 2755), paragraph 8.8), and estimated that, overall, the Agreements resulted in savings to the NHS of £15.6 million in the period 2002–2003 (GSK SO Written Response (document 2755), paragraph 2 in summary box on page 68, and Annex 3 to the GSK SO Written Response – Report by Charles River Associates entitled 'Consumer welfare analysis – Impact of the supply agreements on the NHS' (document 2757), paragraphs 2.6 and 31).

²¹⁵⁹ GUK SO Written Response (document 2752) paragraphs 5.7 and 5.9 and Annex 1 to GUK SO Written Response (document 2753) page 3 and section 2.4.3. GUK noted that entry by the Generic Companies pursuant to the Agreements had a marked impact on reducing the Drug Tariff by 12% which coincided with a category change of paroxetine from C to A on 1 June 2002 (Annex 1 to GUK SO Written Response (document 2753), Annex A.1, pages 32–33). GUK speculated that although GUK prices did not directly influence the Drug Tariff, they may have done so indirectly since the overlap between GUK and IVAX customers was around 60% and IVAX customers may have been able to negotiate price discounts by credibly threatening to switch to GUK (Annex 1 to GUK SO Written Response (document 2753), page 16). The CMA observes that GUK's market entry was not likely to influence the Drug Tariff price because, as a consequence of the volume restriction, it was not incentivised to price materially below prevailing levels and to constrain the price charged by IVAX. Indeed, its entry under the terms of the GUK-GSK Agreement did not have a material impact on market prices (see paragraph 7.44). In any case, for the reasons explained in paragraph I.4, the CMA does not consider the Drug Tariff reimbursement price to be an appropriate measure of the impact of the Agreements.

²¹⁶⁰ Teva written response dated 21 November 2014 to the SSO (document 3645), paragraphs 15–18.

²¹⁶¹ GSK SO Written Response (2755), paragraph 8.13.

- GSK and the Generic Companies supplied paroxetine to pharmacies, either directly or indirectly through wholesalers. Therefore, to the extent that the Agreements had any impact on price, this impact would be reflected in the price pharmacies paid for medicines. For this reason, the CMA considers that prices to pharmacies, not Drug Tariff reimbursement prices, are the most accurate and direct measure of the competitive impact of the Agreements.
- The question of whether pharmacy price changes were ultimately passed on to the NHS is a function of the pharmacy reimbursement processes put in place by DH. The allocation of monies between pharmacies and the NHS is not relevant to the competition assessment in this case, which concerns competition in the supply of paroxetine to pharmacies.
- The CMA does not consider representations concerning the allocation of monies between pharmacies and the NHS to be capable of reversing a finding that a given agreement has restrictive effects. For example, it would be perverse to find a restriction of competition where a competitive agreement lowered prices to pharmacies but, through a quirk in the remuneration system, resulted in higher costs to the NHS. The converse is equally true, in that an agreement that restricts competition should not be held non-infringing according to the functioning of the reimbursement system as adopted by the NHS and pharmacies.

I.5 In any case, the CMA observes that the reimbursement systems designed by DH are intended to ensure that any decrease in the price paid by pharmacies is passed on to the NHS. As explained at paragraph 3.110, DH uses a mechanism referred to as ‘clawback’ to regulate pharmacy buying profits, which works by providing pharmacies with an initial reimbursement price (set by reference to the Drug Tariff in relation to generic medicines), but then using ‘discount inquiries’ to determine what pharmacies have spent on medicines, and how much of their buying profits DH should take back through ‘clawback’.

I.6 Although GSK²¹⁶² and GUK²¹⁶³ claimed that changes in prices to pharmacies were not ultimately reflected in the ‘clawback’ rate, the CMA observes that this is *ex post* reasoning being used in an attempt justify the Agreements (see paragraphs I.17 to I.24). The reality is that, at the time the Agreements were entered into, a process was in place (using discount inquiries and clawback) that was designed to ensure that NHS costs would vary in line with the prices

²¹⁶² GSK SO Written Response, Annex 3 (document 2757) paragraphs 4–8, GSK SO Written Response (document 2755), paragraphs 2.13–2.15.

²¹⁶³ GUK supplementary submission dated 13 November 2013 (document 3003), page 3.

actually paid by pharmacies. In any case, the evidence does not support the claims made by GUK and GSK. In particular:

- The clawback rate applies across the entire portfolio of medicines, so the impact of paroxetine changes cannot be separately identified in changes to the overall clawback rate.
- Although GSK and GUK assumed that the discount inquiry was only carried out infrequently, and that based on the timing of the changes, earlier entry would have left clawback unaffected,²¹⁶⁴ DH has confirmed that data to inform discount inquiries was usually gathered annually. Therefore, the CMA considers that the fact that no adjustment was made to the clawback rate does not mean that changes in paroxetine prices were not identified. Rather, it suggests that across the range of medicines dispensed by pharmacies, the overall extent of price increases and decreases was such that no change was necessary to ensure that pharmacies received the appropriate level of buying profit.
- Although GSK suggested that paroxetine accounted for less than 1% of the drugs bill and that earlier entry would have had only a small effect on clawback calculations,²¹⁶⁵ the CMA observes that small changes in the clawback rate can equate to significant expenditure on the part of the NHS, whose expenditure on branded medicines in England totalled £5.44 billion in 2003 (such that each 0.1% decrease in branded drug expenditure would have equated to £5 million per annum).²¹⁶⁶

I.7 The CMA notes that, as explained in paragraph 3.387, and set out in the individual effects sections, actual prices remained broadly at prevailing levels following the Generic Companies' entry into the Agreements, and the fact that paroxetine reimbursement prices fell is an artefact of the way that the Drug Tariff and PPRS price mechanisms function (specifically that a generic product being available caused a reduction in the Drug Tariff price, but the parallel imports whose supply was largely displaced by the Generic Companies, and which were being sold at a similar price level, did not reduce the Drug Tariff).²¹⁶⁷

²¹⁶⁴ GSK SO Written Response, Annex 3 (document 2757), paragraphs 5–7.

²¹⁶⁵ GSK SO Written Response, Annex 3 (document 2757) paragraph 8.

²¹⁶⁶ This figure represents branded medicines dispensed in the community (that is, excluding hospital dispensing) in England. The comparable expenditure was £4.769 billion and £5.212 billion in 2001 and 2002 respectively. Source: Table 6 of Prescriptions Dispensed in the Community, Statistics for England - 2001–2011: Tables (available at: <http://www.hscic.gov.uk/catalogue/PUB06941>).

²¹⁶⁷ Indeed, GSK acknowledged the latter point in its representations by stating that because of the way the NHS reimbursement system operated, the reduction in the Drug Tariff price in June 2002 would have resulted from the

B. Counterfactual

i) *The counterfactuals identified by the CMA are not realistic*

1.8 A number of the SO Addressees submitted that the alternative settlement agreements referred to by the CMA are not commercially realistic, and suggested that the evidence indicates that GSK and the Generic Companies were unwilling to consider such agreements.²¹⁶⁸ GUK²¹⁶⁹ and Actavis²¹⁷⁰ made the related submission that they were unable to negotiate supply terms that were more competitive than those adopted in the IVAX-GSK Agreement.

Agreements even if the Agreements had no effect on the prices paid by pharmacies (GSK SO Written Response (document 2755), paragraph 8.13).

²¹⁶⁸ GSK submitted that (i) isolating the value transfer from the alternative settlement negotiations is *'artificial and economically and commercially inaccurate.'*; (ii) it cannot be assumed that GSK and the Generic Companies necessarily would have reached agreement absent value transfers; (iii) an early entry date settlement may not have been commercially realistic, by reference to [GSK's Finance Director A's] statement that *'from a commercial perspective, an agreement by the originator to allow independent entry significantly in advance of patent expiry would, at least in the UK, send a very powerful signal to the market that the originator lacks the determination to defend its patents.'* Witness statement of [GSK's Finance Director A] dated 1 August 2013 (document A 0059), paragraph 3.11; and (iv) the royalty settlement counterfactual contained too many complexities and imponderables to be useful for analysis (GSK SO Written Response (document 2755), paragraphs 1.137, 1.141, 1.146–1.147 and 1.151).

Teva stated that (i) *'GSK would be unlikely to have entered into an agreement on different terms'*; (ii) *'it is not realistic to assume that GSK would have been prepared to facilitate IVAX's immediate entry as a distributor on terms different to those that were agreed'* and (iii) the CMA must show that any alternative contract is commercially realistic and likely to have been mutually acceptable for both parties (Teva SO Written Response (document 2750), paragraphs 21, 232 and 233). GUK submitted that (i) there is no evidence that the Parties could have settled on different terms or that a compromise would have been achieved without any compensation being paid to GUK; (ii) there is no evidence that GSK would have been willing to improve on its settlement offer to GUK, or that any such offer was ever made by GSK and turned down by GUK; (iii) the CMA has not demonstrated that entry would have occurred earlier than December 2003 had GUK agreed an entry date with GSK in the absence of value transfers and (iv) cited the witness statement of [GSK's Finance Director A] dated 1 August 2013 (document A 0059), paragraph 3.11 as evidence that GSK would not have settled on the basis of an early entry date (Slides for GUK SO Oral Hearing dated 15 October 2013 (document 2957), slide 30, GUK SO Written Response (document 2752), paragraphs 3.55, 3.57–3.59 and 6.14–6.15). Merck submitted that the CMA did not provide evidence that alternative agreements would be *'either possible or more competitive'* including, for example, explaining why lower supply prices under an alternative agreement would have been passed on by GUK to consumers and that *'there is no reason to suppose that there existed alternative agreements that might have been acceptable to the parties; or if there were, what those agreements would have looked like'* (Merck SO Written Response (document 2764), paragraphs 5.61, 5.63 and 5.70). Actavis submitted that Alpharma was unsuccessful in attempts to negotiate better terms with GSK and that no settlement would have been achievable absent the value transfers. As regards an early entry agreement Actavis stated that *'GSK was not prepared to allow generics to enter the market with their own product while its patents were still valid and infringed.'* (Actavis SO Written Response (document 2754), paragraphs 10.29, 10.31 and 10.36 and Actavis written response dated 25 November 2014 to the SSO (document 3653), paragraph 3.19). Xellia-Zoetis submitted that (i) *'there is no evidence that Alpharma could have entered on better terms'* and (ii) *'Alpharma accepting to enter on the basis of GSK supply alone cannot be defined as restriction unless the OFT can evidence that there was an alternative proven non-infringing source.'* (Xellia-Zoetis SO Written Response (document 2767), paragraphs 170 and 288).

²¹⁶⁹ GUK submitted that it could not have obtained more competitive terms from GSK because *'GSK was constrained in what it could offer to GUK as a result of its agreement with IVAX.'* (GUK SO Written Response (document 2752), page 8, paragraphs 3.60 and 6.15 and Annex 1 to GUK SO Written Response (document 2753), pages 12–13). GUK also stated that: *'the IVAX/GSK arrangement pre-determined the maximum concessions which GSK could make.'* (GUK SO Written Response (document 2752), paragraph 3.55). See also GUK written response dated 25 November 2014 to the SSO (document 3647), paragraphs 3.9–3.12.

²¹⁷⁰ Actavis submitted that the arrangements between GSK and IVAX pre-determined the parameters of any settlement GSK was prepared to offer (Actavis written response dated 25 November 2014 to the SSO (document 3653), paragraphs 3.21–3.23).

- I.9 The CMA accepts that it cannot be stated with certainty what settlement terms may otherwise have been acceptable to GSK and the Generic Companies. The CMA has instead contrasted the competitive situation under the terms of each Agreement with the range of realistic situations that could have existed in a counterfactual in which each of the Generic Companies remained potential competitors that were seeking to enter the UK paroxetine market independently of GSK whose incentives were not affected by value transfers made in return for (or to incentivise) their acceptance of the relevant entry and/or supply terms.²¹⁷¹
- I.10 The CMA is satisfied that the negotiation of an alternative settlement agreement, including more competitive entry terms, was one of two realistic outcomes in the counterfactual (the other being continued litigation (see, for example, paragraphs 7.48 to 7.53 as regards the GUK-GSK Agreement)). In particular:
- Given the litigation costs that can be saved by settling (rather than deferring) litigation, it is evident that in the counterfactual GSK and the Generic Companies could have had an incentive to explore settlement.
 - Settlement agreements that do not involve value transfers are common in the pharmaceutical sector. For example, empirical evidence from the United States supports the position that branded and generic suppliers can settle their patent disputes without using payments and similar value transfers that are made in return for entry restrictions.²¹⁷²
 - Absent recourse to value transfers in return for entry restrictions which had the purpose of delaying potential generic competition and/or which were made to incentivise a potential entrant to delay its efforts to enter the market independently, it is likely that GSK would have been required to offer more competitive terms to the Generic Companies to provide them with alternative sources of remuneration and a sufficient incentive to settle.
- I.11 GSK's and the Generic Companies' unwillingness to conclude a settlement agreement that did not include value transfers in return for entry restrictions and/or to incentivise the deferral of potential independent generic entry is not

²¹⁷¹ The Court of Appeal's judgment in *National Grid* is relevant to this point. The Court of Appeal stated at paragraphs 56–57 of the judgment: “There is no rule of law that the counterfactual has to take particular form. The Commission's guidance document refers to a range from “the simple absence of the conduct in question” to “another realistic alternative scenario, having regard to established business practices”. It does not say that the alternative scenario must be based on alternative arrangements that the parties to the contracts in issue would or might realistically have made instead, and there is no principle requiring the adoption of such a restrictive approach. The purpose of the counterfactual is simply to cast light on the effect of the conduct at issue.” *National Grid Plc v Gas & Electricity Markets Authority and Others* [2010] EWCA Civ 114.

²¹⁷² For example, see footnote 1169.

evidence that such agreements were not commercially realistic in a situation in which it was not possible to enter into the Agreements. An analysis of the counterfactual must consider the likely outcomes in a situation in which the Agreements were absent. As such, the potential for other settlement agreements to be concluded cannot be dismissed on the basis that GSK preferred to enter into agreements involving value transfers in return for entry restrictions or made to incentivise a potential entrant to defer its efforts to independently enter the market. GSK's actions in discounting alternative (more competitive) settlement agreements are evidence only that it considered the Agreements to be the most profitable option, but not that such other agreements were not realistic options had GSK been unable to enter into the Agreements.

- I.12 The CMA does not consider that, in an analysis of the counterfactual to the GUK-GSK and Alharma-GSK Agreements, the starting point to that assessment should be the existence of entry terms that were a consequence of the IVAX-GSK Agreement induced by value transfers from GSK. The counterfactual should consider the competitive situation in the absence of the Conduct and Agreements covered by the Decision, and GUK and Alharma cannot therefore claim that in the counterfactual there was no alternative settlement agreement that involved terms that were less restrictive than those included in the IVAX-GSK Agreement. In any case, in a counterfactual in which the IVAX-GSK Agreement existed but in which GUK and Alharma were precluded from entering into the GUK-GSK and Alharma-GSK Agreements respectively, the Parties would have had to consider whether they preferred an alternative settlement agreement to further litigation. In GSK's case, it would have had to consider the implications for its arrangement with IVAX, in the knowledge that (i) had it entered into a more competitive settlement with GUK and/or Alharma, IVAX was likely to seek to renegotiate the terms of its Agreement, and (ii) had it declined to settle on less restrictive terms with GUK and/or Alharma, it faced litigation and the threat of true generic competition that would have led to significant price declines and the termination of the IVAX-GSK Agreement. In that scenario, the CMA maintains that renegotiated settlement terms, with both GUK and IVAX or Alharma and IVAX respectively, represented a realistic counterfactual outcome.
- I.13 In any case, the CMA observes that absent an alternative settlement agreement, the only other plausible outcome, that of the Generic Companies continuing to seek to enter the market independently of GSK and therefore continuing litigation and the associated threat of independent generic entry, represented a more competitive outcome. It is evident that GSK was of the same view, as it was for this reason that it was willing to commit to making

value transfers totalling at least £50.9 million to defer that litigation and the associated threat of true generic competition.

ii) *The litigation outcome in the counterfactual*

- I.14 The SO Addressees submitted that the CMA's counterfactual analysis proceeded on the assumption that the Generic Companies would have prevailed in any litigation, and submitted that such an assumption is misplaced.²¹⁷³
- I.15 The CMA's counterfactual analysis does not assume the outcome of the litigation. Rather, the CMA considers that in the counterfactual, and at the time each of the Agreements was entered into, each of the Generic Companies would have remained a potential competitor seeking to enter the market independently of GSK, and GSK remained exposed to the threat of true generic competition.
- I.16 Had GSK continued to pursue patent law claims against the Generic Companies, and had GSK and the Generic Companies declined to settle and accept value transfers that incentivised them to delay their efforts to enter the market independently, or which were in return for entry restrictions, the

²¹⁷³ For example:

- a. GSK submitted that the counterfactual of continued litigation would only have been *'better'* if it were presumed that the litigation would have been won by the generic company in question. With this assumption not being correct, GSK submitted, this cannot be a valid counterfactual. Additionally, GSK stated that *'no reformulation of the language can mask the fact that all that is being contemplated is a chance.'* (GSK SO Written Response (document 2755), paragraphs 1.125–1.130, 1.133, 8.7 and 24).
- b. Teva submitted that the CMA's counterfactuals *'disregard the fact that alternative options would have almost certainly faced successful injunction applications by GSK'* (Teva SO Written Response (document 2750), paragraph 21) and that *'the prospect of a successful outcome in litigation was at best uncertain'*. (Teva SO Written Response (document 2750), paragraphs 21 and 201). See also Teva SO Written Response (document 2750), paragraphs 220, 225 and 228: *'the evidence suggests that IVAX would have lost any litigation'*.
- c. GUK submitted that the CMA assumed that GUK would have prevailed in litigation and that the prospect of GUK's independent entry could only have been maintained if GUK would have won the litigation. (GUK SO Written Response (document 2752), paragraphs 3.15 and 6.8). GUK also submitted that *'it is therefore not enough for the CMA to show that GUK might have succeeded.'* (Annex 1 to GUK SO Written Response (document 2753), page 8 and section 2.1, and GUK SO Written Response (document 2752), paragraphs 3.15 and 6.7–6.8).
- d. Merck submitted that the CMA's analysis assumed GUK would have prevailed in litigation in the counterfactual. Similarly, Merck stated that the CMA seemed to argue that *'the mere continuance of litigation, would, in and of itself, lead to increased competition.'* (Merck SO Written Response (document 2764), paragraphs 5.17–5.23 and 5.45).
- e. Actavis submitted that the CMA's counterfactuals take the position that *'Alpharma should have launched'* and therefore that it would have prevailed in litigation, and that the [CMA]'s *first counterfactual relies on the assumption that Alpharma would have prevailed in litigation.'* (Actavis SO Written Response (document 2754), paragraphs 1.26 and 10.16).
- f. Xellia-Zoetis submitted that both versions of the counterfactual presume that the patent would have been found invalid or non-infringed. (Xellia-Zoetis SO Written Response (document 2767), paragraphs 25, 120 and 148).

realistic prospect of the Generic Companies' independent entry, and of true generic competition, would have been maintained rather than deferred.

iii) *The timing of generic entry in the counterfactual*

- I.17 A number of the SO Addressees²¹⁷⁴ submitted that the assessment of the effects of each Agreement should take into account whether the Generic Companies could have entered independently prior to the date on which Apotex ultimately entered the UK paroxetine market. For example, those submissions rely on an *ex post* analysis to argue that absent the relevant Agreements, generic entry would not have occurred any sooner than was ultimately the case. Teva,²¹⁷⁵ GUK²¹⁷⁶ and Actavis²¹⁷⁷ also submitted that IVAX, GUK and Alpharma respectively would not have entered 'at risk' pending an appeal, which would further extend the likely timeline for their entry.
- I.18 The CMA considers that the approach suggested by the SO Addressees runs contrary to the well-established principle that actions must be assessed at the time when they are committed²¹⁷⁸ and would run contrary to the principle of legal certainty, which mandates that parties should be able to determine whether conduct may raise competition concerns at the time of the conduct itself. The logical consequence of the *ex post* analysis is that the Agreements would have been illegal had Apotex delayed its market entry or had the court processes been delayed, but would become legal if Apotex was able to enter the market before the date on which they claim that they would have entered the market had their disputes progressed.

²¹⁷⁴ Actavis noted that the CMA does not substantiate when Alpharma could have entered the market or that continuing the litigation would have resulted in earlier entry than actually occurred. Actavis stated that contemporaneous documents place estimated entry (even on an optimistic basis) in October 2003 (Actavis SO Written Response (document 2754), paragraphs 1.27, 1.31, 1.46, 4.13, 4.15, 10.16). Teva submitted that the '*Agreement provided a quicker route to market*' and '*the earliest IVAX could have launched its own product, assuming it would overcome the risk of infringing any of GSK's other paroxetine patents, was after the expiry of the GSK hemihydrate patent in 2006.*' (Teva SO Written Response (document 2750), paragraph 199). Similarly, GUK submitted that the CMA did not evaluate how long it would have taken for GUK to enter the market or that this would have been before 2003 (GUK SO Written Response (document 2752), page 5, section 1B, paragraphs 3.47–3.49, and 6.8, Annex 1 to GUK SO Written Response (document 2753), page 2, section 2.1 (pages 5–8)). Xellia-Zoetis stated that in the context of Alpharma facing an interim injunction preventing it from entering the market and likely litigation timescales, continuing litigation would not produce better results for competition than immediate generic entry under the Agreements and also submitted that the CMA did not show when Alpharma would have entered (Xellia-Zoetis SO Written Response (document 2767), paragraphs 135–152 and 272).

²¹⁷⁵ In particular, Teva submitted that IVAX was risk averse. In this context Teva cited [IVAX's Managing Director's] witness statement in which he noted that at that time IVAX had absolutely no record of launching 'at risk' (Teva SO Oral Hearing Transcript, page 32).

²¹⁷⁶ GUK SO Written Response (document 2752), paragraphs 3.38–3.49.

²¹⁷⁷ Actavis SO Written Response (document 2754), paragraphs 7.35–7.45 and Actavis written response dated 25 November 2014 to the SSO (document 3653), paragraph 3.18.

²¹⁷⁸ Judgment in *AstraZeneca v Commission*, C 457/10P, EU:C:2012:770, paragraph 110.

- I.19 As set out at paragraphs 7.5 to 7.10, the assessment of the likely restrictive effects of an agreement should be carried out at the time of the relevant settlement, taking into account the relevant context in which it operated. The CMA's analysis has therefore considered the likely effect of each Agreement at the time it was entered into.
- I.20 Having established the likely effect on competition at the time each Agreement was entered into, the CMA does not consider the timing of a third party's (in this case Apotex's) ultimate entry to be capable of undermining this finding. This is because, at the time the Agreements were entered into, it was not known whether or when Apotex would enter the market, and all that could be assumed was that any entry would be subject to the same challenges by GSK and on the basis of a later litigation timetable. The likely effect of each Agreement was therefore to enable GSK to continue to pursue its strategy of delaying the potential emergence of true generic competition and the representations advanced by the SO Addressees cannot alter that assessment.
- I.21 The CMA considers that, irrespective of the timing of the other challenges being made, the Agreements would still have the likely effect of restricting competition, as each served to defer one of the limited number of threats to GSK. The CMA notes that at the time that each of the Generic Companies entered into their Agreements with GSK, each was one of a limited number of potential entrants, and each Generic Company's challenge represented one of a limited number of threats to GSK's position of market power and the preservation of the barriers to entry that were key to maintaining it. The Agreements therefore each served to decrease the likelihood of GSK facing a challenge to its patent position and of the potential for true generic competition emerging. Further, each Agreement enabled GSK to maintain its strategy in response to the proposed entry of other generic suppliers and to prolong the period over which its patents, and its position of market power, would not be challenged.
- I.22 In this context, arguments concerning whether or not the Generic Companies would have entered 'at risk' pending an appeal are incapable of reversing a finding that the likely effect of each Agreement was to restrict competition. Whatever the Generic Companies' supposed intentions were in this regard, their acceptance of the entry restrictions (or, in the case of IVAX, the delay to its potential independent entry that the value transfers incentivised) deferred the prospect of one potential entrant, each Generic Company respectively, from continuing its strategy to enter the market, and enabled GSK to defer a challenge to its position of market power.

I.23 In any case, in relation to the Generic Companies' claims that they (unlike Apotex) would not have entered 'at risk' pending an appeal of a successful first judgment, the CMA observes that their intentions are not the only consideration of relevance to the impact of any such judgment. This is because such a scenario would likely have lowered the barriers to entry faced by all suppliers, and it would have been open to other companies (including Apotex) to choose to enter 'at risk' at that time. Further, the CMA notes that:

- the SO Addressees' *ex post* claims that they would not have entered 'at risk' are inconsistent with the actions that they were taking at the time. Prior to the imposition of the GUK Interim Injunction and the Alharma Undertaking, both GUK and Alharma were prepared to enter 'at risk' even in the absence of a judgment in their favour. This fact is of particular relevance, as the damages to which each of GUK and Alharma would have been exposed (as the first generic entrant) would have been comparable to the damages faced by the Parties following a first judgment. Similarly, IVAX had entered into the IVAX-Tillomed Heads of Agreement, and was continuing its efforts to enter the market independently of GSK (see paragraphs B.33 to B.45).
- whilst it may have been likely that GSK would appeal any first instance judgment in the relevant Generic Company's favour, this was not inevitable. Similarly, were GSK to appeal, there is no guarantee that an injunction would have remained in place for the appeal period – this would depend on whether GSK sought to maintain the injunction and, if so, where the balance of convenience lay at the relevant time.²¹⁷⁹ Following the first instance judgment in the Apotex Litigation, for example, GSK decided not to seek to maintain an interim injunction while the appeal was pending.²¹⁸⁰

I.24 For completeness, the CMA observes that the SO Addressees' reliance on *ex post* events in relation to the timing of their entry is at odds with the approach they advocate in relation to other analyses. For example, GSK submitted that it is inappropriate to take account of the fact that generic entry was ultimately

²¹⁷⁹ Note that the considerations in the balance of convenience pending an appeal may be different from those at first instance. For example, in *SmithKline Beecham v. Apotex* the judge considered the fact that the potential entry of other generics, following the first instance judgment in Apotex's favour, could deprive Apotex of a 'small and no doubt significant' first mover advantage. (*SmithKline Beecham PLC v Apotex Europe Ltd* [2003] EWHC 3383 (Ch), paragraph 17).

²¹⁸⁰ GSK explained that its reasons for not applying for an interim injunction against Apotex for the period to judgment on appeal were (i) that such an injunction would not prevent other generic companies from entering 'at risk', and (ii) GSK had a cross-undertaking in damages against Apotex on which it could rely if it was successful in its appeal (response dated 19 February 2015 to the Section 26 Notice dated 4 February 2015 sent to GSK (document 3872), question 5).

found not to infringe valid patents held by GSK.²¹⁸¹ Similarly, when highlighting the uncertainty in the outcome of the litigation at the time of the settlement, GUK submitted that *'the counterfactual must be assessed from the perspective of when the Agreement was signed and not with the benefit of hindsight.'*²¹⁸²

iv) Detailed model submitted by GSK

I.25 GSK submitted that had the GSK and the Generic Companies agreed on an alternative settlement with an early entry date (as the CMA set out as a likely counterfactual), this would not have resulted in savings to the NHS. GSK calculated that for an early entry date agreement to have resulted in savings to the NHS, it would have needed to provide for independent generic entry to occur in November 2002 or earlier. However, GSK's hypothetical bargaining model suggested that an agreed entry date would not have been until August 2004 at the earliest.²¹⁸³

I.26 The CMA does not accept GSK's analysis for the following reasons:

- GSK's model does not address likely effects at the time that the Agreements were entered into (see paragraph I.19). Instead, GSK's model represents an *ex post* analysis that compares the estimated saving to the NHS from the Agreements (calculated based on true generic entry having occurred on the date on which it was actually observed) with the estimated savings to the NHS based on likely entry dates had an early entry agreement been negotiated.
- The CMA observes that, had such agreements been assessed at the time they were entered into, they would have provided for guaranteed generic entry from the specified date. Moreover, the threat of generic entry on the part of other generic suppliers would have remained, such that independent generic entry could have taken place prior to the negotiated entry date had another generic entrant successfully challenged GSK's patents (as happened following the Apotex Litigation when multiple generic suppliers successfully entered the UK paroxetine market). By contrast, the Agreements in this case did not provide for a date by which entry could take place unchallenged, and nor did they provide for a material increase in the actual competitive constraints which GSK faced

²¹⁸¹ GSK submission to the OFT dated 27 June 2012 (document 0746), paragraphs 2.1–2.8.

²¹⁸² GUK SO Written Response (document 2752), Annex 1, page 9.

²¹⁸³ GSK SO Written Response (document 2755), summary box page 68, paragraphs 3–4, and paragraphs 2.24–2.52 and Annex 3 to the GSK SO Written Response – Report by Charles River Associates entitled 'Consumer welfare analysis – Impact of the supply agreements on the NHS' (document 2757).

when the Generic Companies entered the market as GSK distributors (see paragraphs B.143 to B.161 (IVAX), 7.25 to 7.41 (GUK), 7.76 to 7.94 (Alpharma)).

- I.27 In any case, the CMA observes that GSK's model relies on a calculation of estimated savings to the NHS from the Agreements based on the Drug Tariff, although GSK stated that its results still held if prices to pharmacies were considered instead of Drug Tariff reimbursement prices.²¹⁸⁴ As set out at paragraphs I.2 to I.7, the CMA does not consider the Drug Tariff reimbursement price to be the appropriate measure of price when considering the impact of the Agreements. Furthermore, the CMA does not agree that the same result would hold if prices to pharmacies were considered instead of Drug Tariff reimbursement prices because, as set out at paragraph 3.387, there was no material fall in prices to pharmacies as a consequence of the Agreements and therefore the savings which GSK sought to attribute to the Agreements did not arise.

²¹⁸⁴ GSK stated that in the revised analysis an early entry agreement could only reduce prices to pharmacies if entry happened prior to December 2003, whereas its bargaining model suggested an agreed entry date of August 2004 at the earliest. GSK SO Written Response (document 2755), paragraph 2.56.

ANNEX J: REPRESENTATIONS ON CHAPTER II OF THE ACT

A. GSK's representation that its conduct does not fall within recognised heads of abuse, and that there is no relevant precedent

J.1 GSK stated that it is striking that its conduct in this case is very different to other examples of an exclusionary abuse.²¹⁸⁵ GSK submitted that the CMA did not cite any cases that a series of settlement agreements, including financial settlement, can properly be considered abusive within the meaning of Chapter II.²¹⁸⁶ GSK submitted that:

- Exclusionary abuses can be divided into pricing and non-pricing forms. Given the terms of entry and the profit margin provided for under the settlement agreement, it cannot be argued that there is an exclusionary pricing abuse. In relation to non-pricing exclusionary abuses, GSK stated that the two principal categories are (i) tying and bundling and (ii) refusal to supply. Given that GSK provided paroxetine to the Generic Companies, GSK observed that the facts could not be further from the '*refusal to supply category*'.
- GSK stated that a third category of non-pricing abuse might be located in the *AstraZeneca* case consisting of misuse of the regulatory system. GSK stated that such conduct has nothing to do with the present case.
- GSK then stated that there is also no analogy with other cases in the area of IP, such as *Volvo v Veng*, *Magill* or *IMS Health*, which involved a refusal to licence, leading to the limitation of technical development or the prevention of a new product.

J.2 As has been made clear throughout the development of case law applicable to Chapter II of the Act and Article 102 TFEU, there is no barrier to different forms of conduct being established as abusive. Recent examples include the *Astra Zeneca* and *Reckitt Benckiser* cases.²¹⁸⁷

²¹⁸⁵ GSK SO Written Response (document 2755), paragraph 9.6.

²¹⁸⁶ GSK SO Written Response (document 2755), paragraph 9.7.

²¹⁸⁷ In *Astra Zeneca*, the Commission found, and the CJ largely upheld, that AstraZeneca had misused the patent system and procedures for marketing pharmaceuticals to block/delay market entry for generic competitors to its PPI ulcer drug, Losec (omeprazole), and preventing parallel imports of Losec. The first abuse involved the provision of misleading information to national patent offices with the aim of preventing or delaying market entry

- J.3 The case law relied upon by the CMA is described in Part 8. It is clear that where a dominant company's conduct has the purpose of restricting competition, it cannot be considered to be 'normal competition' or 'competition on the merits'. Such a principle is well recognised in Chapter II and Article 102 TFEU case law. On the basis of the framework established in that section, the CMA considers that where a dominant company makes value transfers to induce potential competitors to delay their entry, such conduct cannot properly be considered to be competition on the merits.
- J.4 Finally, the CMA notes that the fact that GSK provided the Generic Companies with a restricted volume of paroxetine to supply does not undermine a finding that the value transfers were aimed at deferring the emergence of true generic competition. In particular, GSK's submissions do not affect the CMA's finding that the purpose of the value transfers was to induce each of the Generic Companies to delay their efforts to enter the market independently of GSK. Further, as established at paragraphs 8.46 and 8.47, the supply of a restricted volume of product from GSK to the Generic Companies was itself a value transfer and cannot reasonably have been expected to materially increase the actual competitive constraints faced by GSK during the period in which the threat of generic entry was deferred.

B. GSK's representation that the Agreements were 'settlement' and not 'inducement'

- J.5 GSK submitted that it did not make value transfers to the Generic Companies to induce their acceptance of restrictions on their potential independent entry to the UK paroxetine market.²¹⁸⁸ In this regard, GSK presented the following submissions:

- The CMA is in no position to find that the Generic Companies were potential competitors at the time of the Agreements.²¹⁸⁹ The litigation concerned the issue of whether the Generic Company concerned had the

of competing generic products. See Case C-457/10 P, *AstraZeneca v Commission*, EU:C:2012:770. The second abuse involved the deregistration of the market authorisation for AstraZeneca's bestselling ulcer medicine Losec in selected countries with the aim of raising barriers against generic entry and parallel trade. In *Reckitt Benckiser*, the OFT found that Reckitt Benckiser abused its dominant position by withdrawing Gaviscon Original Liquid with the intention of limiting pharmacy choice and hindering competition from suppliers of generic medicines. In particular, Reckitt Benckiser removed Gaviscon Original Liquid medicine from the NHS prescription market once the patent had expired, but before the generic name had been published, causing more prescription orders for Reckitt Benckiser's alternative product, Gaviscon Advance Liquid which was patent protected and did not have a generic alternative. See *Reckitt Benckiser*, Case CE/8931/08.

²¹⁸⁸ GSK SO Written Response (document 2755), paragraphs 9.8–9.9.

²¹⁸⁹ GSK SO Written Response (document 2755), paragraph 9.9.

ability to enter the market, and said nothing about the potential for any other generic supplier to enter.²¹⁹⁰

- The Agreements embodied terms of settlement including the terms on which the Generic Companies could enter, and it is artificial to treat the value transfers as having been given specifically in exchange for particular terms of entry rather than as one facet of a multi-faceted settlement.²¹⁹¹
- The CMA has failed to appreciate the context of the '*IP bargain*'.²¹⁹² The CMA's suggestion that there was no GSK rationale for the Agreements other than eliminating or delaying the threat of true generic competition is therefore misconceived, as the rationale was the settlement of genuine disputes. The CMA cannot argue that such settlement is not 'normal competition', as a dominant firm has a right to litigate provided its case is not manifestly unfounded. The corollary of that proposition is that a dominant firm has a right to settle, provided its case is not unfounded.²¹⁹³
- GSK stated that the reality is that the payments were part of an overall settlement of complex, uncertain and costly litigation with substantial downside risks for GSK. GSK noted that the payments were not simply offered upfront but as part of the outcome of a tough negotiation with give and take on both sides. GSK stated that there is therefore no basis for a conclusion that this constitutes conduct that is not 'normal competition' within the meaning of the test for abuse.²¹⁹⁴

J.6 For the reasons set out below, the CMA does not consider that GSK's submissions undermine a finding that its conduct does not constitute 'normal competition' or 'competition on the merits':

- The CMA finds that each of the Generic Companies was a potential competitor at the time of the Agreements (see paragraphs 6.47 and 6.64 (GUK), paragraphs 6.65 to 6.82 (Alpharma) and Annex B.2 (IVAX)). The CMA also notes that GSK's submission that GSK was defending presumptively valid patents is in any case irrelevant to the value transfers made to Alpharma, as the Alpharma Litigation was concerned with whether

²¹⁹⁰ GSK SO Written Response (document 2755), paragraph 9.10.

²¹⁹¹ GSK SO Written Response (document 2755), paragraph 9.9.

²¹⁹² GSK SO Written Response (document 2755), paragraph 9.1 and paragraph 9.11. In paragraph 1.9, GSK describes the IP bargain as '*a bargain between society and (relevantly here) the pharmaceutical industry, allowing the patentee to exploit and to oppose copying of his invention for a defined period in return for innovation and disclosure*'.

²¹⁹³ GSK SO Written Response (document 2755), paragraph 9.12.

²¹⁹⁴ GSK SO Written Response (document 2755), paragraph 9.13.

the Alparma Product infringed claim 11 of the Anhydrate Patent (see paragraph 3.326 and 3.353).

- The CMA has taken full account of the various elements of the Agreements, and the justifications presented by the SO Addressees, and established that value transfers were made either to incentivise the Generic Companies to defer their efforts to enter the market independently or in return for the Generic Companies' acceptance of entry restrictions (see Part 8). General references to the '*multi-faceted*' nature of the Agreements are insufficient to otherwise justify committing to make value transfers totalling at least £50.9 million. In any event, the Agreements merely deferred rather than settled the relevant disputes.
- The relevant legal test is not whether GSK's claims in litigation were manifestly unfounded. Such a test is relevant to determining whether vexatious litigation is being used of itself to inhibit competition, not whether value transfers have been used to induce potential competitors' acceptance of ongoing entry restrictions or, in the case of IVAX, to incentivise them to defer their efforts to enter the market independently. In both assessments, the common theme is the need to determine whether the relevant conduct constitutes 'normal competition' or not, including whether the purpose of the conduct was to restrict competition. The CMA does not consider that settlement agreements are immune from competition law scrutiny simply because the litigation itself was not manifestly unfounded. The acts of bringing litigation and settlement are distinct, as are their likely effects.
- The CMA's approach in this case does not deprive dominant companies of the right to settle litigation nor enforce their patents, provided their conduct is compatible with the special responsibility imposed upon them.²¹⁹⁵
- The fact that negotiations were '*tough*', and the payments were not offered '*upfront*', does not undermine the CMA's assessment that GSK's conduct was not 'normal competition'. Neither point undermines the CMA's finding that GSK's decision to make value transfers to the Generic Companies was designed to induce delays to their potential independent entry to the UK paroxetine market. As explained at paragraphs 8.60 to 8.68, the CMA does not accept GSK's submission that the value transfers are justified by the complexity, risk and cost of the relevant litigation.

²¹⁹⁵ See further paragraph 8.7.

ANNEX K: PENALTIES

A. General representations of the Parties against the imposition of penalties

K.1 The Parties submitted, as summarised below, that imposing penalties would not be justified, in light of the novelty of the case. In particular:

(a) Various Parties submitted that the CMA's case is novel, since there was no specific precedent regarding patent settlements including 'reverse payments' in UK or EU law at the time the Agreements were signed. Some Parties cited certain statements of the Danish Competition Authority and the Commission in support of their submissions that genuine uncertainty existed at the time of the events in question.²¹⁹⁶

(b) Some Parties also submitted that certain aspects of the case were novel, such as market definition, or the analysis that conduct infringed both the Chapter I prohibition and the Chapter II prohibition.²¹⁹⁷

K.2 Further to the submissions summarised above in relation to novelty, the Parties submitted that even if there was an infringement of competition law, it was not committed intentionally or negligently.²¹⁹⁸ Certain Parties submitted that the illegality of any Agreement was not foreseeable due to a general

²¹⁹⁶ Xellia-Zoetis SO Written Response (document 2767), paragraphs 191, 262, 406 and 437, included the following as an unofficial translation of parts of a Danish Competition Authority public statement in January 2004: '*The connection of the agreements to patent law may mean in certain situations that entering into a mediation agreement may be authorised based on consideration of resources and for the purpose of creating clarification in the competition situation in the market in question. The issue is, in part, whether the amount of the payment only covers payment that corresponds to the financial dispute that ensues from a patent lawsuit, or whether the payment is of a size that goes much further, such that in reality this is a matter of buying a competitor out of the market. [...] [these agreements concern] a legal grey zone, and it has not been clarified how close we are in this case to the black zone. [...] It is therefore doubtful whether the agreements serve to limit competition. For that reason the Commission does not wish to initiate a case against Lundbeck.*'; see also Xellia-Zoetis DPS Written Response (document 4055), paragraphs 7–8. The Commission stated in November 2008 that '*...it might also be argued that [patent] settlements contain arrangements that could fall within the scope of competition rules*': see GSK SO Written Response (document 2755), paragraphs 10.22–10.27.

²¹⁹⁷ See, for example: GSK DPS and Proposed NGFA Written Response (document 4064), paragraphs 3.4, 3.15, 4.8 and 7.12(c); GSK DPS Hearing Transcript (document 4099), page 8, lines 4–13, and page 11, line 14, to page 12, line 2, and page 18, line 8, to page 20, line 6; Merck Response dated 29 July 2015 to the GUK DPS ('Merck DPS Written Response') (document 4033), paragraph 8.1.

²¹⁹⁸ See, for example: Actavis SO Written Response (document 2754), Section 15; Actavis Response dated 21 August 2015 to the Alpha Pharma DPS ('Actavis DPS Written Response') (document 4067), paragraphs 2.2–2.7; GSK SO Written Response (document 2755), Section 10; GSK DPS and Proposed NGFA Written Response (document 4064), Sections 3 and 4; GUK SO Written Response (document 2752), Section 8; GUK Response dated 25 August 2015 to the GUK DPS ('GUK DPS Written Response') (document 4075), paragraphs 2.1–2.9; Merck SO Written Response (document 2764), paragraphs 8.2–8.9; transcript of Merck DPS Oral Hearing dated 17 September 2015 on the GUK DPS (document 4105), page 17, line 15, to page 19, line 17; Xellia-Zoetis SO Written Response (document 2767), paragraphs 436–439; Xellia-Zoetis DPS Written Response (document 4055), paragraphs 4 and 6.

policy at the time of non-intervention in relation to vertical agreements, the Agreements having been pro-competitive in nature, and/or the Agreements' connection with the settlement of litigation, the existing patents and/or the related interim injunction/undertaking.²¹⁹⁹ Further, certain Parties referred to previous cases where no, or only nominal, penalties had been imposed when the relevant conduct was found to infringe competition law for the first time.²²⁰⁰

- K.3 The Parties submitted that, to the extent that the CMA imposes any penalty, it should exercise its discretion to impose only a symbolic penalty, by lowering the seriousness percentage at step 1 and/or applying a mitigating factor (such as '*genuine uncertainty*') at step 3.²²⁰¹
- K.4 The CMA rejects the Parties' submissions regarding novelty and lack of intent or negligence, for the reasons set out below.
- K.5 Although there was no specific precedent concerning the competition law assessment of reverse payment settlement agreements at the time of the Infringements, it was already well established that excluding actual or potential competitors from the market was likely to infringe competition law, and that market exclusion in exchange for a payment was likely to constitute a restriction by 'object' under the Chapter I prohibition and Article 101 TFEU. It was also well established that agreements were not immune from the application of competition law because they concerned intellectual property rights and/or purported to effect a settlement of litigation.²²⁰²

²¹⁹⁹ See, for example: Actavis SO Written Response (document 2754), Section 15; Actavis DPS Written Response (document 4067), paragraph 2.5(d); GSK SO Written Response (document 2755), Section 10; GSK DPS and Proposed NGFA Written Response (document 4064), paragraphs 4.9–4.12 and 4.15; GSK DPS Hearing Transcript (document 4099), page 17, line 6, to page 18, line 7; GUK SO Written Response (document 2752), paragraphs 8.3–8.4; GUK DPS Written Response (document 4075), paragraph 2.7; Xellia-Zoetis DPS Written Response (document 4055), paragraph 6.

²²⁰⁰ For example, GSK, GUK Merck and/or Xellia-Zoetis referred to the imposition of no fines in the Commission cases COMP/38096 *Clearstream*; and COMP/36.915 *Deutsche Post*. See, for example: Actavis DPS Written Response (document 4067), paragraphs 3.11(b), 3.12–3.13; GSK SO Written Response (document 2755), paragraphs 10.56–10.69; Transcript of GSK SO Oral Hearing dated 18 October 2013 (document 3053), page 12, line 9, to page 13, line 2; GSK DPS and Proposed NGFA Written Response (document 4064), paragraphs 3.17–3.18 and 6.5–6.9; GSK DPS Hearing Transcript (document 4099), page 12, lines 6–24, and page 22, line 9, to page 23, line 12; GUK DPS Written Response (document 4075), paragraph 3.3; Merck SO Written Response (document 2764), paragraphs 8.2–8.6; Merck DPS Written Response (document 4033), paragraphs 3.2–3.4 and 5.8–5.15; transcript of Merck DPS Oral Hearing dated 17 September 2015 on the GUK DPS (document 4105), page 9, line 19, to page 10, line 7; Xellia-Zoetis DPS Written Response (document 4055), paragraph 17.

²²⁰¹ See, for example: Actavis DPS Written Response (document 4067), paragraphs 2.27, 3.8, 3.13, 3.23(c) and 3.25; GSK DPS and Proposed NGFA Written Response (document 4064), Section 6 and paragraph 8.6; GUK SO Written Response (document 2752), paragraph 8.6(d); GUK DPS Written Response (document 4075), paragraphs 3.3 and 3.20; Xellia-Zoetis DPS Written Response (document 4055), paragraphs 17, 19 and 26.

²²⁰² See for example, paragraph 3.84.

K.6 The CMA finds, in this Decision, that the Parties were aware that the Infringing Agreements and Infringing Conduct were aimed at excluding competition. Notwithstanding the absence of directly applicable case law, the Parties must have been aware or could not have been unaware – and in any case ought to have known – that the Agreements carried considerable competition law risks at the time. In particular, given the clear aim of the value transfers within the Infringing Agreements and the Infringing Conduct, the Parties should have expected their conduct to be incompatible with competition law. The CJ observed in *AstraZeneca v Commission* that:²²⁰³

‘... concerning the novelty of the two abuses of a dominant position, it must be stated that those abuses, as the General Court pointed out at paragraph 900 of the judgment under appeal, had the deliberate aim of keeping competitors away from the market. It is therefore common ground that even though the Commission and the Courts of the European Union had not yet had the opportunity to rule specifically on conduct such as that which characterised those abuses, AZ was aware of the highly anti-competitive nature of its conduct and should have expected it to be incompatible with competition rules under European Union law.’

K.7 For an infringement of competition law to be regarded as having been committed intentionally, *‘it is not necessary for an undertaking to have been aware that it was infringing... it is sufficient that it could not have been unaware that its conduct was aimed at restricting competition’*; the previous publication of a specific precedent is not required.²²⁰⁴ The CMA’s view is that the anti-competitive consequences of the Infringing Agreements and the Infringing Conduct were plainly foreseeable and the Parties must have been aware or could not have been unaware – and in any case ought to have known – that the Infringing Agreements and the Infringing Conduct had the objective purpose of incentivising each relevant Generic Company to defer its efforts to enter the relevant market independently of GSK, thereby restricting competition.

K.8 As regards GSK’s dominant position and the assessment of its conduct, the CMA considers that GSK must have been aware, and could not have been unaware, that:

²²⁰³ Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770, paragraph 164.

²²⁰⁴ See, for example, judgment dated 5 October 2011, *Romana Tabacchi Srl v Commission*, T-11/06, ECR, EU:T:2011:560, paragraph 227.

- (a) the fact that it expected significant falls in its prices and profits following generic entry was indicative of it holding substantial market power at the time the Agreements were entered into;
- (b) committing to make value transfers totalling at least £50.9 million, whose only rational purpose was to delay generic entry, would represent conduct that was aimed at restricting competition.

K.9 The Parties have not provided sufficient evidence to establish that any Infringement was not committed as a result of negligence. The Parties ought to have known that excluding actual or potential competitors from the relevant market, in particular in exchange for substantial payments, was likely to infringe competition law.

K.10 The CMA does not accept that any statements made in 2004 by the Danish Competition Authority created uncertainty which should preclude the imposition, or result in any reduction, of any penalties in this case. First, these statements were made after the Agreements were entered into. Second, the parts of those statements quoted by the Parties specifically indicate that reverse payment settlements limiting generic entry (in particular, those involving value transfers greater than the relevant litigation costs) could give rise to competition law concerns.²²⁰⁵ Finally, no Party has provided evidence that when it entered into any Agreement it was specifically aware of, and relied upon, any statement by the Danish Competition Authority, the OFT or the Commission.

K.11 The CMA's discretion to impose penalties is not bound by the approach taken in previous decisions in relation to the calculation of financial penalties in previous cases under the Act, or as a result of any case cited by the Parties. The CMA's discretion as to whether to impose a penalty and, if so at what level, in a given case will depend on the specific circumstances of that case, having regard to the need for appropriate deterrence.²²⁰⁶

B. Legal certainty, Article 7 ECHR and other principles

K.12 Certain Parties submitted that the imposition of penalties would infringe several legal principles: the principle that provisions of criminal law may not be applied retroactively to any act or omission which did not constitute a

²²⁰⁵ See footnote 2196 – for example: '*The issue is, in part, whether the amount of the payment only covers payment that corresponds to the financial dispute that ensues from a patent lawsuit, or whether the payment is of a size that goes much further, such that in reality this is a matter of buying a competitor out of the market*'.

²²⁰⁶ See paragraphs 11.19–11.20 of this Decision.

criminal offence under applicable law at the time when it was committed (Article 7 of the European Convention on Human Rights); *nullum crimen, nulla poena sine lege* (no crime/punishment without law); and the principle of legal certainty.²²⁰⁷

- K.13 The principle of *nullum crimen, nulla poena sine lege* implies that provisions of criminal law may not have retroactive effect, as embodied in Article 7 of the European Convention on Human Rights. It is settled case law that this principle cannot be interpreted as prohibiting the gradual clarification of the rules of criminal liability through interpretation by the courts.²²⁰⁸ Whilst the principle may preclude the retroactive application of a new interpretation of a rule establishing an offence, in particular if that interpretation was not reasonably foreseeable at the time when the offence was committed, as set out at paragraphs K.1 to K.11, the illegality of ‘pay for delay agreements’ was reasonably foreseeable at the time the Agreements were entered into. The principle of legal certainty has not been breached in this case, given the explicit wording of the Chapter I prohibition, the Chapter II prohibition and Article 101 TFEU,²²⁰⁹ and settled case law that any practice or agreement which has the object or effect of preventing, restricting or distorting competition may fall within the scope of EU and UK competition law. The elements determining liability were, therefore, already sufficiently precise.²²¹⁰

C. Passage of time, rights of defence and limitation periods

- K.14 Certain Parties submitted that the CMA should impose no penalties, or reduce any penalties imposed, to reflect an unnecessarily long period of time since the Agreements – and in particular the period between the Agreements and the launch of the Investigation and/or the duration of the Investigation having been unnecessarily long.²²¹¹ Certain Parties submitted that, irrespective of

²²⁰⁷ See, for example: Actavis SO Written Response (document 2754), paragraphs 15.6–15.7; GSK SO Written Response (document 2755), paragraphs 10.10–10.15; GUK SO Written Response (document 2752), paragraph 8.5; Merck SO Written Response (document 2764), paragraphs 8.2–8.7; Transcript of Xellia-Zoetis SO Oral Hearing dated 22 October 2013 (document 3126), page 59, lines 3–7; Slides for Xellia-Zoetis SO Oral Hearing (Session 2) dated 22 October 2013 (document 2994B), Slide 38.

²²⁰⁸ Judgment in *AC-Treuhand AG v Commission*, C-194/14, ECLI:EU:C:2015:717, paragraph 41. See also judgment of 8 July 2008, *AC-Treuhand AG v Commission*, T-99/04, ECR, ECLI:EU:T:2008:256, paragraph 141.

²²⁰⁹ Each of these provisions refer to agreements or conduct which, in particular, limit ‘production’, ‘markets’ and/or ‘technical development’. During the Relevant Period, Article 101 TFEU was Article 81 EC.

²²¹⁰ Judgment of 8 July 2008, *AC-Treuhand AG v Commission*, T-99/04, ECR, ECLI:EU:T:2008:256, paragraph 147.

²²¹¹ Actavis DPS Written Response (document 4067), paragraphs 2.9–2.10; transcript of Actavis DPS Oral Hearing dated 23 September 2015 on the Alpharma DPS (document 4090), page 11, line 12, to page 13, line 7; GSK SO Written Response (document 2755), paragraphs 11.1 and 11.4–11.18; GSK DPS and Proposed NGFA Written Response (document 4064), paragraph 8.7; GSK DPS Hearing Transcript (document 4099), page 13, line 3, to page 14, line 15; GUK SO Written Response (document 2752), paragraphs 2.1–2.2; Slides for GUK SO Oral Hearing dated 15 October 2013 (document 2957), Slide 55 (as printed), third and fifth bullets; GUK DPS

whether any rights of defence have been breached, (a) the OFT did not act expeditiously, and delayed unnecessarily its launch of the Investigation, since the OFT may have first become aware of the Agreements in 2005 or in 2009, and (b) any breach of the principle that an action must be brought within a reasonable period should result in the imposition of no – or at least reduced – penalties.²²¹²

K.15 Further, certain Parties submitted that, given the passage of time since the Infringing Agreements and the Infringing Conduct would prevent the Commission from imposing penalties (by virtue of the limitation period applying to it), the CMA should impose no, or reduced, penalties notwithstanding there being no equivalent limitation period under the Act.²²¹³

K.16 The CMA does not accept that the Investigation was launched after any unnecessary delay,²²¹⁴ or was unduly long; rather, the CMA considers that the Investigation has been conducted diligently and within a reasonable period, given the particular circumstances of, and the number of parties involved in, the Investigation. Notwithstanding this, the CMA has taken into account, in the round, the passage of time between the Relevant Period and the launch of this Investigation (given the possibility that searching for contemporaneous evidence and/or data relevant to this Investigation may have involved an increased administrative burden for the Parties) and other relevant circumstances when making a 10% reduction of the penalty for each Party at step 4 of the penalty calculation.²²¹⁵

Written Response (document 4075), paragraphs 3.17–3.18; transcript of GUK DPS Oral Hearing dated 14 September 2015 on the GUK DPS (document 4102), page 24, lines 1–5; Xellia-Zoetis DPS Written Response (document 4055), paragraph 27. The CMA has rejected, for the reasons set out at paragraphs L.2–L.7, any submission(s) contained with these (or any other) representations that this Investigation has resulted in any breach of any Party's rights of defence.

²²¹² See, for example: Actavis SO Written Response (document 2754), paragraphs 14.18–14.21; Actavis DPS Written Response (document 4067), paragraphs 2.8–2.10; GSK SO Written Response (document 2755), paragraphs 11.34–11.35; GSK DPS and Proposed NGFA Written Response (document 4064), paragraph 8.7; GUK SO Written Response (document 2752), paragraphs 2.11–2.17; Transcript of GUK SO Oral Hearing dated 15 October 2013 (document 3098R), page 9 (as printed), lines 5–12; Slides for GUK SO Oral Hearing dated 15 October 2013 (document 2957), Slide 6 (as printed).

²²¹³ Actavis DPS Written Response (document 4067), paragraph 2.8; transcript of Actavis DPS Oral Hearing dated 23 September 2015 on the Alpharma DPS (document 4090), page 9, line 10, to page 10, line 6; GUK SO Written Response (document 2752), paragraph 2.16(c); Xellia-Zoetis DPS Written Response (document 4055), paragraph 16. The six-year limitation period under the Limitations Act 1980 does not apply to the issue of a statement of objections, decision or a penalty notice by the CMA (*Quarmby Construction Company Limited and Another v Office of Fair Trading* [2011] CAT 11, at [56]).

²²¹⁴ In particular, the OFT discussed the Agreements with – and received the Agreements from – the Commission in July 2010 (see paragraph 2.1). In addition, whilst an inspection at GSK took place in 2005, this was led by Commission officials and the OFT assisted by providing personnel only – and that inspection was concerned with the investigation referred to at footnote 2242, rather than the Agreements (see note of meeting between the OFT and GSK on 12 September 2012 (document 2355), paragraph 18).

²²¹⁵ See paragraphs 11.59–11.60.

K.17 The CMA does not consider that any submission summarised in paragraphs K.14 and K.15 justifies any further reduction to any penalty. No statutory limitation period applies to the CMA's power to impose penalties under section 36 of the Act, and – whether or not a limitation period would prevent the Commission from imposing penalties – for the reasons set out at paragraph 11.17, the CMA considers that it is appropriate to exercise its discretion to impose penalties in this case.

D. The deterrent value of financial penalties in this case

K.18 The Parties have also submitted that the CMA should impose no penalty, or a substantially reduced penalty, on the basis that a decision imposing substantial penalties would have no, or limited, deterrence value. In support of their submissions, the Parties referred to the passage of time since the Agreements and subsequent changes in business structure and/or focus.²²¹⁶

K.19 The applicable deterrence objective is concerned with deterring both the Parties (specific deterrence) as well as other parties that may be considering similar infringing activity and/or other forms of infringing activity aimed at delaying actual or potential generic competition.²²¹⁷ The CMA considers that given the nature of the Infringements, there is a need to deter both the Parties in this case, and other parties, from engaging in similar anti-competitive behaviour in the future. The CMA considers that neither corporate restructuring nor the passage of time removes the need for such deterrence.²²¹⁸

E. Liability of a parent

K.20 Merck submitted that, if the CMA were to impose a penalty on Merck only on the basis that GUK was directly involved in an Infringement and that Merck wholly owned GUK during the Relevant Period, the CMA could not legally impose a penalty on Merck exceeding that imposed on GUK.²²¹⁹ Merck cited certain rulings of the GC and the CJ in support of this submission.

²²¹⁶ Xellia-Zoetis DPS Written Response (document 4055), paragraph 16.

²²¹⁷ The Act, section 36(7A), and Penalty Guidance, paragraphs 1.4–1.5.

²²¹⁸ As set out at Part 9 of this Decision, the CMA notes the relevant corporate changes, but has attributed liability where it has found functional and economic continuity.

²²¹⁹ Merck DPS Written Response (document 4033), paragraphs 2.6–2.17; slides for Merck DPS Oral Hearing dated 17 September 2015 on the GUK DPS (document 4079), Slide 5; transcript of Merck DPS Oral Hearing dated 17 September 2015 on the GUK DPS (document 4105), page 8, line 11, to page 9, line 18; judgment dated 24 March 2011, *Tomkins v Commission*, T-382/06, ECR, EU:T:2011:112, paragraph 38; judgment in *Commission v Tomkins*, C-286/11 P, EU:C:2013:29, paragraph 39; judgment in *Areva and Others v Commission*, C-247/11 P,

K.21 The CMA notes that a former parent may have liability imputed to it and be fined more than its relevant former subsidiary,²²²⁰ and that any penalty imposed on an entity should reflect the economic reality for the entity as at the imposition of that penalty.²²²¹

F. Representations on the step 1 seriousness assessment

K.22 The Parties submitted that 21% was too high a starting point and that:

- (a) The Infringements were not serious in nature, given the specific circumstances of the case, and in particular the uncertainty as to the relevant competition law analysis;²²²²
- (b) the relevant percentage should reflect considerations relevant to each specific counter-party, so the CMA should not apply the same percentage to each of GSK, GUK and Alpharma;²²²³ and
- (c) for legal certainty reasons given the version(s) in force during the Agreements and/or the passage of time, the CMA should apply the 2000 and/or the 2004 versions (rather than the 2012 version) of its Penalty Guidance, at least in terms of a maximum starting point of 10%.²²²⁴

K.23 The CMA has set out, at paragraphs 11.26 to 11.28, the basis for a starting point of 21% and for the CMA's view that each Infringement was serious in nature and that there is no basis for differentiating between the respective roles of GSK, GUK and Alpharma in the Infringements for the purposes of determining penalty starting points.

EU:C:2014:257, paragraphs 137–138; judgment in *Akzo Nobel v Commission*, C-97/08P, EU:C:2009:536, paragraph 62.

²²²⁰ For example, as a result of the application of the relevant statutory maximum: see, for example, judgment in *Kendrion v Commission*, C-50/12, EU:C:2013:771, paragraphs 55–58, in relation to the maximum financial penalty provided for in the Modernisation Regulation, Article 23(2).

²²²¹ See, for example, judgment in *YKK v Commission*, C-408/12P, ECLI:EU:C:2014:2153, paragraphs 84–94.

²²²² In support, certain Parties referred to lower starting points having been set in certain previous UK decisions on appeal, namely: *Kier Group and Others v OFT* [2011] CAT 3; *Quarmby Construction Company Limited and Another v OFT* [2011] CAT 11; and *National Grid Plc v Gas and Electricity Markets Authority and Others* [2010] EWCA Civ 114. See, for example: Actavis DPS Written Response (document 4067), paragraphs 3.6–3.7 and 3.12–3.13; GSK DPS and Proposed NGFA Written Response (document 4064), paragraphs 6.3–6.8; GUK DPS Written Response (document 4075), paragraphs 3.3–3.4 and 3.9–3.10; Merck DPS Written Response (document 4033), paragraphs 5.8–5.14; Xellia-Zoetis DPS Written Response (document 4055), paragraph 19.

²²²³ Actavis DPS Written Response (document 4067), paragraphs 3.4–3.10; GUK DPS Written Response (document 4075), paragraph 3.6; Merck DPS Written Response (document 4033), paragraphs 5.3–5.7.

²²²⁴ Actavis DPS Written Response (document 4067), paragraphs 2.11–2.16 and 3.11(a); transcript of Actavis DPS Oral Hearing dated 23 September 2015 on the Alpharma DPS (document 4090), page 10, line 7, to page 11, line 11 and page 16, lines 6–9; GUK DPS Written Response (document 4075), paragraph 3.3.

K.24 Paragraph 1.11 of the Penalty Guidance states that OFT/CMA will apply that guidance in cases where the SO was issued after the guidance came into force in 2012. Whether or not any penalty in this case may be higher at an intermediate step (ie, after step 1) than at the counterpart stage under the 2000 or 2004 versions of the Penalty Guidance,²²²⁵ the penalties in this case exceed neither the current statutory maximum nor, where applicable, the pre-2004 statutory maximum.²²²⁶ That is, moreover, in line with case law regarding Article 7 of the European Convention on Human Rights.²²²⁷

G. Representations on the step 1 relevant turnover

K.25 Certain Parties submitted that the relevant turnover of GUK and Alpharma should not include value transfers, as these are not (related to) ‘sales’ within the meaning of the statutory maximum for financial penalties under the Act.²²²⁸ In addition, GUK submitted that its relevant turnover should be net of certain costs or investments.²²²⁹

K.26 The CMA has included certain value transfers in the relevant turnover of GUK and Alpharma for the reasons set out in paragraphs 11.35 to 11.36 of this Decision, and in particular to ensure that relevant turnover for GUK and Alpharma reflects the true scale of each of those undertaking's activities in the relevant market.

K.27 The CMA notes that the CAT has previously stated that ‘relevant turnover’ for step 1 purposes may be determined differently to turnover for statutory maximum purposes, given that the two measures have different purposes.²²³⁰ The definition of ‘sales’ in relation to the statutory maximum is not therefore determinative in relation to the relevant turnover that should be adopted in this case.

²²²⁵ The OFT noted publicly, before it adopted the Penalty Guidance in 2012, that an increased starting range (to up to 30%) may not necessarily result in higher fines overall – see the summary of responses to consultation on a draft version of the Penalty Guidance, available at http://webarchive.nationalarchives.gov.uk/20140402142426/http://www.of.gov.uk/shared_of/consultations/OFT423resp.pdf, paragraphs 3.9–3.13.

²²²⁶ The 2012 Penalty Guidance provides that, in relation to any infringement that ended before 1 May 2004, the OFT/CMA will not impose an overall penalty exceeding either the current statutory maximum or the pre-2004 statutory maximum in force at the time of that infringement.

²²²⁷ Article 7 of the European Convention on Human Rights does not effectively require the CMA to apply, when calculating penalties in the Investigation, any previous version of its Penalty Guidance that was in force during the Relevant Period: see *GF Tomlinson Group Limited & Others v OFT* [2011] CAT 7, at [106]–[110].

²²²⁸ See, for example: Merck DPS Written Response (document 4033), paragraphs 6.1–6.8; transcript of Merck DPS Oral Hearing dated 17 September 2015 on the GUK DPS (document 4105), page 15, lines 11–23; Xellia-Zoetis DPS Written Response (document 4055), paragraphs 22–23.

²²²⁹ GUK DPS Written Response (document 4075), paragraph 3.12.

²²³⁰ *Eden Brown and Others v OFT* [2011] CAT 8, at [57].

- K.28 The CMA's calculation of relevant turnover, without netting off costs, is consistent with its usual practice and with the Penalty Guidance, which envisages the extraction of turnover data from audited accounts (in which revenues appear on a separate line from costs). The CMA does not consider there to be any exceptional circumstances which warrant a different approach in this case.
- K.29 Each of Actavis and Xellia-Zoetis submitted that it could not verify the net sales values cited in paragraph 2.10 of the Alpharma DPS.²²³¹ Actavis submitted that the CMA had not justified referring to a net sales value of £4,328,620, in particular as Actavis submitted that this figure was based on data (in document 3788) containing calculation errors, and that the CMA should instead refer to a net sales value of £3,887,921.²²³²
- K.30 The CMA rejects these submissions. The CMA does not accept the submission regarding the reliability of the data in document 3788.²²³³ The CMA notes that the value of £3,887,921 would overstate the level of rebates that should be applied to paroxetine, because the level of rebates used would include those that were specific to products other than paroxetine. The CMA therefore considers £4,328,620 to be the appropriate net sales value.

H. Representations regarding step 3 mitigating factors

- K.31 GSK submitted that it should receive a cooperation discount, on the basis that GSK initiated a meeting with the OFT in December 2011 at which GSK provided, including through the voluntary attendance of certain individuals, a substantial amount of information relevant to the Investigation.²²³⁴
- K.32 As noted at paragraph 11.45 of this Decision, having assessed matters in the round the CMA does not consider that GSK has provided voluntary

²²³¹ See, for example: Actavis DPS Written Response (document 4067), paragraphs 3.14(a) and 3.15; Xellia-Zoetis DPS Written Response (document 4055), paragraph 24.

²²³² Actavis DPS Written Response (document 4067), paragraphs 3.14(a) and 3.15; transcript of Actavis DPS Oral Hearing dated 23 September 2015 on the Alpharma DPS (document 4090), page 17, lines 6–18. Actavis stated that, as an example, a cell in the relevant spreadsheet referred to 'Total 2004' but should read 'Total 2003': response dated 30 January 2015 to the Section 26 Notice dated 16 January 2015 sent to Actavis (document 3786) with reference to accompanying spreadsheet entitled 'YR2003 Budget Sheet' (document 3788). Actavis also submitted that document 3788 was 'referred to as a "Forecast" yet it appears to be some form of reconciliation of prior numbers rather than a forecast and it is stated to be a "September Estimate 03" yet appears to contain some actual numbers in columns K to M for the final quarter of 2003': Actavis response dated 21 October 2015 to the Section 26 Notice dated 1 October 2015 sent (document 4092).

²²³³ The CMA considers that an incorrect column heading (stating 'Total 2004' instead of 'Total 2003') does not undermine the quality of the data contained in that column, or in document 3788 more generally. Moreover, the CMA considers that if, as Actavis notes, document 3788 is stated to be a forecast but includes certain actual numbers, this would tend to increase the reliability of document 3788 rather than cast doubt on its accuracy.

²²³⁴ GSK DPS and Proposed NGFA Written Response (document 4064), paragraphs 8.6 and 8.8.

cooperation sufficient to justify any reduction at step 3 of the relevant penalty calculation. In particular, the CMA notes that GSK refused nine requests made by the OFT, at various points in 2012 and 2014, to make GSK staff available voluntarily for interview.²²³⁵

- K.33 GUK submitted that it should also receive a cooperation discount on the basis that the OFT conducted voluntary interviews with individuals who worked at GUK during the Relevant Period, and that GUK provided '*extensive documentation*', going beyond the requirements of the Section 26 Notice dated 12 August 2011 sent to GUK, by making more than 5,000 documents available for inspection and offering to provide various categories of paroxetine litigation documents.²²³⁶
- K.34 The CMA rejects GUK's submissions, for several reasons. First, the individuals interviewed were former employees who agreed to attend voluntary interviews after being approached directly by the OFT, before any involvement of GUK in the process. Second, the CMA also considers that provision of the '*extensive documentation*' referred to by GUK does not constitute voluntary cooperation over and above applicable legal obligations, as GUK made the relevant documents available for inspection in response to a formal request, and offered the various categories of documents on the basis that they were '*at least potentially*' responsive to that request.²²³⁷

²²³⁵ The CMA acknowledges that one of the key GSK personnel, [GSK's Finance Director A], subsequently agreed to produce, with GSK, a witness statement that was annexed to the GSK SO Written Response. However, the CMA does not consider that this enabled the Investigation to be concluded more effectively and/or speedily.

²²³⁶ GUK DPS Written Response (document 4075), paragraphs 3.19–3.20; transcript of GUK DPS Oral Hearing dated 14 September 2015 on the GUK DPS (document 4102), page 24, lines 5–11, page 27, lines 9–15, and page 28, line 13, to page 29, line 13; email from [GUK's external lawyer] of [external law firm] to [CMA official] dated 12 October 2015 (document 4089).

²²³⁷ Email from [GUK's external lawyer] of [external law firm] to [OFT official] dated 9 September 2011 (document 1188).

ANNEX L: PROCEDURE AND RIGHTS OF DEFENCE

L.1 During the Investigation, the Parties submitted representations in relation to the procedure followed during the Investigation.²²³⁸

A. Passage of time between the Agreements and the commencement of the Investigation

L.2 The Parties submitted that the passage of time since the Agreements were entered into and the OFT initiating the Investigation has compromised their rights of defence. The Parties submitted, in particular, that their ability to locate documentary evidence and to access relevant witnesses has been hindered (and, for GUK-Merck and Alpharma, given certain changes in corporate structure since the Agreements).²²³⁹

L.3 For the reasons given below, the CMA does not accept the Parties' submissions.

L.4 The Parties have been in a position to provide a significant volume of documents relevant to the Investigation, and the CMA's case file contains thousands of documents, including the Agreements, internal emails and documents, sales and cost data, and court documents in relation to the Patent Disputes. Contrary to the Parties' submissions, a number of witnesses who were directly involved in the negotiation of the Agreements, including ex-employees, have provided relevant information about those Agreements – both in contemporaneous witness statements provided to the courts in 2001 to 2003, in meetings and interviews²²⁴⁰ with the OFT and CMA, and in transcripts and witness statements prepared during the Investigation.

²²³⁸ To the extent that these representations contained submissions that the CMA should impose no penalties, or reduce any penalties which it imposes, see paragraphs K.14–K.17.

²²³⁹ See, for example: Actavis SO Written Response (document 2754), paragraphs 14.1–14.22; Transcript of Actavis SO Oral Hearing dated 23 October 2013 (document 3088), page 72 (as printed), line 14, to page 73 (as printed), line 29; GSK SO Written Response (document 2755), paragraphs 11.4–11.12 and 11.19–11.35; GUK SO Written Response (document 2752), paragraphs 2.9 and 8.6(f); Merck SO Written Response (document 2764), paragraphs 7.11–7.18; Transcript of Merck SO Oral Hearing dated 17 October 2013 (document 3028), page 74 (as printed), lines 8–15; Merck response dated 17 September 2014 to the First Letter of Facts (document 3489), paragraph 3; Xellia-Zoetis submission of 21 May 2014. See Xellia-Zoetis SO Written Response (document 2767), paragraphs 398–404. The Parties submitted similar representations in response to the Draft Penalty Statements – see, for example: Actavis DPS Written Response (document 4067), paragraphs 2.17–2.26; GSK DPS and Proposed NGFA Written Response (document 4064), paragraph 5.3(a); GUK DPS Written Response (document 4075), paragraphs 3.16–3.18; Merck DPS Written Response (document 4033), paragraphs 4.4.1 and 4.6; transcript of Merck DPS Oral Hearing dated 17 September 2015 on the GUK DPS (document 4105), page 14, lines 4–8; Xellia-Zoetis DPS Written Response (document 4055), paragraph 15.

²²⁴⁰ Some individuals (or their current employer, in the case of GSK) declined requests to be interviewed.

- L.5 The CMA further notes that the Parties are under a duty of care to maintain adequate business records in the event of legal or administrative proceedings.²²⁴¹ There is a general duty of care on the Parties to take reasonable steps to recover relevant evidence for the purposes of CMA or other investigations. This duty to maintain documents is especially relevant once the Parties were notified of the commencement of the Investigation.
- L.6 In the case of GSK, documents relating to paroxetine were placed under a document hold since the launch of the Commission's investigation into paroxetine mesylate in 2005,²²⁴² only one year after the end of the Infringements. This has ensured that a significant volume of contemporaneous GSK documents were retained.²²⁴³ Further, in its representations on the SO, GSK referred to preservation notices which GSK placed on information for specific purposes in relation to unrelated litigation, and information supplied to the Commission during the Sector Inquiry.²²⁴⁴
- L.7 While some Parties have referred to certain documents or witnesses which are now inaccessible or unavailable,²²⁴⁵ these Parties have not set out in sufficient detail how such documents or witness evidence would likely be exculpatory and/or would likely have affected the outcome of the Investigation. Finally, the CMA does not consider that the inability of some Parties to access certain documents or witness testimony due to the passage of time constitutes a breach of any Party's rights of defence, in circumstances where the CMA has demonstrated that the standard of proof is met in establishing the Infringements. The CMA therefore finds that the Parties have

²²⁴¹ See, for example, judgment dated 14 March 2013, *Fresh Del Monte v Commission*, T-587/08, ECR, EU:T:2013:129, paragraph 684 which states that: '*It should be borne in mind that, by virtue of a general duty of care attaching to any undertaking, the applicant was required to ensure, even in the circumstances of the sale of its interest [...], the proper maintenance of records in its books and files of information enabling details of its activities to be retrieved, in order, in particular, to make the necessary evidence available in the event of legal or administrative proceedings [...].*'

²²⁴² Case COMP/38.574 *Synthon/GlaxoSmithKline*, which focussed on an abuse of dominance complaint brought by Synthon against GSK in various EEA Member States. The investigation was subsequently closed by the Commission after Synthon withdrew its complaint, although litigation continued in the UK with respect to GSK's patent position.

²²⁴³ GSK stated that this preservation notice on the relevant documents was removed in 2010, when GSK had not heard anything further from the European Commission about the investigation for several years and that this reduced the number of documents that were available. See OFT-GSK Meeting Note dated 12 September 2012 (document 2355), paragraph 21.

²²⁴⁴ See GSK SO Written Response (document 2755), footnote 902.

²²⁴⁵ See, for example: Actavis SO Written Response (document 2754), paragraphs 1.48(a) and 14.5–14.7, and paragraphs 1.48(c) and 14.14–14.17; GSK SO Written Response (document 2755), paragraphs 11.22, 11.25; GSK DPS and Proposed NGFA Written Response (document 4064), paragraph 5.3(a). Otherwise, the CMA considers that the Parties' representations are general, abstract and non-specific in nature.

not provided ‘*convincing evidence*’ to establish a breach of their rights’ of defence in this case.²²⁴⁶

B. Late notice of the Investigation and equal treatment

- L.8 Merck²²⁴⁷ and Xellia-Zoetis²²⁴⁸ submitted that their rights of defence have been breached on the basis that: (i) they were brought into the Investigation just prior to the issuing of the SO, and therefore were not afforded the opportunity to meet with the OFT, submit relevant evidence or make legal representations at the pre-SO stage of the Investigation; and (ii) the OFT had failed to satisfy the principle of equal treatment given that the other SO Addressees were brought into the Investigation at a much earlier stage.
- L.9 In March 2013, the OFT informed Merck and Xellia-Zoetis in writing that the Investigation was being extended to those entities and that the ‘*provisional target is to complete the first stage of the Investigation by April 2013, at which point we are likely to issue a Statement of Objections.*’²²⁴⁹ In order to accommodate these companies being based outside the UK, the OFT subsequently conducted conference calls with each of the relevant SO Addressees and their representatives to explain the context of the Investigation.²²⁵⁰
- L.10 The OFT considered that holding face-to-face meetings at that point in time would not have materially altered the nature of the discussions. Neither Merck, Xellia-Zoetis, nor their legal representatives, objected at the time to the conduct of the Investigation or the lack of a face-to-face meeting being critical to their rights of defence.

²²⁴⁶ C-105/04 *P Nederlandse Federatieve Vereniging voor de Groothandel op Elektrotechnisch Gebied v Commission* EU:C:2006:592 at paragraphs 56, 60. This case arose in the context of a case in which a party claimed that, owing to the time taken by the Commission to conduct the administrative proceedings (in that case eight years), it found it increasingly difficult to obtain information, particularly witness evidence, relating to the Commission’s objections. Although that case related to the duration of proceedings, rather than the time taken to initiate proceedings, the same principles with respect to rights of defence would be relevant. See also the judgment of 6 February 2014 in Case T-40/10 *Elf Aquitaine v Commission*, EU:T:2014:61, paragraphs 75-76.

²²⁴⁷ Merck SO Written Response (document 2764), Section 7; Merck DPS Written Response (document 4033), paragraphs 4.4–4.10; transcript of Merck DPS Oral Hearing dated 17 September 2015 on the GUK DPS (document 4105), page 13, line 19, to page 14, line 3.

²²⁴⁸ Xellia-Zoetis SO Written Response (document 2767), paragraphs 413–430; Xellia-Zoetis DPS Written Response (document 4055), paragraphs 13 and 15–16.

²²⁴⁹ Letter from the OFT to Xellia dated 11 March 2013 (document 2620), letter from the OFT to Zoetis dated 12 March 2013 (document 2638) and letter from the OFT to Merck dated 12 March 2013 (document 2625).

²²⁵⁰ Note of teleconference between the OFT and Xellia on 27 March 2013 (document 2664); Note of teleconference with [Alpharma ApS’s and Alpharma Inc’s external lawyer] and [Alpharma ApS’s and Alpharma Inc’s external lawyer] of [external law firm] on 9 April 2013 (document 2660) and Note of teleconference between OFT and Merck re paroxetine investigation on 21 March 2013 (document 2630).

- L.11 Merck and Xellia-Zoetis were granted extensions to the time limit for responding in writing to the SO, in order to reflect that the Investigation was extended to these entities shortly before the issuing of the SO.²²⁵¹ Moreover, Merck and Xellia-Zoetis were given the opportunity to submit oral representations on the SO, and submit written representations on the First Letter of Facts, SSO, Draft Penalty Statements,²²⁵² Second Letter of Facts and Third Letter of Facts, and provided additional evidence/submissions throughout the Investigation. The OFT/CMA provided regular updates to all SO Addressees on the Investigation after the issue of the SO²²⁵³ and the SSO.²²⁵⁴
- L.12 Merck and Xellia-Zoetis have therefore had sufficient opportunity to understand the factual and legal basis for the OFT/CMA's provisional findings and to make representations on those provisional findings. In this regard, Merck and Xellia-Zoetis have been treated similarly to other Parties to the Investigation and therefore their rights of defence have not been breached.

C. Representations that the CMA should have issued a further Statement of Objections

- L.13 GUK submitted that the CMA misdirected itself procedurally by failing to issue a new Statement of Objections to the Parties following the Proposed NGFA Decision and by proceeding directly to issue the Draft Penalty Statements. GUK stated that following the issue of the Proposed NGFA Decision, the SO could no longer be considered as setting out all of the relevant legal and factual elements of the case made by the CMA against GUK, on the basis that the Proposed NGFA altered the CMA's assessment of the GUK-GSK Agreement.²²⁵⁵
- L.14 In response to the Proposed NGFA Decision, Actavis stated that the CMA had failed to meet its procedural obligations because it had not specified the

²²⁵¹ In Xellia-Zoetis' case, it also made additional submissions on 9 October 2013 and 18 October 2013. Xellia-Zoetis - Written representations on additional evidence dated 9 October 2013 (document 2985) and Xellia-Zoetis – Submissions of additional evidence dated 18 October 2013 (document 2990A). These submissions were in response to the OFT granting an additional period to Xellia-Zoetis to conduct further searches and submit additional evidence following its submission of the Xellia-Zoetis SO Written Response on 7 August 2013.

²²⁵² Merck and Xellia-Zoetis were also afforded the opportunity to submit oral representations on the SSO, as well as the GUK DPS and Alpharma DPS respectively.

²²⁵³ For example, the CMA held state of play meetings with Merck on 18 June 2014 (document 3210) and with Xellia-Zoetis on 19 June 2014 (document 3211).

²²⁵⁴ For example, the CMA held separate telephone conferences on 17 June 2015 with Merck and Xellia-Zoetis. The purpose of these telephone conferences was for the CMA to give these Parties a procedural update on developments in the Investigation since the oral hearings on the SSO took place in December 2014.

²²⁵⁵ GUK response dated 25 August 2015 to the Proposed NGFA Decision ('GUK Proposed NGFA Response'), paragraphs 4.1, 4.2 and 4.4.

aspects of the evidence and assessment relevant to the IVAX-GSK Agreement that remained relevant to the other aspects of the Investigation.²²⁵⁶

- L.15 The CMA does not accept these submissions. First, the Proposed NGFA Decision did not alter the CMA's assessment of the GUK-GSK and Alpharma-GSK Agreements as set out in the SO and SSO. The SO and SSO, as supplemented by the First Letter of Facts, Second Letter of Facts and Third Letter of Facts, set out the facts on which the CMA relied, the objections raised by the CMA, the action the CMA proposed to take and its reasons for doing so in relation to the GUK-GSK and Alpharma-GSK Agreements. Second, the aspects of the evidence and assessment of the IVAX-GSK Agreement that are relevant to the other aspects of the Investigation are clear from the SO and SSO and are not vitiated by the fact that the CMA does not make a finding that the IVAX-GSK Agreement infringed Chapter I of the Act and/or Article 101 TFEU.
- L.16 The Parties also submitted that, in analysing the impact of Apotex's entry on the IVAX-GSK Agreement in the Proposed NGFA Decision, the CMA had taken the approach of assessing events which had occurred *after* an agreement has been entered into as relevant to the assessment of whether that agreement had the object of restricting competition. The Parties submitted that this constitutes a significant departure from the analytical approach adopted in the SO.²²⁵⁷
- L.17 The CMA does not accept that it has taken an *ex-post* approach to the analysis of whether the Agreements infringe competition law. The CMA has assessed the Infringing Agreements in light of the relevant legal and economic context prevailing at the time they were entered into. However, where relevant, the CMA has taken account of market changes in determining the duration of the Infringements under the Chapter I prohibition and Article 101 TFEU.

²²⁵⁶ Actavis Response dated 21 August 2015 to the Proposed NGFA Decision ('Actavis Proposed NGFA Response'), page 4.

²²⁵⁷ GUK Proposed NGFA Response, paragraph 4.3; Actavis Proposed NGFA Response, page 4.

ANNEX M: REPRESENTATIONS RELATING TO THE PROPOSED NGFA DECISION

A. Representations that the GUK-GSK and Alharma-GSK Agreements are excluded from the Chapter I prohibition by virtue of the Vertical Agreements Exclusion Order

M.1 The Parties submitted, in response to the Proposed NGFA Decision that, if the CMA has reached the conclusion that the IVAX-GSK Agreement was excluded from the Chapter I prohibition by virtue of the Vertical Agreements Exclusion Order, then the same conclusion should also apply to the GUK-GSK and the Alharma-GSK Agreements. In particular, the Parties submitted that:

- (a) GUK and Alharma were operating at a separate level of the supply chain to GSK (and IVAX) for the purpose of the Agreements. They also stated that the fact that GUK and Alharma's dispute resulted in litigation (whilst IVAX's dispute did not) should not affect the assessment of their position in the production or distribution chain.²²⁵⁸
- (b) The limits imposed on GUK and Alharma's commercial conduct were largely identical to those imposed on IVAX (both supply agreements were exclusive dealing arrangements, which are not contrary to the Vertical Agreements Exclusion Order).²²⁵⁹

M.2 The key distinction is that the GUK-GSK and Alharma-GSK Agreements specifically related to the settlement or deferral of litigation that concerned the relevant entity's proposed market entry. Each of GUK and Alharma (as potential competitors to GSK in the UK paroxetine market) expressly agreed to restrictions preventing them from entering the UK paroxetine market independently of GSK.²²⁶⁰ Therefore, for the purposes of each of the GUK-GSK Agreement and the Alharma-GSK Agreement, GUK and Alharma respectively were not '*at a different level of the production or distribution chain*' to GSK.²²⁶¹ The fact that GUK and Alharma ultimately distributed GSK's product does not alter that conclusion. Accordingly, the GUK-GSK

²²⁵⁸ GSK DPS and Proposed NGFA Written Response (document 4064), paragraph 2.4; GUK Proposed NGFA Response (document 4074), paragraphs 3.4(b)–(d); Actavis Proposed NGFA Response (document 4068), pages 2–3.

²²⁵⁹ GUK Proposed NGFA Response (document 4074), paragraphs 3.4(c)–(d); Actavis Proposed NGFA Response (document 4068), page 3.

²²⁶⁰ See paragraphs 3.305–3.310 of this Decision in respect of the GUK-GSK Agreement, and paragraphs 3.363–3.369 of this Decision in respect of the Alharma-GSK Agreement.

²²⁶¹ Vertical Agreements Exclusion Order, Article 2.

Agreement and the Alpharma-GSK Agreement were not '*vertical agreements*' within the scope of the Vertical Agreements Exclusion Order and therefore do not benefit from the disapplication, by virtue of that Order, of the Chapter I prohibition.

- M.3 Further, as the GUK-GSK and Alpharma-GSK Agreements were not '*vertical agreements*' for the purposes of the Vertical Agreements Exclusion Order, the Parties' representations on the limits imposed on GUK's and Alpharma's commercial conduct are not determinative.

B. Representations that the CMA cannot reach an infringement finding under Chapter I in light of its Proposed NGFA Decision in relation to the IVAX-GSK Agreement

- M.4 GUK submitted that the degree of competition that it could bring to the market was pre-determined by the IVAX-GSK Agreement, and that it would be illogical to find the GUK-GSK Agreement restricted competition if the IVAX-GSK Agreement did not.²²⁶²

- M.5 The CMA notes that the key component of the Vertical Agreements Exclusion Order is whether the Agreement in question is a '*vertical agreement*'. The application of the Vertical Agreements Exclusion Order does not involve a substantive assessment of the object and/or effect of the particular Agreement in question. The application of the Vertical Agreements Exclusion Order to the IVAX-GSK Agreement does not preclude a finding that the GUK-GSK and Alpharma-GSK Agreements restricted competition contrary to the Chapter I prohibition and, in the case of the GUK-GSK Agreement, Article 101 TFEU.

C. Representations that the IVAX part of the Chapter II case must fail if the IVAX-GSK Agreement is excluded

- M.6 GSK submitted that the Chapter II case makes no distinction between the Agreements with IVAX, GUK and Alpharma, and that the CMA was wrong in proposing to find that GSK infringed the Chapter II prohibition by inducing IVAX to enter into a legal agreement.²²⁶³

²²⁶² GUK Proposed NGFA Response (document 4074), paragraphs 1.5 and 2.2–2.14.

²²⁶³ GSK DPS and Proposed NGFA Written Response (document 4064), paragraph 2.7. Recipients of the Draft Penalty Statements also made this submission in the context of the duration for the purposes of penalty calculations: see, for example, GSK DPS and Proposed NGFA Written Response (document 4064), paragraph 8.2.

- M.7 As set out above, the CMA notes that the application of the Vertical Agreements Exclusion Order does not involve a substantive assessment of the object and/or effect of the IVAX-GSK Agreement. Moreover, the Vertical Agreements Exclusion Order operates to disapply only the Chapter I prohibition for agreements which benefit from that Order; it does not disapply the application of the Chapter II prohibition.²²⁶⁴
- M.8 The CMA therefore finds that there is no inconsistency between the NGFA Decision and a finding of infringement against GSK under the Chapter II prohibition (which includes the CMA's finding that the main economic purpose of the value transfers, including those made to IVAX, was to induce the Generic Companies to delay their potential independent generic entry).

D. The CMA's findings in relation to the object and effect of the IVAX-GSK Agreement after 1 May 2004

- M.9 The Parties submitted that the CMA's findings in relation to the duration of the restrictions of competition by 'effect' are also relevant to the purported anti-competitive 'object' of the Agreements. The Parties submitted that the GUK-GSK and Alpharma-GSK Agreements could not have had an anti-competitive object after November 2003.²²⁶⁵
- M.10 The CMA notes that the term 'object' (both for the purposes of Article 101(1) TFEU and the Chapter I prohibition) refers to the sense of 'purpose', 'objective', 'intent' or 'aim' (see paragraphs 6.11 to 6.17). It is settled case law that if an agreement has as its object the prevention, restriction or distortion of competition, it is not necessary to prove that the agreement has had, or would have, any anti-competitive effects in order to establish an infringement. The CMA finds that, for as long as the entry restrictions contained in the GUK-GSK and Alpharma-GSK Agreements remained in place, in return for which value transfers were paid, the anti-competitive object of those Agreements continued.

²²⁶⁴ Vertical Agreements Exclusion Order, Article 3.

²²⁶⁵ GUK Proposed NGFA Response, paragraphs 3.8–3.9; Actavis Proposed NGFA Response, page 4; GSK DPS and Proposed NGFA Written Response, paragraph 8.3.

ANNEX N: ATC AND EPHMRA CLASSIFICATION

Table N.1: Summary of the Anatomical Therapeutically Chemical (ATC) classification in the N group

First level	Second level	Third level (therapeutic use)	Fourth level (mode of action)
N – NERVOUS SYSTEM
	N06 PSYCHOANALEPTICS –	<p>N06A – ANTIDEPRESSANTS</p> <p>This group comprises preparations used in the treatment of endogenous and exogenous depressions. The group is subdivided mainly according to mode of action. The various Antidepressants have different modes of action, and the classification will not reflect the exact mode of action of the various Antidepressants.</p> <p>The DDDs are based on treatment of moderately severe depressions.</p> <p>Lithium, see N05AN - Lithium Combination with psycholeptics, see N06C.</p>	<p>N06AA – Non-selective monoamine reuptake inhibitors (some are Tricyclic Antidepressants) - Fifth level (individual active substances):</p> <p>N06AA01 desipramine N06AA02 imipramine N06AA03 imipramine oxide N06AA04 clomipramine N06AA05 opipramol N06AA06 trimipramine N06AA07 lofepramine N06AA08 dibenzepin N06AA09 amitriptyline N06AA10 nortriptyline N06AA11 protriptyline N06AA12 doxepin N06AA13 iprindole N06AA14 melitracen N06AA15 butriptyline N06AA16 dosulepin N06AA17 amoxapine N06AA18 dimetracrine N06AA19 amineptine N06AA21 maprotiline N06AA23 quinupramine</p>
			<p>N06AB – Selective Serotonin Reuptake Inhibitors (SSRI)</p> <p>N06AB02 zimeldine N06AB03 fluoxetine N06AB04 citalopram N06AB05 paroxetine N06AB06 sertraline N06AB07 alaproclate N06AB08 fluvoxamine N06AB09 etoperidone N06AB10 escitalopram</p>

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First level	Second level	Third level (therapeutic use)	Fourth level (mode of action)
			N06AF – Monoamine oxidase inhibitors, non-selective (MAOI). N06AF01 isocarboxazid N06AF02 nialamide N06AF03 phenelzine N06AF04 tranylcypromine N06AF05 iproniazide N06AF06 iprovlozide
			N06AG – Monoamine oxidase A inhibitors (MAOI) N06AG02 moclobemide N06AG03 toloxatone
			N06AX – Other Antidepressants N06AX01 oxitripan N06AX02 tryptophan N06AX03 mianserin N06AX04 nomifensine N06AX05 trazodone N06AX06 nefazodone N06AX07 minaprine N06AX08 bifemelane N06AX09 viloxazine N06AX10 oxaflozane N06AX11 mirtazapine N06AX12 bupropion N06AX13 medifoxamine N06AX14 tianeptine N06AX15 pivagabine N06AX16 venlafaxine (it's an SNRI) N06AX17 milnacipran N06AX18 reboxetine N06AX19 gepirone N06AX21 duloxetine N06AX22 agomelatine N06AX23 desvenlafaxine
		N06B – PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS	...
		N06C – PSYCHOLEPTICS AND PSYCHOANALEPTICS IN COMBINATION	...
		N06D – ANTI-DEMENTIA DRUGS	...
...

Source: ATC website: http://www.whocc.no/atc_ddd_index/?code=N06AB&showdescription=yes

Table N.2: Summary of the EPhMRA classification in the N group

First level	Second level	Third level	Fourth level
N – NERVOUS SYSTEM
	N6 PSYCHOANALEPTICS EXCLUDING ANTI- OBESITY PREPARATIONS	N6A – ANTI-DEPRESSANTS AND MOOD STABILISERS	N6A2 – Antidepressants, herbal: Includes products containing <i>herbal substances only</i> , e.g. St. John's Wort. Products containing <i>both a synthetic and a herbal</i> substance are classified in N6A4, N6A5 or N6A9.
			N6A3 – Mood stabilisers: These products affect the manic phases of bipolar disorders, e.g. products containing lithium. Includes products containing valproate semisodium when indicated exclusively for mood stabilisation.
			N6A4 – SSRI Antidepressants: Selective serotonin re-uptake inhibitor Antidepressants. Includes e.g. citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline.
			N6A5 – SNRI Antidepressants: Serotonin-noradrenaline re-uptake inhibitor Antidepressants. Includes e.g. duloxetine when used in Depression, milnacipran, venlafaxine.
			N6A9 – Antidepressants, all others: Includes e.g. amitriptyline, imipramine, clomipramine (all Tricyclic Antidepressants)
		N6B – PSYCHOSTIMULANTS	...
	N6C – PSYCHOLEPTIC-PSYCHOANALEPTIC COMBINATIONS	...	
N6D – NOOTROPICS	...		
N6E – NEUROTONICS AND OTHER MISCELLANEOUS PRODUCTS	...		
...

Source: EPhMRA Anatomical Classification Guidelines 2009

Table N.3: Summary of the British National Formulary (BNF) classification in Chapter 4:

First level Chapter	Second level Section	Third level Sub-section or Paragraph

	4.3 - Antidepressant Drugs	4.3.1 – Tricyclic and related antidepressant drugs Tricyclic antidepressants Amitriptyline hydrochloride Clomipramine hydrochloride Dosulepin hydrochloride Doxepin Imipramine hydrochloride Lofepamine Nortriptyline Trimipramine Tricyclic-related antidepressants Mianserin hydrochloride Trazodone hydrochloride
		4.3.2 – Monoamine-oxidase inhibitors (MAOIs) Phenelzine Isocarboxazid Tranylcypromine Reversible MAOIs (e.g. Moclobemide)
		4.3.3 – Selective serotonin re-uptake inhibitors (SSRIs) Citalopram Escitalopram Fluoxetine Fluvoxamine Paroxetine Sertraline
		4.3.4 – Other antidepressant drugs Agomelatine Duloxetine Flupentixol Mirtazapine Reboxetine Tryptophan Venlafaxine

Source: <http://bnf.org/bnf/bnf/current/index.htm>.

ANNEX O: SIDE EFFECTS FOR SELECTED ANTIDEPRESSANTS

Table O.1: Side-effect profiles and lethality in overdose of commonly used antidepressant drugs

Medicine	Anti-cholinergic	Sedation	Insomnia/agitation	Postural hypertension	Nausea/gastro intestinal	Sexual dysfunction	Weight gain	Inhibition of hepatic enzymes	Lethality in overdose
citalopram, sertraline	-	-	+	-	++	++	-	-	Low
Fluoxetine, fluvoxamine, paroxetine	-	-	+	-	++	++	-	++	Low
venlafaxine ²²⁶⁶	-	-	+	-	++	++	-	-	Low
amitriptylene, dothiepin	++	++	-	++	-	+	++	++	High
reboxetine	+	-	-	-	-	+	-	-	Low
nefazodone	+	+	-	+	+	-	++	++	Low
mirtazapine	-	++	-	-	-	-	++	-	Low

Categories of side-effect strength: ++ relatively common or strong, + may occur or moderately strong, - absent or rare/weak.

Source: Reproduced from Journal of Psychopharmacology.²²⁶⁷

²²⁶⁶ Hypertension as listed as a specific adverse effect.

²²⁶⁷ 'Evidence-based guidelines for treating depressive disorders with antidepressants: a revision of the 1993 British Association for Psychopharmacology guidelines', I. M. Anderson, D. J. Nutt and J. F. W. Deakin, Journal of Psychopharmacology 2000, 14:3.

Table O.2: Side-effects profiles of antidepressants

Generic name of medicine	Anti-cholinergic ²²⁶⁸	Nausea/gastro intestinal	Sedation	Insomnia/agitation	Sexual dysfunction	Orthostatic hypotension	Weight gain	Lethality in overdose
amitriptyline	+++	-	+++	-	+	+++	+++	High
citalopram	-	++	-	++	++	-	-	Low
dothiepin	+++	-	+++	-	+	+++	+++	High
fluoxetine	-	++	-	++	++	-	-	Low
fluvoxamine	-	++	+	++	++	-	-	Low
mirtazapine	-	-	++	-	-	+	++	Low
paroxetine	+	++	-	++	++	-	-	Low
reboxetine	-	+	-	++	+	++	-	Low
sertraline	-	++	-	++	++	-	-	Low
venlafaxine	-	++	-	++	++	-	-	Low

Categories of side effect strength: +++ (high/strong), ++ (moderate), + (low, mild), - (very low/mild)

Source: reproduced from WFSBP.²²⁶⁹

²²⁶⁸ These refer to symptoms commonly caused by muscarinic receptor blockade including dry mouth, sweating, blurred vision, constipation and urinary retention.

²²⁶⁹ WFSBP Guidelines for Biological Treatment of Unipolar Depressive Disorders, Part 1: Acute and Continuation Treatment of Major Depressive Disorder, Michael Bauer, Peter C. Whybrow, Jules Angst, Marcio Versiani, Hans-Jürgen Möller, WFSBP Task Force on Treatment Guidelines for Unipolar Depressive Disorders, World J Biol Psychiatry (2002) 3, 5–43.

ANNEX P: INDIVIDUAL PENALTY CALCULATIONS**Table P.1: GSK**

Party	GSK (GUK-GSK Agreement)		GSK (Alpharma-GSK Agreement)		GSK (Chapter II)	
	Adjustment	Figure	Adjustment	Figure	Adjustment	Figure
Relevant turnover	-	£67,122,000	-	£67,122,000	-	£75,800,000
Step 1 – starting point	21%	£14,095,620	21%	£14,095,620	21%	£15,918,000
Step 2 – adjustment for duration	x 2.5	£35,239,050	x 1.5	£21,143,430	x 2.25	£35,815,500
Step 3 – adjustment for aggravating and mitigating factors	-	£0	-	£0	-	£0
Step 4 – adjustment for specific deterrence and proportionality	-10%	-£3,523,905	-10%	-£2,114,343	-10%	-£3,581,550
	-	£0	-85%	-£17,971,916	+15%	+£5,372,325
Step 5 – adjustment to take account of the statutory maximum penalty	-	£0	-	£0	-	£0
Step 6 – leniency/settlement discount	-	£0	-	£0	-	£0
Total penalty after step 6	£0, reduced from £31,715,145*		£0, reduced from £1,057,172*		£37,606,275	

* As explained at paragraph 11.62 of the Decision, since GSK's Chapter I/Article 101 penalties combined (£32,772,317) are lower after step 6 than GSK's Chapter II penalty (£37,606,275), the CMA has reduced GSK's Chapter I/Article 101 penalties to zero.

Table P.2: GUK-Merck

Party	Generics (UK) Limited		Merck KGaA	
	Adjustment	Figure	Adjustment	Figure
Relevant turnover	-	£13,013,169	-	£13,013,169
Step 1 – starting point	21%	£2,732,765	21%	£2,732,765
Step 2 – adjustment for duration	x 2.5	£6,831,914	x 2.5	£6,831,914
Step 3 – adjustment for aggravating and mitigating factors	-	£0	-5% <i>(Mitigating: cooperation)</i>	-£341,596
Step 4 – adjustment for specific deterrence and proportionality	-10%	-£683,191	-10%	-£649,032
	-50%	-£3,415,957	-	£0
Step 5 – adjustment to take account of the statutory maximum penalty	-	£0	-	£0
Step 6 – leniency/ settlement discount	-	£0	-	£0
Total penalty after step 6	£2,732,765, jointly and severally liable with Merck KGaA		£5,841,286 (of which, Generics (UK) Limited is jointly and severally liable for £2,732,765)	

Table P.3: Alpharma

Party	Actavis UK Limited		Xellia Pharmaceuticals ApS		Alpharma LLC	
	Adjustment	Figure	Adjustment	Figure	Adjustment	Figure
Relevant turnover	-	£5,728,620	-	£5,728,620	-	£5,728,620
Step 1 – starting point	21%	£1,203,010	21%	£1,203,010	21%	£1,203,010
Step 2 – adjustment for duration	x 1.5	£1,804,515	x 1.5	£1,804,515	x 1.5	£1,804,515
Step 3 – adjustment for aggravating and mitigating factors	-5% <i>(Mitigating: cooperation)</i>	-£90,226	-5% <i>(Mitigating: cooperation)</i>	-£90,226	-5% <i>(Mitigating: cooperation)</i>	-£90,226
Step 4 – adjustment for specific deterrence and proportionality	-10%	-£171,429	-10%	-£171,429	-10%	-£171,429
Step 5 – adjustment to take account of the statutory maximum penalty	-	£0	-	£0	-	£0
Step 6 – leniency/ settlement discount	-	£0	-	£0	-	£0
Total penalty after step 6	£1,542,860, jointly and severally with Xellia Pharmaceuticals ApS and Alpharma LLC		£1,542,860, jointly and severally with Actavis UK Limited and Alpharma LLC		£1,542,860, jointly and severally with Actavis UK Limited and Xellia Pharmaceuticals ApS	