EUROPEAN COMMISSION
Competition DG

CASE AT.39226 - LUNDBECK

(Only the English text is authentic)

ANTITRUST PROCEDURE
Council Regulation (EC) 1/2003

Article 7 Regulation (EC) 1/2003

Date: 19/06/2013

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EUROPEAN
COMMISSION

Brussels, 19.6.2013
C(2013) 3803 final

COMMISSION DECISION

of 19.6.2013

addressed to
- Lundbeck Limited
- H. Lundbeck A/S
- Generics [UK] Limited
- Merck KGaA
- Arrow Generics Limited
- Arrow Group ApS
- Resolution Chemicals Limited
- Xellia Pharmaceuticals ApS
- Zoetis Products LLC
- A.L. Industrier AS
- Ranbaxy (U.K.) Limited
- Ranbaxy Laboratories Limited

relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement

AT.39226 - LUNDBECK

(Only the English text is authentic)

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- Zoetis Products LLC
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- Ranbaxy Laboratories Limited

relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement

AT.39226 - LUNDBECK

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union[1],

Having regard to the Agreement on the European Economic Area,

Having regard to 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[2], and in particular Article 7 and Article 23(2) thereof,

Having regard to the Commission decisions of 7 January 2010 and 24 July 2012 to initiate proceedings in this case,

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1 OJ C 115, 9.5.2008, page 47.

2 OJ L 1, 4.1.2003, page 1. With effect from 1 December 2009, Articles 81 and 82 of the EC Treaty have become Articles 101 and 102, respectively, of the Treaty on the Functioning of the European Union ("TFEU", hereafter also referred to as "the Treaty"). The two sets of provisions are, in substance, identical. For the purposes of this Decision, references to Article 101 and 102 TFEU should be understood as references to Articles 81 and 82, respectively, of the EC Treaty where appropriate. The TFEU also introduced certain changes in terminology, such as the replacement of "Community" by "Union" and "common market" by "internal market". Where the meaning remains unchanged, the terminology of the TFEU will be used throughout this Decision.

Having given the undertakings concerned the opportunity to make known their views on the objections raised by the Commission pursuant to Article 27(1) of Regulation (EC) No 1/2003 and Article 12 of Commission Regulation (EC) No 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles 81 and 82 of the Treaty[3],

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

Having regard to the final report of the hearing officer in this case[4],

Whereas:

1. INTRODUCTION

(1) This Decision concerns six agreements which operated in the years 2002 and 2003 (hereafter also referred to as "the period concerned") between the Danish originator pharmaceutical undertaking Lundbeck on the one hand and each of four generic pharmaceutical undertakings on the other hand. The generic pharmaceutical undertakings concerned by this Decision are:

- Merck: two agreements with Lundbeck, one regarding the United Kingdom (from 24 January 2002 until 1 November 2003), one regarding the EEA excluding the United Kingdom (from 22 October 2002 until 22 October 2003);
- Arrow: two agreements with Lundbeck, one regarding the United Kingdom (from 24 January 2002 until 20 October 2003), one regarding Denmark (from 3 June 2002 until 1 April 2003);
- Alpharma: one agreement with Lundbeck regarding the EEA (from 22 February 2002 until 30 June 2003); and
- Ranbaxy: one agreement with Lundbeck regarding the EEA (from 16 June 2002 until 31 December 2003).

These six agreements will hereafter also be referred to as "the agreements in question", "the agreements covered by this Decision" or "the agreements that are the subject of this Decision."

(2) The product concerned by each of the agreements was the anti-depressant citalopram, whether in the form of an active pharmaceutical ingredient (hereafter also referred to as 'API') or in the form of a medicinal product (hereafter also referred to as 'medicine').[5]

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3 OJ L 123, 27.4.2004, page 18.

4 OJ

5 Article 1 of Directive 2001/83 of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, as amended (OJ L 311, 28.11.2004, pages 67 to 128), defines a 'medicinal product' as "(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis." Article 10(2)(b) of the same Directive defines a 'generic medicinal product' as "a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal

(3) At the time the agreements were concluded, Lundbeck's patents and data protection on the citalopram compound and the two original production processes had expired, meaning that Lundbeck no longer had complete blocking power against production and sales of citalopram by generic undertakings. Lundbeck did still have a number of process patents, which gave Lundbeck exclusivity rights on certain (but not all) new ways of producing citalopram to the extent such patents would be found to be valid and infringed. But any undertaking using either the original production processes or any production process not covered by valid Lundbeck process patents could in principle freely enter EEA markets with generic citalopram, provided the product and its production process met regulatory requirements applicable in the EEA at that time.

(4) Each of the agreements was concluded in the context of at least a potential patent dispute[6] between Lundbeck and the generic undertaking concerned regarding the (intended) marketing by the generic undertaking of citalopram API or medicine in the geographic area concerned by the agreement. Prior to the agreements concerned, Lundbeck had usually claimed infringement of one or more of its process patents and the generic undertaking concerned had usually claimed non-infringement of the patent(s) concerned or invalidity of the patent(s) Lundbeck invoked. Each of the agreements was concluded before a court ruling on these issues was given, even by way of interim measures, and all except one (Lundbeck's agreement with Alpharma regarding the EEA) were concluded before any litigation had started.

(5) The Commission wants to emphasise that it is not, of course, as such illegal to settle patent disputes. Patent dispute settlements are, in principle, a generally accepted, legitimate way of ending private disagreements. They can also save courts or competent administrative bodies such as patent offices' time and effort and can therefore be in the public interest. Lundbeck in fact concluded several patent settlements on citalopram that are not the subject of this Decision.

(6) What is important from the perspective of Union competition law is that each of the agreements covered by this Decision prohibited entry by a potential competitor. Each agreement was characterised by the fact that it contained a transfer of value from Lundbeck to a potential or actual generic competitor, which was related to the latter's agreement not to market generic citalopram in the geographic area concerned for the duration of the agreement. The value which Lundbeck transferred, took into consideration the turnover or the profit the generic undertaking expected if it had successfully entered the market. The agreements in question did not resolve any patent dispute; they rather postponed the issues raised by potential generic market entry. It was also established that the agreements contained no commitment from Lundbeck to refrain from infringement proceedings if the generic undertaking entered the market with generic citalopram after expiry of the agreement. Finally, the agreements concerned obtained results for Lundbeck that Lundbeck could not have achieved by enforcing its process patents before the national courts: Each of the agreements in question prevented the generic company concerned from selling

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product has been demonstrated by appropriate bioavailability studies." See chapter 5 for a further description of the medicinal product in this case, citalopram.

6 The term "patent dispute" as used in this Decision refers to a disagreement between two or more parties over a patent and includes the notion of patent litigation as one possible stage of such a dispute.

generic citalopram, irrespective of whether such citalopram would be produced in infringement of Lundbeck's process patents.

(7) This Decision examines the agreements in question under the competition provisions of Article 101 of the Treaty on the Functioning of the European Union (hereafter also referred to as "the Treaty") and of the corresponding Article 53 of the EEA Agreement. This Decision finds that the agreements in question infringed Article 101 of the Treaty and, where appropriate in light of the geographic scope of the agreement, Article 53 EEA, in that they had the object of restricting competition. As the two agreements between Merck and Lundbeck should be considered a single and continuous infringement, and as the same applies for the two agreements between Arrow and Lundbeck, the Commission finds four separate infringements.

2. PROCEDURE

2.1. The Commission's investigation

(8) The Commission first became aware of the agreements in question in October 2003 through information from the Danish Competition Authority. As most of the agreements covered the EEA or other parts of the EEA than Denmark, it was agreed at that time with the Danish Competition Authority that the Commission would further examine the legality of the agreements under Union competition law. In consequence, the Danish Competition Authority did not pursue the matter further.

(9) Between December 2003 and October 2005, while the Commission was pursuing its examination of the agreements in question, it also became aware, inter alia through information from the Hungarian Competition Authority, of other behaviour of Lundbeck that in the Commission's view required further examination. As a result, inspections pursuant to Article 20(4) Council Regulation (EC) No 1/2003[7] took place in October 2005 at the premises of:

– H. Lundbeck A/S in Denmark;

– Lundbeck Pharmaceuticals Italy S.p.A. (formerly known as VIS Farmaceutici S.p.A.) in Italy;

– Lundbeck Hungária Kft in Hungary; and

– [company name]*.

(10) Based on the Commission's analysis of the documents gathered during the inspections, requests for information were sent in 2006 to:

– the Hungarian Competition Authority in April 2006 pursuant to Article 12 of Council Regulation (EC) No 1/2003;

– the Danish Competition Authority in June 2006 pursuant to Article 12 of Council Regulation (EC) No 1/2003;

– [company name]* in July 2006 pursuant to Article 18(2) of Regulation (EC) No 1/2003;

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[7] 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, 4.1.2003, pages 1 to 25.

* Parts of this text have been edited to ensure that confidential information is not disclosed. Those parts are replaced by a non-confidential summary in square brackets or are shown as […].

– H. Lundbeck A/S in July 2006 pursuant to Article 18(2) of Regulation (EC) No 1/2003; and

– the Competition Authorities of the Member States in August 2006 (covering national rules on pricing, reimbursement and substitution).

(11) Throughout 2007, the replies to these requests for information were examined and preliminary work on establishing the Commission's position in respect of Lundbeck's practices and those of other undertakings involved took place.

(12) In January 2008, the Commission decided to launch a broad inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003.[8] This inquiry helped the Commission to obtain a better understanding of the regulatory and economic framework within which originator and generic undertakings operate in the pharmaceutical sector in EEA and, in particular, of possible competition issues in this sector, including with respect to observed delays in the entry of generic medicines to the market. The final report of the sector inquiry was released on 8 July 2009.

(13) In December 2009, the Commission conducted inspections pursuant to Article 20(4) in Italy at the premises of Lundbeck Italia S.p.A. and [company names]*. These inspections allowed the Commission to exclude from this Decision a settlement concluded between Lundbeck on the one hand and [company names]*on the other hand.

(14) On 7 January 2010, the Commission opened formal proceedings against Lundbeck. The Commission's press statement indicated:

"The knowledge acquired during the pharmaceutical sector inquiry[illegible] ways originator companies use [to] obstruct the entry of generic drugs onto the market, has allowed the Commission to draw conclusions on where Commission action based on competition law could be appropriate and effective. The Commission has decided that the investigation focusing on Lundbeck's conduct should be dealt with as a matter of priority, and as a result has opened proceedings."[9]

(15) In 2010 and the first half of 2011, while preparing the current Decision, the Commission sent out a considerable number of requests for information to Lundbeck, the generic companies with which the agreements concerned were concluded, their parent companies and third parties, including notably IMS Health, a data provider in the health sector.

(16) On 24 July 2012, the Commission opened proceedings against the generic companies that concluded the agreements concerned with Lundbeck and issued a Statement of Objections to Lundbeck and to those generic companies.

(17) A hearing was held with all parties who had requested a hearing on 14 and 15 March 2013.

(18) On 12 April 2013, the Commission sent a Letter of Facts to all parties. On 6 May 2013, the Commission sent an additional Letter of Facts to Merck KGaA and A.L. Industrier AS related to chapters 3 and 15 of this Decision.

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[8] Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003 (Case No COMP/D2/39.514).

[9] IP/10/8 of 7 January 2010.

(19) The Hearing Officer issued his final report on 17 June 2013.

2.2. The main evidence relied on

(20) The main evidence relied on is the actual text of the agreements concluded between Lundbeck and each of the generic undertakings concerned, together with documents found during the inspections and replies to requests for information. These documents concern in particular the negotiation, conclusion and implementation of the agreements covered by this Decision.[10]

(21) In order to respond to the Commission's requests for information requesting relevant contemporaneous documents, Lundbeck established a list of "custodians" whose documents were searched by Lundbeck to identify relevant documents. This list of individuals included three [position in Lundbeck]*, three [position in Lundbeck]*, four [position in Lundbeck]*, two [position in Lundbeck]*, one [position in Lundbeck]* and three [position in Lundbeck]* (one of whom was the [position in Lundbeck]*).[11] Most of the Lundbeck documents referred to in this Decision either originated with one or more of these senior managers or were sent to one or more of them. Knowledge of the facts identified in this Decision therefore existed at the highest levels of the undertaking Lundbeck.[12] Indeed, the same [position in Lundbeck]* of Lundbeck signed all but one of the six agreements, while the remaining one was signed by a [position in Lundbeck]* of Lundbeck.

(22) As for the generic companies, participation in the negotiation, conclusion and implementation of the agreements covered by this Decision occurred at the highest levels of the legal entities concluding the agreements. Merck (GUK)'s agreement for the United Kingdom was signed by Merck (GUK)'s [employee function]*. Merck (GUK)'s agreement for other Contracting Parties of the EEA Agreement than the United Kingdom was signed by the [employee function]* of the Merck Generics Group.[13] Arrow's agreement regarding the United Kingdom was signed by [employee name]*, who was at that time […]* of the two Arrow companies that signed the agreement, Arrow Generics Limited and of Resolution Chemicals Ltd. Arrow's agreement with Denmark was signed by a [employee function]* of Arrow Group A/S, at that time the parent company of the Arrow Group. As for Alpharma, its agreement with Lundbeck was signed by the [employee function]* and the [employee function]* of Alpharma ApS, the legal entity within the Alpharma group that concluded the agreement. For Ranbaxy, the agreement was signed by an [employee function]*of the parent company in India.

3. UNDERTAKINGS SUBJECT TO THE PRESENT PROCEEDINGS

3.1. Introduction

(23) The undertakings described below in sections 3.2 to 3.6 below are undertakings that are subject to the present proceedings. Section 3.7 below briefly describes certain other market players, which are not subject to these proceedings, but which played a relevant role in the events described in this Decision.

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10 These sources of evidence are mentioned only for ease of reference. The Commission relies on the entirety of the evidence presented in this Decision to prove the infringements identified in this Decision.

11 ID 577, page 6.

12 See also ID 2057.

13 ID 1977, page 1.

3.2. Lundbeck

(24) H. Lundbeck A/S, the parent company of the Lundbeck group of companies, is based in Denmark and is a publicly-traded corporation ("Aktieselskab" or "A/S"). It has been listed on the Copenhagen stock exchange since 1999. About 70% of its shares are owned by the Lundbeck Foundation, while the remaining 30% are traded on the stock exchange.[14] The Lundbeck group of companies as a whole in the period concerned will hereafter be referred to as "Lundbeck".

(25) Lundbeck, founded in 1915, is a pharmaceutical undertaking specializing in the research, development, manufacturing, marketing, selling and distribution of pharmaceuticals for the treatment of disorders in the central nervous system (CNS), including depression, schizophrenia, Alzheimer's disease, Parkinson's disease, Huntington's disease, epilepsy and insomnia. In the period concerned, CNS medicines represented around 15% of the total spectrum of sales of pharmaceuticals.[15] Lundbeck is a so-called "originator" undertaking, a term used for pharmaceutical undertakings that specialise in developing new medicines and bringing them to the market. In the period concerned, Lundbeck employed around 5 000 people worldwide.[16] At that time Lundbeck was an important global player in the area of medicines for CNS disorders[17].

(26) Lundbeck concluded the agreements that are the subject of this Decision in 2002 and 2003. In 2002, Lundbeck's sales of citalopram in the EEA amounted to EUR [400-600]* million.[18] This figure represented [80-90]* per cent of Lundbeck's total sales revenue of EUR [400-600]* million for all products and services in that year in the EEA.[19] Lundbeck was therefore, at that time, heavily dependent for its revenues on sales of citalopram. Lundbeck's sales of citalopram in the United Kingdom in 2002 were EUR [40-150]* million[20] and those in Denmark in 2002 EUR [0-30]* million.[21] The total worldwide sales revenue of Lundbeck for all products and services in 2002 was EUR 1 278 million.[22] In 2011, the worldwide consolidated turnover for all products and services of H. Lundbeck A/S was EUR 2 148 million.[23]

(27) In the period concerned the undertaking Lundbeck was composed of a considerable number of companies around the world, participating in the group's research and development, manufacturing and sales on a global scale. All of these companies were, directly or indirectly, wholly owned by H. Lundbeck A/S.[24] Lundbeck had its own synthesis factories in Denmark, the United Kingdom and Italy. In the period concerned, Lundbeck had sales subsidiaries in virtually all of the then EEA member countries[25], selling citalopram mainly under the brand names Cipramil and

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14 Lundbeck website, http://www.lundbeck.com.
15 ID 9, page 656.
16 ID 1499, page 9.
17 ID 291, page 22.
18 ID 972.
19 ID 972, page 2.
20 ID 983, page 18.
21 ID 970, page 20.
22 ID 1499, page 6.
23 Using an average annual exchange rate for 2011 of 1 EUR = 7.4506 DKK. Source European Central Bank. See ID 4408.
24 ID 841, page 2.
25 ID 1499, page 101.

Seropram[26] depending on the Member State. In a few Member States, Lundbeck also sold citalopram in partnership with local or generic pharmaceutical companies. Lundbeck had a co-marketing partnership for the sale of citalopram in Italy with Recordati (selling under the brand name Elopram) and in Spain with Almirall Prodesfarma (selling under the brand name Prisdal). In Denmark, in anticipation of expiry in January 2002 of its patent on the citalopram compound, Lundbeck authorised the company Nycomed to distribute citalopram under the brand name Akarin.[27] After expiry of the compound patent, Lundbeck also introduced rebranded versions of its own citalopram in Finland and Sweden.[28] In the United Kingdom, as part of the agreements that are the subject of this Decision, Lundbeck allowed the generic undertakings Merck and Ranbaxy to distribute a certain amount of citalopram, to be sold under Lundbeck's brand name Cipramil.[29]

(28) H. Lundbeck A/S is the legal entity within the Lundbeck group that signed all except one of the agreements that are the subject of this proceeding. The remaining one was signed by Lundbeck Limited, Lundbeck's 100%-owned United Kingdom sales subsidiary. The worldwide consolidated turnover for all products and services of Lundbeck Limited in 2011 was EUR 53 million.[30]

3.3. Merck

(29) The company Generics [UK] Limited (hereafter also referred to as "Merck (GUK)") is a United Kingdom company established in 1981. In the period concerned, Merck (GUK) was an indirect 100% subsidiary of the German company Merck KGaA)[31], the ultimate parent company of the Merck group of companies, including of the Merck Generics Group of companies within which Merck (GUK) functioned. The group of Merck companies as a whole in the period concerned will hereafter be referred to as "Merck".[32]

(30) In the period concerned, Merck (GUK) was engaged in the development, production and marketing of generic pharmaceutical products. Within the Merck Generics Group, Merck (GUK) was not only responsible for marketing generic medicines in the United Kingdom, but acted, in the words of Merck KGaA, as "the operative lead company for MG's [Merck Generic's] European business. it appears that all material decisions relating to the European business had to "go through the UK"."[33] Merck (GUK) also acted as the raw material support group for the entire Merck Generics Group in the EEA.[34] In this capacity it bought APIs (including citalopram

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26 ID 1053, page 137. This Decision will generally use the non-proprietary name citalopram, also when referring to citalopram sold by Lundbeck.

27 ID 813, page 8.

28 ID 9, page 331.

29 See sections 7.2 and 7.7 respectively.

30 Using an average annual exchange rate for 2011 of 1 EUR = 0.8679 GBP. Source European Central Bank. See ID 4408.

31 In the period concerned notably via the legal entities Merck Generics Group B.V., which owned 100% of Generics (UK) Ltd, and via Merck Generics Holding GmbH, which owned 100% of Merck Generics Group B.V. Merck Generics Holding GmbH was 100% owned by Merck KGaA, first indirectly and later directly. See ID 516, pages 11 to 16.

32 The company Generics [UK] Limited as a party to the proceedings will hereafter be referred to as "GUK". The company Merck KGaA as a party to the proceedings will hereafter be referred to as "Merck KGaA".

33 ID 1707, page 1; ID 5960, page 371.

34 See for instance ID 673, page 95.

API) for the entire Merck Generics Group in the EEA.[35] Moreover, as Merck KGaA explained at the Oral Hearing, "GUK, although being just a sister out of many generic companies, was having almost a full set of business operations and as such was delivering all the services to all its sister companies".[36] Merck KGaA specified that "its sister companies" meant sister companies within the Generics Group.[37] Although Merck (GUK) formed part of the Merck Generics Group and the Merck group of companies, Merck (GUK)'s logo remained different from the logo used by other Merck companies, also after Merck had implemented certain corporate identity measures.[38] In 2002, Merck (GUK) concluded two of the agreements with Lundbeck that are the subject of this Decision, one concerning the United Kingdom and one concerning the EEA excluding the United Kingdom.

(31) Merck (GUK)'s worldwide turnover for all products and services in 2002 was EUR 95 million.[39] However, Merck (GUK) did not have any sales revenue for citalopram in 2002 in the United Kingdom and hardly any in the rest of the EEA, the geographic areas for which it concluded agreements with Lundbeck, because in these agreements Merck (GUK) agreed not to sell citalopram in those areas.

(32) In the period concerned, Merck (GUK)'s accounts were consolidated with Merck KGaA's accounts.[40] Furthermore, on 15 January 2002, Merck KGaA entered into a domination and profit & loss transfer agreement ("Beherrschungs- und Gewinnabführungsvertrag") with Merck Generics Holding GmbH.[41]

(33) In October 2007, Merck KGaA sold the Merck Generics business, including all shares in Merck (GUK), to the American company Mylan Inc., the ultimate parent company of the Mylan group of companies (hereafter also collectively referred to as "Mylan"). Mylan is a pharmaceutical undertaking focusing on the production and sale of generic medicines. Since its acquisition by Mylan, the company Generics [UK] Limited has continued to exist as a separate legal entity and to be active in the generics business, with its own turnover and assets. In 2010, the worldwide consolidated turnover for all products and services of Generics [UK] Limited was EUR 88 million.[42]

(34) In 2011, the worldwide consolidated turnover for all products and services of Merck KGaA was EUR 10.2 billion.[43]

3.4. Arrow

(35) The company Arrow Generics Limited is a United Kingdom company established in 2001. Until February 2002, Arrow Generics Limited was a wholly-owned subsidiary

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35 See for instance the preferred supplier agreement Merck (GUK) concluded, on behalf of the Merck Generics Group, with the Swiss company Schweizerhall on citalopram from the Indian API producer Natco, ID 670, page 52. See also ID 1509, page 1.

36 Recording of the Oral Hearing of 14 March 2013, ID 6775, at: 5:11-5:12.

37 See ID 6991, page 4.

38 ID 6633, page 56.

39 Using an annual exchange rate for 2002 of 1 EUR = 0.62883 GBP, source European Central Bank.

40 See ID 516, pages 11 to 16.

41 ID 5982.

42 See ID 1534, page 1 and ID 3670, page 1 (using an annual exchange rate for 2010 of 1 EUR = 0.85784 GBP, source European Central Bank); at the time of writing, Generics [UK] Limited did not yet have its 2011 revenue figures available in audited form.

43 ID 3828.

of Arrow Group A/S in Denmark. In February 2002, as a result of a new share issue, the percentage ownership by Arrow Group A/S of Arrow Generics Limited was diluted to 76%, with 24% of shares being distributed among individual key staff members of Arrow Generics Limited. [44]

(36) Arrow Group A/S, which was established in 2000, was in the period concerned also the 100% parent company of Arrow Group sales subsidiaries in France and Sweden and moreover wholly owned the company Resolution Chemicals Ltd, a producer of generic APIs for the Arrow Group of companies.[45] As of 15 May 2003, Arrow Group A/S became itself wholly-owned by the holding company Arrow International Limited, incorporated in Malta, which in turn at that time became a wholly-owned subsidiary of the company Robin Hood Holdings Limited, also incorporated in Malta. This group structure is still unchanged, with two exceptions: Arrow Group A/S was re-named Arrow Group ApS in August 2003 and Resolution Chemicals Ltd was divested from the Arrow Group in 2009.[46] The latter is at present an independent company. In 2011, the worldwide consolidated turnover for all products and services of Resolution Chemicals Ltd was EUR 10.2 million.[47]

(37) In the period concerned, the principal activity of the Arrow group of companies was the development and marketing of generic pharmaceutical products. The Arrow group began trading in 2001. Resolution Chemicals Ltd was at that time engaged in its own project to develop citalopram API.[48]

(38) In 2002, the Arrow Group concluded, through its United Kingdom subsidiaries Arrow Generics Limited and Resolution Chemicals Ltd, an agreement with Lundbeck for the United Kingdom. Later in the same year the Arrow Group concluded a similar agreement with Lundbeck for Denmark, through the Danish parent company Arrow Group A/S. The group of Arrow companies as a whole in the period concerned will hereafter be referred to as "Arrow".

(39) In 2002, Arrow's total worldwide sales revenue for all products and services was EUR 70 million.[49] However, Arrow did not have any sales revenue for citalopram in 2002 in the United Kingdom or Denmark, the countries for which it concluded agreements with Lundbeck because in these agreements Arrow agreed not to sell citalopram in those countries.

(40) In December 2009, the Arrow Group of companies was acquired by the American company Watson Pharmaceuticals Inc. This did not affect the legal structure within the Arrow group of companies. In 2008, the last full year before the acquisition by Watson, the Arrow Group had a worldwide turnover of around EUR 484 million.[50] In 2011, the worldwide consolidated turnover for all products and services of Arrow

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44 In 2009, in preparation for the acquisition by Watson, Robin Hood Holdings Limited took ownership of these shares previously owned by staff.

45 ID 1517, pages 1 and 3.

46 ID 2601, pages 1 to 7.

47 Using an average annual exchange rate for 2011 of 1 EUR = 0.86788 GBP, source European Central Bank. See ID 3673.

48 ID 610, page 5.

49 Using an annual exchange rate for 2002 of 1 EUR = 0.9456 USD, source European Central Bank. See ID 1517, page 3.

50 ID 610, page 14.

Generics Limited was EUR 42 million.[51] In the same year, the worldwide consolidated turnover for all products and services of Arrow Group ApS was EUR 580 million.[52]

3.5. Alpharma

(41) Alpharma ApS was a company registered in Denmark. It received its name on 30 November 2000, when the company Dumex-Alpharma ApS, which was already part of the Alpharma group of companies, was re-named into Alpharma ApS.[53] In the period concerned, Alpharma ApS owned several other subsidiaries of the Alpharma group of companies, notably in France, Germany, the United Kingdom, the Netherlands, Sweden, Finland, Norway and (as of 3 June 2003) Belgium.[54] In 2002, Alpharma ApS concluded an agreement with Lundbeck covering the Union and Norway.

(42) Alpharma ApS was in the period concerned an indirectly wholly-owned subsidiary of Alpharma Inc., a United States company.[55] Alpharma, Inc., a multinational pharmaceutical company, comprised four business divisions: human generics, branded pharmaceuticals, API manufacture and animal health.[56] The main activity of the human generics division was the development and sale of generic medicines throughout the world, including in the EEA. Alpharma ApS was primarily active in the human generics division as well as in the API manufacture division.[57] The Alpharma group of companies as a whole in the period concerned will hereafter be referred to as "Alpharma".

(43) Alpharma, Inc. was in the period concerned in turn controlled by the Norwegian company A.L. Industrier AS. In 1974, A.L. Industrier AS, at the time operating under a different name, founded a U.S. subsidiary, Alpharma, Inc. (also at the time operating under a different name).[58] In 1984, A.L. Industrier AS listed Alpharma, Inc.'s Class A-shares on the New York Stock Exchange, while keeping control over all Class B-shares (which granted four voting rights). In 1994, Alpharma, Inc. acquired from A.L. Industrier AS "the pharmaceutical, animal health, bulk antibiotic

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51 Using an average annual exchange rate for 2011 of 1 EUR = 1.3920 USD, source European Central Bank. See ID 3823.

52 Using an average annual exchange rate for 2011 of 1 EUR = 1.3920 USD, source European Central Bank. See ID 3823.

53 ID 529, page 7.

54 In particular through an American company named Alpharma Operating Corporation. See ID 529, pages 7-8, ID 1004, pages 7-9 and 11.

55 ID 529, page 1, ID 1004, pages 7-9 and 11.

56 ID 746, page 5.

57 ID 1220, page 3.

58 At that time, A.L. Industrier AS was called Apothekernes Laboratorium A.S. In turn, until 1994, Alpharma, Inc. was called "A. L. Laboratories, Inc." (and for a short time thereafter "A.L. Pharma, Inc."). See Form 8K of 3 October 1994, available at: http://www.secinfo.com/dM9Ba.b5.htm
In its Form 10K of 30 March 1995, page 2, Alpharma reported: "The Company was originally organized in 1975 as a wholly-owned subsidiary of Apothekernes Laboratorium A.S, a Norwegian health care company established in 1903. In February 1984, the Company's Class A Common Stock was initially listed on the American Stock Exchange through a public offering and such stock is currently listed on the New York Stock Exchange. Available at: http://www.secinfo.com/dM9Ba.ad.htm

and aquatic animal health businesses" that was still with A.L. Industrier AS.[59] A.L. Industrier AS explained that when this concentration was negotiated in 1994, it had to be decided which company should be the group parent. Because a United States group parent was considered the best solution, A.L. Industrier AS' board decided to make Alpharma, Inc. "the actual and real group parent". For this reason, Alpharma, Inc. acquired A.L. Industrier AS' businesses, and not the other way around.[60]

However, it is undisputed that from 1994 until the sale by A.L. Industrier AS of Alpharma, Inc. in 2006, A.L. Industrier AS owned all of the outstanding shares of Alpharma, Inc.'s Class B common stock, which gave it the right to ultimately elect a qualified majority of Alpharma, Inc.'s Board of Directors (thus 6 out of 9 directors) and to cast a majority of the votes in any vote of Alpharma, Inc.'s shareholder meetings (the B-shares alone represented around 55% of all votes).[61] Throughout the period concerned, the overall shareholding of A.L. Industrier AS fluctuated between 26,8% and around 23%.[62]

With respect to the acquisition of A.L. Industrier AS' assets in 1994, Alpharma, Inc. reported in its Form 8K to the U.S. Securities and Exchange Commission (hereinafter "SEC"):

"The Company [Alpharma, Inc.] is required to account for the acquisition of the Related Norwegian Businesses of A. L. Oslo as a transfer and exchange between companies under common control."[63]

(44) Alpharma, Inc. stated in its annual reports for the years 2001-2003:

"Industrier has the ability to make decisions affecting the Company's capital structure including, in some instances, the issuance of additional indebtedness."[64]

Alpharma "[…] engages in various transactions with Industrier from time to time, and conflicts of interest are present with respect to the terms of such transactions".[65]

Among these various transactions, according to Alpharma, Inc.'s annual reports, were A.L. Industrier AS' 1998 purchase of a convertible subordinated note and the 2001 conversion of that note into shares of Class B common stock. Furthermore, Alpharma rendered management services to A.L. Industrier. Finally, in January 2003 Alpharma, Inc. divested its vitamin business to Nopal AS ("Nopal"), a subsidiary of

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59 See ID 2555, page 3 and Form 8K of 3 October 1994, available at: http://www.secinfo.com/dM9Ba.b5.htm

60 See ID 6974, pages 1-2.

61 ID 1599, page 2; ID 2555, pages 4-5, ID 6631, page 3 and ID 2562, page 2 (according to Section 2.6 of Alpharma, Inc.'s bylaws, the "Vote Required" is "… D PDMRULW\ RI WKH YRWHV ZKR SHU shares had four voting rights per share, whereas A-shares had only one voting right. See also Form 10K of 30 March 1995, available at: http://www.secinfo.com/dM9Ba.ad.htm. See also ID 6974, page 7, where A.L. Industrier AS pointed out that board members of Alpharma, Inc. are formally suggested and nominated by Alpharma, Inc. A.L. Industrier AS voted on those suggestions. See further the references in footnote 62.

62 ID 4921, page 3; see also ID 1599, page 2 and ID 2555, page 4. Before Alpharma concluded the agreement with Lundbeck, on 31 December 2001, the Norwegian company A.L. Industrier AS owned all of the outstanding shares of Alpharma Inc.'s Class B common stock (11.872.897 shares), and 39.293.180 shares of Class A common stock, amounting in total to 26,8% of the common stock of Alpharma Inc.

63 Form 8K of 3 October 1994, page 2, available at: http://www.secinfo.com/dM9Ba.b5.htm

64 E.g., Form 10K for 2001, available at: http://www.secinfo.com/dM9Ba.3b.htm

65 E.g., Form 10K for 2001, available at: http://www.secinfo.com/dM9Ba.3b.htm

A.L. Industrier AS, for approximately $3.3 million. In connection with this sale, Alpharma, Inc. entered also into a supply agreement with Nopal pursuant to which it would supply Nopal with certain vitamin products, and two distribution agreements pursuant to which both companies would continue to distribute certain of each other's products.[66] According to Alpharma, Inc.'s Form 10K for 2003:

"7KH GLYHVWLWXUH ZDV D WUDQVDFWLRQ "EHWZHHQ [67]

For the period 2000 to 2003, A.L. Industrier AS provided the Commission with an overview and summary of all discussions at A.L. Industrier AS' board meetings of Alpharma, Inc.'s business.[68] The minutes of the board meetings of A.L. Industrier reveal that Alpharma Inc. business activities were from time to time reported to the board of A.L. Industrier (see for instance the minutes of the boards of 22 August 2002 and 13 November 2003). However, A.L. Industrier AS generally discussed Alpharma, Inc.'s business affairs only after the latter had already taken business decisions, based on Alpharma, Inc.'s press releases.[69] The board meeting minutes do not mention any discussion, or approval, of the sale of Alpharma, Inc.'s vitamin business to Nopal and the contracts concluded in this context between Alpharma, Inc. and Nopal.

However, the minutes show that A.L. Industrier AS was involved in the decision-making process concerning the envisaged acquisition of the United States/Australia Company Faulding by Alpharma Inc. in 2000. In this case A.L. Industrier AS' board issued instructions to Alpharma, Inc.'s board already before a decision on the acquisition had been taken. The acquisition would have required a capital increase through the issuance of new stock. Subsequently, A.L. Industrier AS could have lost control over Alpharma, Inc. A.L. Industrier AS' board thus decided on 15 June 2000: "the board decided to instruct the board members of Alpharma Inc appointed by the B-shares to consult the board of A.L. Industrier before they decided to issue so many A shares that A.L Industrier lost the majority vote" [70] However, with respect to the acquisition itself, [employee function]* made clear that "it was the board of directors of Alpharma Inc that are to decide about the projects" [71]

(45) Important personal links existed in the period of the infringement between Alpharma, Inc. and A.L. Industrier AS, because […]*" > « @ [72]

Moreover, the then [employee function]* of A.L. Industrier AS was at the same time […]* of Alpharma ApS.[73]

(46) [employee function]* of A.L. Industrier AS and of Alpharma, Inc. […]*. In 1994, Alpharma, Inc. reported to the U.S. Securities and Exchange Commission:

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66 Form 10K for 2001, available at: http://www.secinfo.com/dM9Ba.2e.htm; "As required of all related party transactions, the sale was determined to be fair to the holders Class A Common Stock by the Company's Audit and Corporate Governance Committee.

67 Form 10K for 2003, available at: http://www.secinfo.com/dM9Ba.11w.htm

68 See ID 6788, pages 11-21.

69 See in particular the discussions of A.L. Industrier AS' board of 21 August 2003 (the discussion of a new strategic plan of Alpharma, Inc.

70 Office translation by A.L. Industrier AS. See ID 6788, page 13; further discussions took place beginning of 2001, see page 14.

71 ID 6788, page 14.

72 Form 10K for the year 2003, available at: http://www.secinfo.com/dM9Ba.11w.htm

73 ID 1601, page 119 and ID 2555, page 6.

"In addition, [employee function]* > «.»[74]

"As a result, A.L. Industrier, and ultimately, […]*, […]*."[75]

Although […]* shares, which were considered to be […]* pursuant to Norwegian law, were considerably lower and did not reach those 50,8%, through proxy or agreement, […]* nevertheless […]*.

The following table summarises […]*, and […]*:[76]

[…]*

These figures show that following the restructuring of the pharmaceutical businesses of A.L. Industrier AS and Alpharma, Inc. in 1994, where […]*, in each and every year following the year 1994 until the expiry of the agreement between Alpharma and Lundbeck on 30 June 2003[77], […]*.[78]

(47) In November 2003, the board of A.L. Industrier AS discussed a law firm memorandum about the […]*. It stated that as [employee function]*of Alpharma, [employee function]* had at any point in time the obligation to […]*. It indicated that […]*.[79] In fact, with respect to the potential financing of Alpharma, Inc.'s acquisition in 2001, [employee function]* could not participate in […]*, because of […]* being [employee function]* also of Alpharma, Inc.[80]

(48) Alpharma explained that on 6 June 2002, it adopted a Contract Policy according to which certain strategic commercial decisions, including all investments over USD 5 million (or USD 7.5 million if the contract was of a type regularly entered into by Alpharma), had to be approved by the Board of Directors of Alpharma, Inc. the majority of which was, as mentioned, appointed by A.L. Industrier AS and which was […]*.[81] Furthermore, Alpharma "also located a document which appears to be WKH YHUVLRQ RI WKH $OSKDUPD &RQWUDFW 3RLF cannot be certain as the Contract Policy does not specify its date of issue". That Contract Policy contained rules similar to the 2002 Contract Policy.[82] A.L. Industrier AS admitted that a Contract Policy was issued on 6 June 2002 (after the agreement with Lundbeck had been concluded), but claimed that the 1998 Contract Policy as submitted by Alpharma, Inc. was not dated, and thus A.L. Industrier AS did not know and it would not be clear whether the 1998 Contract Policy was ever approved by Alpharma, Inc.'s Board of Directors.[83] The 1998 Contract Policy would have been applicable, when Alpharma concluded the agreement with Lundbeck on 22 February 2002.

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74 Form 8K of 3 October 1994, available at: http://www.secinfo.com/dM9Ba.b5.htm

75 Form 10Ks for the years 2000-2003, available at: http://www.secinfo.com/dM9Ba.4f89c.4.htm; http://www.secinfo.com/dM9Ba.3b.htm; http://www.secinfo.com/dM9Ba.2e.htm; http://www.secinfo.com/dM9Ba.11w.htm

76 ID 6863 and 6864, pages 9-10; ID 6793, page 92 (note that the table in ID 6793 was partially amended by the one in ID 6864, page 27).

77 The shareholder meeting of 30 June 2003 is excluded, because the agreement expired on that date.

78 ID 6864, page 27.

79 ID 6788, pages 20-21.

80 ID 6788, page 15.

81 ID 1601, pages 245-246. ID 6559, pages 57-68.

82 ID 6560, page 11.

83 ID 6788, page 7.

(49) The financial accounts of Alpharma Inc. were in the period concerned consolidated into the financial accounts of A.L. Industrier AS.[84] A.L. Industrier AS still exists as a company. Its worldwide consolidated turnover for all products and services in 2011 was EUR 151 000.[85]

(50) On 19 December 2005, Alpharma Inc. sold its worldwide human generics division to the generic pharmaceuticals company Actavis Group hf, established in Iceland. This sale included Alpharma's rights to marketing authorisations for generic citalopram in the EEA, Alpharma's supply agreement for generic citalopram with Tiefenbacher as well as assets of Alpharma ApS.[86] Through this acquisition, Actavis took over Alpharma's sales of generic citalopram in the EEA. This acquisition did not, however, include the legal entities Alpharma ApS or Alpharma Inc, which remained part of the Alpharma group. As Xellia Pharmaceuticals ApS later informed the Commission: "Alpharma ApS was not sold by Alpharma [Inc.] as the company was also used for other Alpharma divisions including the Alpharma API Division."[87]

(51) As part of a subsequent divestment by Alpharma Inc. of its API manufacture division, ownership of Alpharma ApS changed on 31 March 2008 when the company was acquired by a bidder group of companies headed by the company Otnortopco AS with the financial backing of certain investment funds managed by the international investment group 3i. Following the acquisition, Alpharma ApS was renamed Axellia Pharmaceuticals ApS. For trade mark reasons, this name was changed into Xellia Pharmaceuticals ApS in 2010.[88] The company has remained a separate legal entity since then, active mainly in the manufacture of APIs. [89] Its worldwide consolidated turnover for all products and services for 2011 was [...]*.[90]

(52) Alpharma Inc. itself, with its remaining business divisions of branded pharmaceuticals and animal health, was acquired by King Pharmaceuticals, Inc., a United States company, on 29 December 2008.[91] In April 2010, Alpharma Inc. was changed into a limited liability company and in line with that its name became Alpharma, LLC.[92] In February 2011, the King Pharmaceuticals Group was acquired by Pfizer Inc, another United States pharmaceutical company.[93] Alpharma, LLC initially remained a separate legal entity within the Pfizer group of companies.[94] However, on 15 April 2013, Alpharma, LLC changed its name to Zoetis Products LLC as part of re-structuring by Pfizer that consolidated Pfizer's animal health businesses under a new publicly listed company Zoetis Inc.[95] The worldwide

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84 ID 2555, page 8.

85 Using an average annual exchange rate for 2011 of 1 EUR = NOK 7.79337. Source European Central Bank. See ID 3553, page 1.

86 ID 1220, pages 2, 8, 11 and 12.

87 ID 1220, page 2.

88 ID 1220, page 8.

89 ID 529, page 2, ID 1220, pages 1, 7 and 8.

90 Using an annual exchange rate for 2011 of 1 EUR = 7.4506 DKK. Source European Central Bank. See ID 3578.

91 ID 529, page 1, ID 416, page 2.

92 ID 1005, page 22.

93 ID 3950 and http://www.businesswire.com/news/home/20110301006102/en/Pfizer-Completes-Acquisition-King-Pharmaceuticals.

94 ID 529, page 5 and ID 3950.

95 ID 6984.

consolidated turnover for all products and services of Alpharma, LLC (since April 2013: Zoetis Products LLC) for 2011 was […]*.[96]

3.6. Ranbaxy

(53) Ranbaxy Laboratories Limited is an Indian company specialising in the development and production of a wide range of generic APIs and generic medicines. The company was established in 1961 and was listed on the stock market in 1973. Ranbaxy not only sells API to other companies but also sells generic medicines worldwide through its own sales subsidiaries. In the period concerned, Ranbaxy had sales subsidiaries in the United Kingdom, Germany, France, Ireland and the Netherlands. The United Kingdom sales subsidiary, also addressed by this Decision, is called Ranbaxy (U.K.) Limited (hereafter also referred to as "Ranbaxy (UK)" or "Ranbaxy (UK) Ltd"). In 2011, the worldwide consolidated turnover for all products and services of Ranbaxy (U.K.) Limited was EUR 22 million.[97] Ranbaxy has also had a European headquarters in the United Kingdom, Ranbaxy Europe Limited.[98] In 2011, the world-wide consolidated turnover for all products and services of Ranbaxy Laboratories Limited was EUR 1 568 million.[99] The Ranbaxy group of companies as a whole in the period concerned will hereafter be referred to as "Ranbaxy".

(54) In June 2008, Ranbaxy entered into an alliance with Daiichi Sankyo Company Limited, a Japanese pharmaceutical company specialising in innovative medicines. Since then, Ranbaxy has been a member of the Daiichi Sankyo Group, but has kept its own legal personality, assets and turnover.

3.7. Other market players

– Norpharma

(55) As early as October 1998, a small Italian API producer, Norpharma S.p.A. (hereafter also referred to as "Norpharma"), was engaged in the development of a process to manufacture generic citalopram, different from Lundbeck's processes. In October 1999, Lundbeck purchased the patent applications of Norpharma for the process in question.[100]

– VIS

(56) The company VIS Farmaceutici S.p.A. (hereafter also referred to as "VIS"), located in Padua, Italy, was another small producer of APIs. In the late 1990s, VIS cooperated with the German company Tiefenbacher (see recital (57) below) in developing generic citalopram for marketing in the EEA. In October 2000, Lundbeck purchased VIS and withdrew its Drug Master File from Tiefenbacher's application for a marketing authorisation for generic citalopram.

– Tiefenbacher

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96 See ID 3950 and ID 4201, page 1 (using an average annual exchange rate for 2011 of 1 EUR = 1.392 USD, source European Central Bank).

97 Using an average annual exchange rate for 2011 of 1 EUR = 0.86788 GBP, Source European Central Bank. See ID 3646.

98 ID 587, pages 3 to 5.

99 Using an average annual exchange rate for 2011 of 1 EUR = 64.8859 INR, Source European Central Bank. See ID 3632.

100 See recital (174) below.

(57) The company Alfred E. Tiefenbacher GmbH & Co. (hereafter also referred to as "Tiefenbacher"), located in Hamburg, Germany, was established in 1963. In the period concerned Tiefenbacher had around 70 employees and an annual turnover of around EUR 250 million. At that time, Tiefenbacher's business was - and still is - to represent foreign producers of APIs and thus to form a link between producers of active ingredients, often located outside the EEA, and generic companies in the EEA interested in selling medicines using the active ingredient concerned. In this capacity, Tiefenbacher also developed drug registration files and obtained marketing authorisations in Contracting Parties of the EEA Agreement for new generic medicines with a view to allowing the marketing of such new generic medicines as soon as possible after the compound patent for the active ingredient in the EEA had expired. Tiefenbacher commercialised the marketing authorisations it obtained to interested generic companies, the latter normally being committing to buy for a certain period the product concerned via Tiefenbacher from the API producer(s) which Tiefenbacher represented.[101] Tiefenbacher often used two alternative API suppliers to ensure a steady supply. In the case of citalopram, after VIS had been eliminated as a supplier, Tiefenbacher used the Indian API producers Cipla and Matrix.[102]

(58) With respect to citalopram, Tiefenbacher was the first company to obtain a marketing authorisation for generic citalopram in the EEA. This happened in September 2001 in the Netherlands.[103] The marketing authorisation stated Matrix and Cipla as suppliers of the citalopram.[104] Subsequently, in the course of 2002, Tiefenbacher obtained, through the mutual recognition process, similar marketing authorisations in Belgium, Denmark, Finland, Germany, Norway, Sweden and the United Kingdom.[105] Based on API supplies by Cipla and Matrix, Tiefenbacher commercialised these marketing authorisations to a number of companies interested in selling generic citalopram in the EEA. These companies could obtain the API from Cipla or Matrix, either in the form of bulk or in the form of tablets prepared by the company Omega Farma in Iceland.

– Omega Farma

(59) The company Omega Farma ehf (hereafter also referred to as "Omega Farma"), located in Iceland, was used by Tiefenbacher for the production of citalopram tablets.[106] Lundbeck did not have any patents on citalopram in Iceland, thus allowing Omega to obtain a marketing authorisation for citalopram there already in January 2001.[107] In 2005 Omega Farma ehf was acquired by the generic pharmaceutical undertaking Actavis.[108]

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101 ID 291, pages 1-2.

102 ID 291, page 4.

103 ID 280, page 3. In the United Kingdom, however, Merck (GUK) was the first generic undertaking to obtain a marketing authorisation on 9 January 2002 (based on Natco API). See recital (259) below.

104 ID 1713, page 1.

105 ID 301.

106 See for instance Arrow's contract with Tiefenbacher, ID 619, page 2.

107 ID 9, pages 96-97, 230.

108 ID 746, page 8.

– Cipla

(60) The company Cipla Limited (hereafter also referred to as "Cipla") was established in India in 1935. It is active in the production and sale of generic APIs and medicines. In the period concerned, it was involved in the development and manufacture of generic citalopram for Tiefenbacher.

– Matrix

(61) Matrix Laboratories Limited (hereafter also referred to as "Matrix") is an Indian company active in the production and sale of generic APIs and medicines. The company was acquired in 2006 by Mylan. In the period concerned, Matrix was involved in the development and manufacture of generic citalopram for Tiefenbacher.

– Natco

(62) The company Natco Pharma Limited (hereafter also referred to as "Natco") was established in India in 1981. It is active in the production and sale of generic APIs and medicines.[109] In the period concerned, it was involved in the development and manufacture of generic citalopram for Merck.[110]

– Lagap

(63) The United Kingdom company Lagap Pharmaceuticals Limited (hereafter also referred to as "Lagap"), a subsidiary of Sandoz (the generic business of the Novartis group of companies), was in the period concerned a supplier in the United Kingdom of generic citalopram sourced from Matrix (via Tiefenbacher). After it had entered the United Kingdom market with Matrix citalopram in October 2002, Lundbeck launched litigation against Lagap before the United Kingdom courts for infringing Lundbeck's process patents, notably Lundbeck's recently obtained crystallisation patent.[111] Following a court-ordered inspection of Matrix's premises and process technology, the litigation was settled on 13 October 2003. In the settlement Lundbeck granted a non-exclusive royalty-free licence to Lagap to use Lundbeck's crystallisation patent in the EEA. The settlement led Lundbeck to terminate most of its agreements with other companies, as a result of which much fuller generic competition could take place.

4. THE REGULATORY FRAMEWORK

4.1. Patents

(64) A patent is a legal title protecting an invention, which can be a product or a process, by granting its holder the right to prevent third parties from making, using, offering for sale, selling, importing, distributing or stocking the product (including the product obtained directly by a patented manufacturing process) without the patent holder's consent.[112] In order to ensure sufficient compensation to the inventor for the innovative work which is the subject of the patent, patent law gives the innovator an

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109 ID 581, page 3.

110 See sections 7.2 and 7.3 below.

111 See recitals (152) to (165) below.

112 A patent is therefore an intellectual property right ("IPR"). See Article 28(1) of the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

exclusive right to the commercial exploitation of the invention for a certain period of time. 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 exchange for royalties.

(65) A national patent applies only in the States in which it has been granted. At the time of events, European patents granted by the European Patent Office (EPO) were split after grant into a bundle of national patents, and had to be validated in each State (designated by the applicant) before they can be enforced there. Enforcement of patents took place through an infringement procedure in the national court system, which, depending on the Member State, could be a general court or a court specialised in intellectual property issues. An example of the latter is the Patents Court of the Chancery Division in the High Court of Justice in the United Kingdom.

(66) In the EEA, patent protection may be obtained for up to 20 years from the filing date.[113] Because the long period that elapses between the filing of an application for a basic patent for a new medicinal product and authorisation to place the medicinal product on the market made the period of effective protection under the basic patent insufficient to cover the investment put into the research, the European legislator created in 1992 a supplementary protection certificate (also called 'SPC') that extended with a maximum of five years the patent protection of products that are protected by a basic patent in the territory of a Member State and that are subject, prior to being placed on the market as a medicinal product, to a marketing authorisation.[114] Through this extended period of protection, the European legislator encouraged research into new medicinal products in the Union.

(67) During the period of patent exclusivity, from the moment the patent holder (also called 'originator' in the pharmaceutical industry) has obtained a marketing authorisation for a medicinal product until the expiry of the SPC (or of the patent if no SPC was granted), corresponding in practice to a maximum period of fifteen years[115], the patent holder may be able to charge a price for the medicine resulting from the invention that is higher, often far higher, than its marginal cost of production. This allows the originator company to recoup the significant investment

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113 See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 116. In accordance with Article 3 TRIPS, Article 63 of the European Patent Convention (EPC) provides that the term of a European patent is 20 years from the date of filing of the application.

114 The extension applies subject to the limitations in Articles 4 and 5 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, 2.7.1992, p. 1). Article 1 of this Regulation defined 'product' as "the active ingredient or combination of active ingredients of a medicinal product". For the definition of 'medicinal product', see footnote 5 above. After the period concerned by this Decision, Regulation No 1768/92 has been replaced by Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152 of 16.6.2009, pages 1 to 10). Article 13(2) of this Regulation provides that the duration of the certificate may not exceed five years from the date on which it takes effect. See also footnote 115 below.

115 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152 of 16.6.2009, pages 1 to 10) explicitly provides for an overall maximum period of exclusivity of 15 years from the time the medicinal product first obtains authorisation to be placed on the market in the Union (see recital 9 of the Regulation). Under Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, 2.7.1992, p. 1) the maximum period of exclusivity was, in practice, the same. See also European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 131-132.

it makes in research and development of new medicines (not just the particular product that is being successfully marketed, but also numerous projects that never reach the marketing stage). The end of this period reflects the assessment by the legislator that this is the point in time where the cost to society of continued patent protection, in the form of extra profits to the originator company from its exclusive position, starts exceeding the benefits to society.

(68) Once the SPC period has expired and the active ingredient is no longer protected, that active ingredient can in principle be used by third parties, so-called 'generic companies', to produce and sell so-called 'generic' medicines containing the identical active ingredient 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[116], that is to say in the case of active ingredients how the active ingredient can be produced. The right of society (competitors) to freely reproduce the invention after patent expiry is precisely what society gains in exchange for guaranteeing the inventor an initial period of exclusive use. Patent protection for the original production method of the active ingredient therefore normally expires at the same time as the protection for the active ingredient itself. From that moment on, the market is in principle open for entry of generic versions of the active ingredient concerned.

(69) When originator companies have been able, as explained, to charge during the period of patent protection medicine prices far higher than the marginal cost of production and such medicines reach significant sales, typically a highly dynamic process of generic competition starts some time before expiry of the original patent application, which takes the form of a "race" between different generic undertakings to (be the first to) enter the market.[117] In fact, the earlier a generic undertaking comes to the market, the higher its profit margins will be. As concerns citalopram, Merck (GUK), Arrow, Alpharma and, to a lesser extent, Ranbaxy participated in this competitive process and were seeking to enter the market as soon as possible with their generic version of citalopram. These are the generic undertakings with which Lundbeck concluded the agreements covered by this Decision.

(70) As the Commission has analysed in its sector inquiry into the pharmaceutical sector, generic entry into a pharmaceutical market "can have a profound effect as it changes the market from one in which only one firm could sell the product(s) concerned (possibly via licensees) into one where more sources of supply become available for the product. The most direct effect is likely to be on the average price level of the product(s) concerned and the sales volumes of the originator."[118] The Commission found in its report that one year after generic entry, on average the prices for its sample of 75 major products had fallen by almost 20% and by about 25% after two years[119]. The Commission also found for the same sample of 75 major products that

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116 EPC Article 83: The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. See also Article 29 TRIPS.

117 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 559: "7KH YDOXH VDOHV RI WKH RULJLQDWRU GUXJ SULRU WR driver of generic entry"

118 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 98.

119 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 99.

within one year after generic entry, generic companies had acquired on average a market share by volume of 30%, and of 45% after two years.[120]

(71) As long as patent protection for the compound (molecule) exists, it will normally not be possible for a generic company to enter the market with a medicine containing the compound concerned without causing an infringement of the compound patent. However, even after the compound patent has expired, intellectual property obstacles for generic companies can still arise, in particular if patents, usually belonging to the originator company, are still in force that cover inventive, more efficient production methods of producing the compound which itself is no longer patent protected. It may be the case, for instance, that the production method disclosed in the original patent application is sufficient to reproduce the active ingredient in a laboratory, but is unsuitable to industrial production on a large scale. In that case, the originator company may have obtained additional process patents in developing an efficient industrial production method for the active ingredient. If a production method were still under patent protection and such a production method were used by a generic company to produce the compound that was no longer patent protected, the generic company 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. However, this does not mean that market entry is not possible. As the General Court stated for a formulation patent in AstraZeneca "the ability of a formulation patent to confer exclusivity on a product is not equivalent, in any event, to that of a substance patent, since an active substance can be incorporated into different formulations."[121] The same can be said of process patents, in cases where an active substance can be produced by different processes.[122]

(72) The generic company is thus free to develop still another production method that is not patent protected. If a generic company succeeds in inventing a new production process it may apply for a patent for that process.[123] Much of the development work of generic producers of APIs is therefore focused on compounds that are close to patent expiry. Such work tries to reproduce the original production process for such an active ingredient and to render it more efficient, where necessary, or to "invent around" other existing process patents of the originator company concerned. Whether or not a generic challenger has managed to reproduce the original production process without infringing process patents that are still in force or invented around such patents may depend on complex patent law questions and can easily become the subject of a dispute with the originator. Such disputes are common in the pharmaceutical sector and part of the competitive process for generic entry.

(73) Alternatively, the generic company may challenge before the national patent office, the EPO or the national courts the validity of a process patent, claiming, for instance, that it does not represent a true invention. Such challenges are an inherent part of the competitive process between originator and generic companies as well and are useful to society in potentially eliminating unmerited patents that form an unjustified

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120 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 108.

121 Case T-321/05, AstraZeneca v Commission, judgment of 1.7.2010, paragraph 607.

122 As will be explained in section 6.3 below, this was the case for citalopram.

123 Regarding citalopram see, for example, ID 1024, page 83, where Merck (GUK) reported: "several published process patents were identified assigned to Sumika, Cipla, Ranbaxy, Orion and NATCO Norpharma see recital (174) below.

obstacle to effective competition in the market for the compound concerned. The generic company may also seek a ruling from the court that it is not infringing the patent(s) concerned. In the United Kingdom, this is referred to as a "clearing the way" procedure if the procedure is undertaken before actual marketing of the generic product starts.[124]

(74) When a generic company 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 process patents, the patent holder may react by initiating an action before the national court for infringement of one or more of those process patents against the generic company concerned as well as possibly against other companies involved in the production and marketing of the product. Such a generic product launch is called "at risk", as it is at risk of being challenged as a patent infringement before the court by the patent holder. When a generic challenger is being challenged in court, this does not mean that the generic company is indeed infringing the patent holder's process patents. The patent holder often has only insufficient knowledge about the exact API production process used, and therefore has difficulty to know when it launches litigation whether the generic company is in reality infringing its patent rights. The outcome of court proceedings is therefore generally difficult to predict and uncertain.

(75) In an infringement proceeding, the originator company may ask for an interim injunction to prevent (further) damage to its commercial interests. In deciding whether to grant an interim injunction, the judge will duly take into account the interest of the originator company in preventing commercial harm from infringement of its patent. But, before ordering an interim injunction, the judge may and normally will also satisfy itself that the applicant is the right holder and that the applicant has provided reasonably available evidence that its right is being infringed, or that such infringement is imminent.[125] If the interim injunction is granted, the judge will order that the generic company must stop marketing its product until the main proceeding has been decided. In the main proceeding, the originator company may, apart from a finding of infringement, also ask for damages. 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. If the defending generic party was unlawfully excluded from the market, it may also ask for damages. The judge will then decide, first, whether interim measures are justified and secondly, in the main proceeding, whether the patent is valid and whether it has been infringed.

(76) The Commission's report on the sector inquiry into the pharmaceutical sector found for the period between 2000 and 2007 that generic companies won 62% of all patent litigation cases that resulted in a ruling.[126] For process patents, the corresponding figure was 74%.[127] Out of all litigation cases in which a final judgment was given on

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124 "Clearing the way" may also refer to steps that a generic company can take to avoid a preliminary injunction, see footnote 312 below.

125 See Corrigendum to Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights, Article 9 (OJ L 195, 02.06.2004, pages 16 to 26).

126 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 11.

127 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 238.

the issue of the validity of a given patent, the court revoked the patent in 55% of cases and upheld it in the remaining 45%.[128] For litigations initiated by originator undertakings, 32% of the judgments found the invoked patent not to be infringed, and in an additional 12% of cases the court annulled the invoked patent.[129]

When a patent right is litigated, it may therefore be more difficult to predict the outcome than in the case of rights to tangible property, such as a piece of land or a car, for two main reasons:

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.[130]

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. A 2011 "Study on the quality of the patent system in Europe" commissioned by DG MARKT found that in 68% of the cases, "the prior art reported by the patent examiner was accurate and complete".[131] A particular issue is that in the EEA there is at present no mandatory requirement per se for the applicant to disclose knowledge of prior art. However, the EPO may request the applicant to provide information on prior art taken into consideration in the examination of similar patent applications before other Patent Offices. If the applicant fails to provide the information, the application is deemed to be withdrawn.[132]

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. In order to assess inventive step in an objective and predictable manner, the EPO has developed a well-defined procedure the so-called "problem-and-solution approach". This approach provides objective criteria for characterising the invention in terms of a technical problem and its solution when assessing whether an inventive step is present.

The requirement of industrial application means that an invention can be made or used in any kind of industry, including agriculture. This requirement aims to distinguish between aesthetical and scientific inventions, that is to say that only inventions that have a technical character are eligible for patent protection. In addition industrial applicability requires that the invention can be manufactured and does not violate physical laws.

Secondly, the process for examining patent applications is essentially an ex parte process, i.e. a process between the applicant and the patent office. Although third parties - such as actual or potential competitors - have an opportunity to make written observations before the patent office makes a decision on the patent application which might be taken into consideration, if justified, by the examiners, third parties

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128 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 237.

129 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 237.

130 Article 52(1) EPC.

131 See page 46. See: http://ec.europa.eu/internal_market/indprop/docs/patent/patqual02032011_en.pdf

132 Article 124 EPC and rule 141 of the implementing regulations of the European Patent Convention

do not have the right to discuss those observations with the patent office or the applicant before a decision on the application is taken. At this stage, expert witnesses of third parties cannot be heard. However, after the patent has been granted, any third party can formally oppose it within a given time period. Such opposition (followed if necessary by an appeal) may, normally several years later, lead to a decision of the patent office to revoke the patent. Such revocation will apply ab initio, meaning that legally speaking the patent is annulled from the very beginning and is deemed to have never existed. Oppositions may also lead to either a narrowing of the claims in the patent or the rejection of the opposition – the patent is then maintained as it is. The opposition division decision might also be challenged by the parties before the Board of Appeals.

According to the statistics published by the EPO in its Annual Report 2002, the EPO granted on average over the years 33.8% of all patents applied for, while less than 7% of those patents were challenged. [133] However, of the patents challenged through opposition before the EPO in 2002, 35.4% were revoked and 37.9% were amended. Only 26.7% of challenged patents remained intact.[134] It should be noted that even patents confirmed by the EPO, whether in amended form or not, may still be held invalid by national courts, even if this happens only rarely.

(77) Once granted, patents are assumed to be valid and they can be invoked by patent holders against third parties, including before national courts – whether or not there is a disagreements on the validity of the patent. The General Court held in AstraZeneca

"When granted by a public authority, an intellectual property right is normally assumed to be valid and an undertaking's ownership of that right is assumed to be lawful. The mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since public regulations require them to respect that exclusive right."[135]

(78) This assumption of validity of patents does not mean, however, that a generic company which believes that it does not infringe any patent or which believes that the patent in question is invalid would not have be able to try to sell its product in the market. Indeed, in deciding whether to grant a marketing authorisation to a generic company for a particular medicinal product, the marketing authorisation bodies in the EEA are not allowed to take the patent status of that product into account.[136] Moreover, when a patent is invoked against entry of a generic company, that generic company is free to challenge the validity of such patent. In court, the assumption of validity allocates the burden of proof:. Thus, while an originator company claiming before a court that a patent has been infringed in principle bears the burden of proving the infringement[137], a generic company (counter-)claiming that a patent is

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133 This means that roughly 2.4% of the initial patent applications will be opposed if they become a granted patent.

134 EPO, Annual Report for the year 2002, page 16.

135 Case T-321/05, AstraZeneca AB and AstraZeneca plc v Commission, judgment of 1 July 2010, paragraph 362.

136 For a further description of the procedure for marketing authorisation, see section 4.2 below.

137 Lundbeck pointed out in its reply to the Statement of Objections that "Article 34 TRIPS recognizes the difficulty of enforcing process patents. It requires TRIPS contracting parties to provide for a reversal of the burden of proof in litigation concerning the alleged infringement of process patents, meaning that the generic company must, under certain circumstances, demonstrate that it did not infringe a process

invalid bears the burden of proving that. If a counterclaim for invalidity has been lodged at the same court where an infringement action is pending, the judge in question will examine without bias based on the substance whether the patent is truly valid and has indeed been infringed.

(79) Patent disputes can also lead to a settlement between the parties, whether before or after patent litigation has started. A settlement seeks an amicable resolution of the dispute between the parties with a view to avoiding (further) costly litigation and the risk of a potentially adverse ruling (for either party) by the court. A patent settlement between an originator company and a generic company could, for instance, in the light of each party's assessment of the chance that the court will hold the patent (in)valid or (not) infringed, agree on an entry date for the generic product at any point in time between immediate entry and entry at the expiry of the patent protection of the invoked patent(s). Such an agreement may in many cases be pro-competitive enabling the generic company to enter the market prior to the lapse of the patent. In the case of process patents which generic companies are constantly trying to invent around, normally one or the other generic manufacturer will succeed sooner rather than later in finding a way to manufacture the product in a non-infringing manner.[138] This means that a settlement involving process patents may well see an agreed entry date for the generic company concerned a considerable time before the lapse of the patent. Moreover, in the case of process patents, the generic company entering into such a settlement may want to make unilateral termination of the agreement possible as soon as other generic companies freely enter the market. A settlement may also include a licence from the originator company to the generic company authorising the latter to use the invention, with or without royalties.

(80) These types of settlements are to be distinguished from the agreements covered by this Decision, in which the parties did not resolve or terminate any patent dispute and did not agree on any entry date for the generic company but rather agreed on a period in which the generic company would be excluded from the generic market, without any guarantee of unrestricted market entry thereafter, in exchange for a considerable sum of money from the originator company. As Lundbeck wrote to the Commission: "Lundbeck's settlements did not remove uncertainty over whether a generic's challenge would eventually succeed, because they did not finally resolve the dispute" and /XQGEHFN V DJUHHPHQWV GLG QRW « [Company] PDWHO\ could enter the market.[139] Indeed, the agreements covered by this Decision

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patent. However, Article 34 of the TRIPS gives contracting parties the option which most EEA countries have exercised in their national implementing measures to subordinate the reversal of the burden of proof to the condition that the patented process concerns the production of an entirely new product. Therefore, in practice, this reversal of the burden of proof often does not apply in favour of patent holders, which makes proof of infringement very difficult." (ID 5394, page 29).

138 Lundbeck wrote to the Commission: "More fundamentally, in the context of process patents, any company can produce the underlying compound through non-infringing means." See ID 1683, page 21. In its reply to the Statement of Objections, Lundbeck added that, in practice, proof of infringement of a process patent is "very difficult". "Furthermore", according to Lundbeck, « WKH GLIILFXOW\ LQ HQ a particular process patent, as opposed to a product patent, lies in the potentially endless alternatives to that process, which means that the originator will have to investigate every single claim of a generic that it has now produced the same product by means of a non-infringing process. And by fudging slightly with a given process, the generic can at least initially claim it now has a new, non-infringing SURFHVV (ID 5394, page 29).

139 ID 1683, pages 3 and 2. See also, for instance, recital (519) below.

postponed the issue of potential generic market entry, thus effectively extending, at least in respect of the generic companies concerned, the period of exclusivity for Lundbeck well beyond the expiry of the original compound and original process patents. The agreements in question did not settle any patent dispute and should not, therefore, strictly speaking be called "settlements".

(81) In Case 65/86, Bayer AG and Maschinenfabrik Hennecke v Heinz Süllhöfer, the Court of Justice held that an agreement does not fall outside the scope of Article 101 of the Treaty simply because it is a settlement agreement or an agreement related to IP rights. The Court of Justice held that "[i]n its prohibition of certain "agreements" between undertakings, Article 85(1) [now 101(1) of the Treaty] makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind".[140] Thus, while companies in principle have the right to settle their patent disputes, just as they have the right in principle to conclude other kinds of agreements, even if they are actual or potential competitors, in doing so they must respect Union competition law.

(82) In its inquiry into the pharmaceutical sector, the Commission found that in the European Union more than 200 patent settlements had been concluded between 2000 and June 2008, covering 49 medicines. In slightly over 20 of these settlements, that is to say in around 10% of all agreements, the agreement provided for a direct payment from the originator company to the generic company and for a restriction on the generic company's ability to market the product in question.[141] In respect of this latter type of agreement, the Commission noted in its sector inquiry report:

"Agreements that are designed to keep competitors out of the market may also run afoul of EC competition law. Settlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies are an example of such potentially anticompetitive agreements, in particular where the motive of the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets."[142]

(83) The present Decision concerns the concrete application of Union competition law, in casu Article 101 of the Treaty, to a number of agreements "that limit generic entry and include a value transfer from an originator company to one or more generic F R P S D Q L H V «[143]

4.2. Marketing authorisation

(84) With a view to safeguarding public health, no medicinal product for human use, whether a product of an originator company or of a generic company, may be placed

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140 Case 65/86, Bayer AG and Maschinenfabrik Hennecke GmbH v Heinz Süllhöfer [1988] ECR 5249, paragraph 15.

141 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 12-13.

142 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 20.

143 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 20.

on a market in the EEA unless a marketing authorisation has been issued for it.[144] A marketing authorisation is a permit granted by the responsible health authorities to a pharmaceutical company, authorising the sale of a given pharmaceutical product in the territory concerned. The pharmaceutical company must apply for a marketing authorisation, providing data concerning the medicinal product, including its name, pharmaceutical form, indications, dosage and adverse reactions as well as documenting the product's pharmaceutical quality, safety and efficacy. Obtaining a marketing authorisation involves therefore submitting the results of a certain number of pre-clinical toxicological and pharmacological tests as well as clinical trials, which together allow an assessment of the safety and efficacy of the medicine.

(85) In the period concerned by this Decision, the years 2002 and 2003, generic companies obtained for their generic medicines national authorisations, which were issued by the competent authorities of the Member States and covered their own territory.[145] Directive 2001/83 provided that a Member State had to complete the procedure for granting a marketing authorisation within a maximum of 210 days of the submission of a valid application.[146] A national authorisation could be recognised by other Member States by using the mutual recognition procedure (MRP).[147] A decision on whether to recognise the marketing authorisation granted by another Member State (the so-called Reference Member State) had to take place within 90 days after the receipt of that other Member State's assessment report (which in turn had to be prepared within 90 days).[148] Finally, following this recognition, it would

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144 Recital 2 and Article 6 of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, OJ L 311, 28.11.2001, page 67 (hereafter also referred to as "Directive 2001/83").

145 See European Commission, DG Competition: Report on the Pharmaceutical Sector Inquiry, 8 July 2009, page 134. Norway, Iceland and Liechtenstein have, through the EEA Agreement of 1994, adopted the 'acquis communautaire' on medicinal products. They are parties to the Union's marketing authorisation procedures, with the only exception that legally binding acts adopted at Union level do not directly confer rights and obligations but first have to be transposed into legally binding acts in the respective countries. Marketing authorisations granted by Member States are eligible for mutual recognition in Norway, Iceland and Liechtenstein, just as marketing authorisations granted by Norway, Iceland and Liechtenstein are eligible for mutual recognition by Member States of the Union. See European Commission, DG Competition: Report on the Pharmaceutical Sector Inquiry, 8 July 2009, page 134, footnote 274.

146 See Article 17 of Directive 2001/83/EC. This period began to run on the day the authorities accepted that the application was valid. As long as the application was incomplete or incorrect, the period did not start.

147 See European Commission, DG Competition: Report on the Pharmaceutical Sector Inquiry, 8 July 2009, pages 134 and 146-147. See also Articles 10 and 18 of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, OJ L 311, 28.11.2001, page 67. As for the so-called centralised procedure (where a single application is made at Union level) and the decentralised procedure (where identical applications are made to a number of Member States and a single Member State among them acts as reference Member State and prepares the assessment), these came into operation for generic products only in 2005. These two procedures did not, therefore, play a role in the facts concerned by this Decision. See also Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004.

148 Articles 28 and 29 of Directive 2001/83 provided that in the mutual recognition procedure, a Member State had to either recognise the marketing authorisation granted by another Member State, within 90 days of the receipt of the assessment report of that other Member State, or within that period indicate its reasons for believing that the granting of a marketing authorisation would pose a public health risk.

normally take a couple of weeks for a national marketing authorisation to be granted (the so-called "national phase").[149] Thus, in the period concerned, generic companies wanting to sell in the EEA could either make several national applications (which were formally independent of each other), whether simultaneously or consecutively[150], or could use the mutual recognition procedure. In the latter case, they would make an application to a single Member State first, the so-called reference Member State. If the application was correct from the beginning, generic companies could obtain a marketing authorisation in the Reference Member State within around 7 months. This could be followed by marketing authorisations in other Contracting Parties of the EEA Agreement, normally within at most an additional 7 months if no objections arose, bringing the total to 14 months if all went well.[151] If the applicant made several simultaneous applications to different national marketing authorisation bodies, it could, in principle, obtain several marketing authorisations after 7 months, although Member States had the right to suspend examination if they noted that an application was already under active consideration in another Member State.[152] How much longer the procedure would actually take would depend on the number of deficiencies in the application and the speed with which the applicant acted to correct those. According to Lundbeck, a full process including mutual recognition could "in reality" take 25 months or more.[153]

(86) Once a generic undertaking had obtained a marketing authorisation, it could apply for a type I variation to that marketing authorisation to cover any future amendments

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According to the European Generic Medicines Association (EGA), the later decentralised procedure involves the other Member States in an earlier stage of the evaluation than under the mutual recognition procedure in an effort to minimise disagreements. See the EGA webpage on "authorisation" http://www.egagenerics.com/gen-authorisation.htm.

149 Compare Article 34(3) of the original Directive 2001/83 and Article 28(5) of Directive 2001/83 as amended. Article 28 of the original Directive 2011/83, which applied at the time of events, was silent on the period in which the national marketing authorisation had to be issued in the case of recognition. According to Arrow, "There is no VSHFLILF GHDGOLQH IRU WKH QDWLRQDO S significantly from one CMS [Concerned Member State] to another and in the UK can vary from several weeks to several months." See ID 6082, page 31. According to a contemporaneous Lundbeck document: "…normally MCA [the United Kingdom Medicines Control Agency] LVVXHV ZLWKLQ GD\V « See ID 904, page 281. In its reply to the Statement of Objections, Lundbeck pointed out that there were instances where Member States in practice did not comply with the various deadlines; see ID 5394, page 51.

150 Article 17(2) of Directive 2001/83 provided that where a Member State noted that an application for a marketing authorisation was already under active examination in another Member State, it could suspend its own examination in order to await the assessment report prepared by the other Member State.

151 Of course, as mentioned, to the extent that an application was 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.

152 See Article 17(2) of Directive 2001/83. For an example, see recital (558) below, where Ranbaxy stated: "We will file now for UK & Germany, where we have our own subsp expect registration in 8 months."

153 Lundbeck stated in its reply to the Statement of Objections: "Thus, at the time of the Agreements, obtaining an MA in one single EEA country would theoretically have taken a generic at the very least seven months. In reality, obtaining an MA took often much longer, up to 18 months, depending on the time needed by the applicant to submit all required additional information and respond to the queries of the relevant authority. Obtaining an MA in more than one EEA country [through the mutual recognition process] would have taken at the very least 14 months, but could in reality have taken more than 25 months." See ID 5394, page 52; ID 6814, page 18.

to the manufacturing process of its approved API supplier. Based on a previously submitted Drug Master File of another API supplier, a generic undertaking with a marketing authorisation could also apply for a type II variation to its marketing authorisation in order to switch to that different API supplier. According to a March/April 2002 publication of the United Kingdom Medicines Control Agency in the United Kingdom, the Agency processed all type II variations within 90 days from the acknowledgement letter (and 85% within 60 days), resulting either in an approval or a request for supplementary information. For type I variations, the corresponding figures were 100% in 30 days and 84% in 20 days.[154] Whether an applicant actually obtained approval within these time periods depended on the completeness and accuracy of the information supplied to the agency.[155]

(87) With respect to generic medicines which contain the same API as the originator product and are "essentially similar" to that product, the same Directive 2001/83 as well as pre-existing national legislation provided that once a certain period of data exclusivity for the pre-clinical toxicological and pharmacological tests and clinical trials originally performed by the originator company had expired, generic companies were allowed to submit an abridged application for a marketing authorisation, relying for this purpose on the data concerned as originally submitted by the originator company. In the period concerned by this Decision, this period of data exclusivity was six or ten years, depending on the Member State.[156] For most compounds, the period of data exclusivity would normally have expired before the patent protection (including the SPC period) for the compound expired. This was also the case for Lundbeck's citalopram.[157] In such cases, as soon as the patent protection (including SPC) for the compound had expired, generic companies were in principle able to enter EEA markets immediately based on an abridged application for marketing authorisation, which could already have been filed before expiry of the patent protection.[158] The public authorities in charge of granting marketing authorisations could not take into account the patent status of the originator medicine in their decision whether to grant a marketing authorisation to a generic undertaking

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154 ID 1910, page 16.

155 For example, on 7 May 2002, Tiefenbacher filed in the Netherlands, the Reference Member State, for a Type I variation to its marketing authorisation to cover Matrix's "patent free extraction method for purification of Citalopram." This application was completed positively on 16 July 2002, two months and nine days later. See ID 1718, page 1. A filing for Cipla's "patent free purification method" was ready for filing on 24 September 2002. According to Tiefenbacher, this application was also approved around two months after filing, see ID 1713, page 1. With respect to type II variations, Ranbaxy stated to Lundbeck: "We are discussing with a partner for Northern Europe, who will be able to bring our product to the market in 3-4 months". See recital (558) below. In its reply to the Statement of Objections, Lundbeck claimed that a type II variation would require more time, that is to say "…at least QLQH WR " See ID 5304, page 246. However, the example Lundbeck mentioned involved the creation and submission of new stability data by the API producer, taking at least six months. If a Drug Master File had already been submitted by the API producer, this delay could be avoided. See footnote 369 below, referred to in Lundbeck's reply to the Statement of Objections, page 246, footnote 974. See also ID 280, page 6.

156 A period of ten years was used by Belgium, Germany, France, Italy, the Netherlands, Sweden, the United Kingdom and Luxemburg. A period of six year was used by Austria, Denmark, Finland, Ireland, Portugal, Spain, Greece, Norway, Liechtenstein and Iceland. See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 143, footnote 326.

157 See recitals (109) to (111) below.

158 For instance, Merck (GUK) obtained its marketing authorisation in the United Kingdom four days after Lundbeck's compound patent had expired there. See recital (259) below.

and such marketing authorisations could already be applied for and obtained before expiry of the compound patent exclusivity period for the medicine concerned. Once the generic undertaking had received a marketing authorisation, it was therefore entitled to market the product in the Member State concerned, even if it could subsequently be required by a court order to cease marketing because of the court's assessment of (the likelihood of) patent infringement.

4.3. Pricing, reimbursement and substitution

(88) In the period concerned, the setting of price and reimbursement levels of medicines was regulated at Member State level, with each Member State of the EEA following its own policy in this respect. In general, however, it can be said that Member States of the EEA shared three common objectives: (1) patients in need should have access to the necessary medicines; (2) health budgets should remain under control; and (3) incentives for further innovation in medical treatment should exist. Differences between Member States existed mainly in the extent to which they emphasised one or the other of these three objectives, with some Member States with important originator pharmaceutical industries giving a relatively greater weight to the stimulation of innovation. [159]

(89) In several Member States, notably Germany and the United Kingdom, companies were in principle free in the period concerned to set the initial price of new medicines.[160] In other Member States, the initial price of new medicines was the subject of negotiation with or approval by the public authorities. Even when set by the public authorities, the price of a new medicine tends to be much higher than the marginal cost of producing that medicine, as the – normally very significant - R&D expenses of the innovator company need to be covered and a stimulus needs to be given for further innovation. Where a new medicine fulfils a new medical need, uses a new mode of action or shows a stronger performance or fewer side effects than already existing medicines, the producer is in principle in a strong negotiating position to ask a high price, as public authorities will want to ensure that patients have access to that medicine. Where a new medicine has similar therapeutic effects as already existing medicines and no particular advantages over existing medicines, the public authorities may apply "therapeutic reference pricing" and grant the new medicine the same price as the other already existing medicines within the same therapeutic reference group.[161]

(90) In all Member States in the period concerned, reimbursement levels for patients were set by the public authorities, whether at 100% of the price level or at a lower percentage. Even in Member States which leave the pricing of new medicines free, the reimbursement level of a medicine, if lower than 100%, tends to exert a moderating influence on its price, as patients may no longer be willing to buy a certain medicine if they have to pay too much for it directly out of their own pocket (the so-called "co-payment"). The setting of reimbursement levels is subject to the same considerations as the setting of the initial price.

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159 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 149.

160 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 151. See also ID 1053, page 73 (Germany), ID 1072, page 1 (United Kingdom).

161 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 153. The same may apply to the reimbursement level, see recital (90) below.

(91) In the period concerned, a number of Member States compared the price requested by the producer to the prices of the same medicine in a selection of other Member States (so-called "reference pricing"). As prices set in one Member State can thus become a reference point for subsequent price determinations in other Member States, traditionally the United Kingdom and Germany have been "early launch" countries as they allow companies to freely set the price of a new medicine.[162] The same system of reference pricing may work to gradually decrease the prices of medicines over the years, in the sense that any price decrease applied in one Member State (for instance for general budget reasons or because another, more effective medicine has in the meantime entered the market) will indirectly come to affect price levels in other Member States that use the Member State concerned as reference Member State. This in turn may have further ripple effects on yet other Member States.

(92) Because of the above mechanisms, a normal price development for a new medicine is that immediately after its market launch the price (adjusted for inflation) of the medicine is at its highest, at a level far above its marginal cost of production. In subsequent years that price level may either remain stable or gradually go down somewhat, while still remaining at a much higher level than the marginal cost of production. This situation will normally continue for the entire period over which the medicine continues to enjoy patent protection (including the SPC period). While a certain degree of competition may exist with other originator medicines that have the same or a similar therapeutic function, such competition will be much less on price than on the qualitative aspects of the different medicines. This is the more so as other originator products will also tend to be sold at prices far above marginal costs as long as they are still patent-protected. Even if one medicine were considerably cheaper than another one with a different active ingredient, physicians will normally not change the active ingredient they deem appropriate for their patient simply because a different medicine may be cheaper. Nor will patients normally prefer a medicine with an active ingredient that may be less appropriate for their health concern, simply because their co-payment might be lower.

(93) However, once patent protection for the compound has expired and generic competition for the same active ingredient becomes possible, genuine alternatives for the same medicine appear and genuine price competition for that medicine therefore becomes possible, not only between generic companies and the originator company, but also among generic companies. Furthermore, at this point in time, public authorities will tend to put more emphasis on budget control and broad access for patients to the medicine concerned than on continued stimulation of innovation. After all, the basic principle underlying patent protection is that the originator company concerned is sufficiently rewarded for its innovation by the commercial exclusivity it enjoys during the period of patent protection (including SPC protection). Once the period of exclusivity is over, the invention becomes generally and freely accessible to the public. At that time therefore, when generic companies start to enter the market, lower prices for the medicine concerned will normally result, not only from price competition of - and between - generic companies, but

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[162] European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 151-152.

also from certain mechanisms public authorities will tend to apply to reduce the reimbursement cost of the medicine concerned for the public health budget.

(94) Such budget control measures may exist in imposed reductions in the price or reimbursement level of (a) medicines with APIs that are no longer patent protected (including the originator product) or (b) generic medicines (excluding the originator product). Budget control measures may also exist in stimuli to shift demand from the (normally more expensive) originator product to the (normally cheaper) generic product, or even to the cheapest generic product on the market. This can be accomplished by issuing prescription guidelines to the medical profession, with a view to physicians prescribing more often a generic product than the originator product, or by issuing recommendations or binding rules to pharmacists to always substitute a generic product (or even the cheapest generic product) for a prescribed originator product, unless the physician has indicated on the prescription that the originator product is necessary for medical reasons.

(95) Most Member States applied one or more types of budget control measures after generic entry in the period concerned by this Decision. Based on information from Lundbeck, a non-exhaustive list of examples of such measures in the period concerned is:

– Austria: "If a generic entered, a new price for the innovative product was negotiated"[163]

– Belgium: "When an INN has become generic, a cluster based on the same active substance is created with a set reference price. The latter has evolved by law over the years from minimal reduction of 16% to minimal reduction of 30% relative to the price of the branded drug"[164]

– Denmark: "The reimbursement price was set as the lowest average European price for a product within the same medicinal group, or the Danish price, ZKLFKHYHU ZDV ORZHU« *HQHULF HQWU\ ORZHUHG calculate the reimbursement price".[165]

"Since 1997, the pharmacies must substitute a generic for a branded product if the price difference is between DKK 5-20, depending on the price of the SURGXFW XQOHVV WKH GRFWRU KDV VSHFLILFDOO prescription or if the patient requests the original product."[166]

– Finland: "Every time that the PPB [Pharmaceutical Pricing Board] has made a decision on citalopram reimbursement price, it has used the lowest price available to define the price level (i.e., the generic price). When reimbursement status is applied for a new generic product, the generic company in most cases (if not always) applies a price that is 40% lower in comparison to the original product as this way the product in question will be promptly included into the reimbursement and reference price system"[167]

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163 ID 1053, page 21.
164 ID 1053, page 33.
165 ID 1053, pages 42-43.
166 ID 1053, page 44.
167 ID 1053, page 55.

"Mandatory generic substitution was introduced in Finland following the entry into force of the Act on the Amendment of the Medicines Act (80/2003) on April 1, 2003."[168]

– France: "The price of generic medicine is linked to the price of branded medicinal products. The price of the generic is usually 55% lower than the original price of the branded medicinal product. When the first generic enters the market, the price of the branded drug should be decreased by 15%."[169]

"Since 1999, pharmacists have a right to substitute medicinal products listed on the directory (repertoire). Every year, a substitution percentage for each generic group and one that applies to all groups is set. This percentage has increased from 35% in 2000 to 80% in 2010."[170]

– Germany: "The requirement [for pharmacies] to dispense one of the three least expensive drugs has existed since 2002."[171]

– Italy: "Law 549/1995 provided that generics should have a price 20% less than the reference product."[172]

"The entry of a generic determines the application of the reference price system pursuant Law 405/2001, whereby a product is reimbursed within the limit of the lowest price of the products having the same composition an[d] G R V D J H I R U P ³ U H I H U H Q F H S U L F H ´[173]

"Law 405/2001 provides that the pharmacist should dispense the product having the lowest price unless the prescriber expressly writes a non-substitution clause or the patient request the prescribed product and pays the difference."[174]

– Netherlands: "Generic entry may have impacted the prices, since the maximum prices set pursuant to the WGP [Wet geneesmiddelenprijzen] have been amended as a result of generic entry in the reference countries, which led to different G-Standard [official list of suggested retail sales prices] prices and wholesaler prices."[175]

– Norway: "Generic substitution regulation was introduced on March 1, 2003. Under the substitution rules, the pharmacist can offer a generic substitute if the Department of Health and Social Affairs has determined that the product can be used as a substitute. The National Insurance Fund reimburses the full price paid by the patient for the generic substitute. If the patient however prefers the branded medicinal product, he has to bear the additional costs. The prescriber can refuse substitution for the patient."[176]

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168 ID 1053, page 57.
169 ID 1053, page 68.
170 ID 1053, page 70.
171 ID 1053, page 78.
172 ID 1053, page 101.
173 ID 1053, page 98.
174 ID 1053, page 100.
175 ID 1053, page 126.
176 ID 1053, page 108.

– Sweden: "When generic products enter the market, the pharmacies are required to substitute prescription medicine with a lower-priced identical product"[177]

– United Kingdom: "Generic products are subject to reimbursement tariffs, which are set by the government and aim to reflect the actual acquisition cost of a generic, rather than the list price of the branded product"[178]

"The physician decides whether to write a prescription for branded or generic citalopram/escitalopram. In the U.K., 80% of prescriptions are for generic products. If a prescription is for a generic, the pharmacist can choose which product."[179]

(96) Because generic entry tends to strongly intensify or even initiate price competition for the medicine concerned[180] and because the above-mentioned budget control mechanisms will tend to further reduce prices for that medicine and to shift demand to generic versions of it, consumers will benefit from often considerably lower prices for the medicine concerned. The Commission's inquiry into the pharmaceutical sector found that, on average, the price at which generic companies entered the market was 25% lower than the price of the originator medicines prior to the loss of exclusivity. Two years after entry, prices of generic medicines were on average 40% below the former originator price.[181] This average additional price decrease over two years was also the result of an increased number of generic entrants, as shown by the sector inquiry.[182] The number of generic entrants is therefore important for competition. Financial benefits for consumers from generic entry result directly for patients from lower co-payments (in those Member States which use co-payments) and indirectly from reduced financial pressure on public or private health insurance budgets and

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177 ID 1053, page 117.

178 ID 1072, page 6.

179 ID 1072, page 8. In the United Kingdom, national guidelines for physicians strongly encouraged generic substitution. This mechanism was so effective that already in 2002 citalopram was prescribed generically by doctors in 90% of the cases, although no generic citalopram was yet available. Only the remaining 10% of prescriptions were written for Lundbeck's branded Cipramil. See Department of Health (2003) – "Prescription Cost Analysis: England 2002", http://www.dh.gov.uk/en/Publicationsandstatistics/Statistics/StatisticalWorkAreas/Statisticalhealthcare/DH_4000027

180 In the United Kingdom, for instance, wholesalers and pharmacists had the incentive to seek out the cheapest generic citalopram available, as "pharmacies are financed by the payments from the NHS. The NHS pays the pharmacy the wholesale price for any drugs dispensed, with a deduction of an estimated discount given by the wholesaler [clawback]. If the discount given to the pharmacy was in fact larger than estimated by the authorities, the pharmacy may keep the difference. Pharmacies are therefore keen to obtain products from the wholesalers as cheaply as possible" (ID 1489, page 103). If enough generic companies were on the market, selling sufficient supplies of citalopram, this would have triggered a rapid downward price spiral, as indeed happened after October 2003 (see recital ((209) below for more details on the evolution of generic prices in the United Kingdom). The United Kingdom health system would also have benefited from lower citalopram prices, firstly by clawing back some of the discounts obtained by the pharmacists, through a discount recovery scheme, and secondly by lowering the reimbursement tariff for citalopram.

181 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 9 and 85 to 116.

182 European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 107 and 572. Competition may be more intense over time, when generic entrants rely on different APIs that are produced by different production processes with different marginal costs of production as this may increase the scope of price competition among generic entrants.

premiums (to the benefit of all consumers, not just the patients concerned). Actions that delay generic entry will prevent such benefits from arising.

5. THE PRODUCT: CITALOPRAM

5.1. Product characteristics

(97) Citalopram is the international non-proprietary name (INN) of an antidepressant molecule which inhibits the reuptake of the neurotransmitter serotonin in the brain. According to Lundbeck's annual report for the year 2002, "Depression involves an imbalance in serotonin metabolism in the brain. Serotonin acts as a signaling compound by transmitting nerve impulses from one nerve ending to another; too OLWWOH VHURWRQLQ FDQ WULJJHU GHSUHVVLRQ increase the amount of serotonin in the synapse between the nerve endings, by preventing the compound from being taken up into the neurones. An antidepressant using this mode of action is called an SSRI (selective serotonin reuptake inhibitor)."[183]

(98) In the EEA, Lundbeck marketed citalopram as tablets of 10mg, 20mg and 40mg in packs of different tablets counts and as an oral, liquid 40mg formulation. For hospitals, an injection/infusion mode of delivery was also marketed. Citalopram received approval in the EEA for the following medical indications: major depressive disorder, prevention of the recurrence of the depressive episode, the depressive phase of bipolar disorder[184] and anxiety disorders[185], particularly panic disorder with or without agoraphobia.[186] Citalopram was also recommended in co-morbid conditions with dementia or Alzheimer's for the elderly.[187] For these indications, citalopram was prescribed by general practitioners in primary care, as well as by specialists, mainly psychiatrists and neurologists, both in hospitals and in private practices. Citalopram's more common side-effects included insomnia, dry mouth, nausea, sleepiness and increased sweating.[188]

(99) In principle, as long as an anti-depressant has been found to be sufficiently effective and well-tolerated, physicians are unlikely to switch patients to another active ingredient in the course of the treatment.[189] This will be true even if another active

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183 ID 1499, page 23.

184 ID 9, page 498.

185 ID 1499, page 26: "Anxiety can be divided into different indications, but the best known are generalised anxiety disorder, social anxiety disorder, panic disorder, obsessive compulsive disorder (OCD), and post-traumatic stress disorder (PTSD)."

186 ID 1055.

187 ID 1497, page 28.

188 ID 1055.

189 See for instance the following publications:
- Folia Pharmacotherapeutica (2000) - "Place des antidépresseurs dans la prise en charge de la dépression en première ligne chez l'adulte", http://www.cbip.be/Folia/index.cfm?FoliaWelk=F27F01B ;
- DGPPN, BÄK, KBV, AWMF, AkdÄ, BPtK, BApK, DAGSHG, DEGAM, DGPM, DGPs, DGRW (2009) – "S3-Leitlinie/Nationale VersorgungsLeitlinie Unipolare Depression Langfassung", http://www.versorgungsleitlinien.de/themen/depression/pdf/s3_nvl_depression_lang.pdf;
- AFSSAPS (2005) – "Bon usage des antidépresseurs au cours des troubles dépressifs chez l'adulte ", http://www.afssaps.fr/content/download/6201/60125/version/3/file/map.pdf;
- Health Service Executive (2006) – "Guidelines for the Management of Depression and Anxiety Disorders in Primary Care", http://www.icgp.ie/assets/77/77D7A752-C0BD-63AC-448B59552E2A469E_document/GuidelinesontheManagementofDepression.pdf;

ingredient may be considerably cheaper. After an initial period, patients therefore normally remain "loyal" to the anti-depressant medicine they have been prescribed. It is, however, normally possible for a physician to switch existing patients from the originator product to a generic product containing the same active ingredient (unless for instance the patient does not tolerate a different coating used in the generic pill, which, however, is rare) and it is certainly possible for a physician to prescribe a new patient a generic antidepressant instead of the originator product. Given that escitalopram is the S-enantiomer part of citalopram (which also contains the stereoisomer R-citalopram), it may also be possible to switch existing patients from citalopram to the successor product escitalopram, in particular if the patient did not tolerate or respond to citalopram well.[190] It would, in any case, certainly be possible for a physician to prescribe a new patient escitalopram instead of citalopram.[191]

5.2. Citalopram within the antidepressant universe

(100) The European Pharmaceutical Market Research Association (EphMRA) maintains[192] a classification of molecules, in which citalopram belongs to the anatomic therapeutic group of Selective Serotonin Reuptake Inhibitors (SSRIs) within the broader N6A group of antidepressants.[193]

- Agenzia del Farmaco (2001) – "La depressione e gli antidepressivi", http://www.agenziafarmaco.gov.it/wscs_render_attachment_by_id/111.50560.11503794810969ea7.pdf?id=111.50565.1150379481285;
- Nederlands Huisartsen Genootschap (2003) – "Depressieve stoornis M44 (oktober 2003)", http://nhg.artsennet.nl/kenniscentrum/k_richtlijnen/k_nhgstandaarden/Samenvattingskaartje-NHGStandaard/M44_svk.htm;
- National Institute for Clinical Excellence (2004) – "Depression – Management of depression in primary and secondary care", Clinical Guideline 23, http://www.nice.org.uk/nicemedia/live/10957/29592/29592.pdf.

In reply to the Statement of Objections (see ID 5394, footnote 249), Lundbeck pointed out that guidelines recommended switching only when a medicine failed.

190 See recital (108) below, mentioning elderly patients with tolerance problems in particular. See also recitals (139) and (140). When applying for a marketing authorisation for escitalopram in Sweden, Lundbeck "initially submitted an application under the Note for Guidance on Clinical investigation of chiral active substances [...which made it] possible to refer (or bridge) to data for the racemate [that is to say citalopram] if it can be justified that the data will also be relevant for the enantiomer [escitalopram]." See ID 6814, page 20. In other words, Lundbeck considered that it could rely for escitalopram on certain of the pre-clinical data originally submitted for the registration of citalopram based on bridging studies (abridged application) ("pharmaceutical studies have demonstrated that the pharmacological activitiy of citalopram resides only in the S-enantiomer", ID 6815, page 2). This was, however, rejected by the Swedish authorities. See also ID 5394, page 238.

191 See recital (196) below, where a contemporaneous document of Lundbeck is quoted as saying: "Cipralex (escitalopram) is planned to be launched in April 2002. The aim will be to convert the remaining part of the citalopram franchise to escitalopram as fast as possible, with strong focus on the first three months after launch. This implies a cannibalisation of the citalopram business, the effect of which is a reduction of citalopram sales of 65% in total [expected] 2001."

192 This classification is used by IMS Health (IMS), a provider of health data services, as a basis for the data provided by it (http://www.whocc.no/atc_ddd_methodology/the_ephmra_classification_system/). Data and other information from IMS, which are cited or used in this Decision, were obtained by the Commission pursuant to requests for information based on Article 18(2) of Council Regulation 1/2003. IMS has not acted as an advisor, expert, or consultant in connection with this report or, more generally, in connection with the investigation. Further references to IMS in this text should be understood in the same way.

193 See IMS data.

(101) The antidepressant universe, as listed by the EphMRA classification in the N6A group[194], contains one hundred twenty molecules. These molecules are further grouped, by their therapeutic indications, in:

– N6A2 – Herbal antidepressants;

– N6A3 – mood stabilizers;

– N6A4 – SSRI antidepressants, including citalopram;

– N6A5 – SNRI antidepressants;

– N6A9 – other antidepressants.

(102) As Lundbeck mentioned in its annual report for the year 2001: "Drugs for treatment of depression can be divided into two generations. The first generation comprises the so-called tricyclic antidepressants and monoaminooxydase inhibitors (MAOIs). The Selective Serotonin Reuptake Inhibitors (SSRIs) are by far the largest and most important group of the latest generation of antidepressants"[195].

(103) Historically, some of the molecules in group N6A9, referred to hereafter as MAOIs, were the first antidepressants, introduced in the 1950s. They targeted all monoamine neurotransmitters (serotonine, dopamine, norepinephrine, amongst others.). They were considered very effective in treating depression, but had a significant risk profile, as they interacted with other substances, sometimes resulting in the patient's death.

(104) The next group in time of antidepressants to be used were tricyclic antidepressants (or TCAs), thus named because of their molecular structure. They began to be launched in the EEA in the 1960s and were considered to be almost as effective as MAOIs, but less dangerous for the patients. However, overdoses with TCAs were still likely to be lethal. TCAs also belong to the N6A9 class. Together, MAOIs and TCAs were referred to in the industry as "first generation antidepressants".

(105) The 1990s saw the market entry and increasing popularity of new, second-generation anti-depressant medicines: most selective serotonin reuptake inhibitors (SSRIs) entered the EEA markets in the early 1990s[196], followed by serotonin-norepinephrine reuptake inhibitors (SNRIs) in the second half of the decade[197]. SSRIs and SNRIs were as effective as TCAs, but safer to use, and thus by the end of the decade, largely replaced the TCAs: "The main reasons for the massive shift from TCAs, which formerly dominated the pharmacotherapy of depression, to SSRIs and SNRIs are the adverse effect burden of TCAs and their lethality in overdose. An overdose with a TCA is more than 5 times as likely as an overdose with an SSRI to result in death."[198] Throughout the 1990s and early 2000s, the antidepressant market as a whole grew strongly, with more patients being treated with second-generation products for more indications and over longer periods of treatment.

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194 See IMS data.

195 ID 1498, page 16.

196 Some, like fluoxetine and citalopram, already entered one or more national markets in the EEA in the late 1980s. See ID 1053, pages 137-138.

197 ID 1053, page 137.

198 Bodkin, J.A., Gören, J.L. (2007) - Not Obsolete: Continuing Roles for TCAs and MAOIs, Psychiatric Times, Vol 24, No 10.

(106) In the course of the 1990s, SSRIs became the most popular type of anti-depressant. Lundbeck's reports show that, between 1999 and 2005, sales of second generation antidepressants (SSRIs and SNRIs), including citalopram, grew strongly.[199] Lundbeck remarked in its annual report for the year 2001 that "SSRIs are by far the largest and most important group of the latest generation of antidepressants."[200] Indeed, in several of the EEA Member States, SSRIs (including citalopram) were officially recommended as the first-line treatment for depression, anxiety and bipolar disorder by medical guidelines.[201] For example, in the United Kingdom: "When an antidepressive is to be prescribed in routine care, it should be a SSRI, because SSRIs are as effective as tricyclic antidepressants and are less likely to be discontinued because of side effects."[202] As Lundbeck remarked in its annual report for the year 1999: "Because SSRIs have fewer side effects, they can be used to treat patients with chronic depression over longer periods of time in some cases, for the rest of the S D W L H Q W¶V O L I H"[203]

(107) The main difference between SSRIs and SNRIs is that SSRIs inhibit the reuptake of a single neurotransmitter - serotonin at the neuronal level – and belong to the N6A4 group, while SNRIs act upon the levels of two neurotransmitters - serotonin and norepinephrine - and belong to the N6A5 group. The most popular SNRI was venlafaxine (Wyeth's brand Effexor), which was launched in the EEA in 1994. While it had apparently better efficacy than SSRIs, it was considered primarily a second-line treatment[204] because of the high number of side-effects.[205] In addition, other classes such as NRIs[206] (norepinephrine reuptake inhibitors) and TeCAs (tetracyclic antidepressants) also appeared, but sales data seem to indicate that they were less popular than SSRIs and SNRIs.

(108) Aside from citalopram, other SSRIs sold in the period concerned in the Member States of the EEA included fluoxetine (Eli Lilly's brand Prozac), fluvoxamine (Solvay's brand Fevarin), paroxetine (GSK's brand Seroxat) and sertraline (Pfizer's brand Zoloft). In 1995 Lundbeck stated: "Five important unique selling points are

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199 In Europe, a Lundbeck management report (ID 814 page 6) show that in 1998 and 1999, SSRIs and SNRIs had a market share of over 65% of the total N6A market. In 2001, according to Lundbeck's annual report (ID 1498 page 19), SSRIs alone had reached over 85% of the N6A market. This trend continued in 2002, when, according to a Lundbeck document (ID 3416 page 27), SSRIs alone accounted for 90% of the N6A market. In 2003 (ID 3417 page 29), the share of SSRIs and SNRIs in the N6A market remained above 70%, going down to over 60% in 2005 (ID 3415 page 40). At the same time, the N6A market as a whole had a strong potential for growth. The Lundbeck yearly report 2001 shows (ID 1498 page 18) that between 1999 and 2000 the antidepressant market grew 18%. In 2003, the market could still grow nearly 15% a year (ID 3416 page 36).

200 ID 1498, page 16.

201 In many Member States, health agencies and independent bodies provided prescription guidelines, providing guidance to physicians (particularly general practitioners) on how to deal with depressed or anxious patients, reviewing the efficacy and side-effects of a wide array of medicines as well as laying down the recommended duration for the treatment and eventual treatment alternatives.

202 National Institute for Clinical Excellence (2004) – "Depression – Management of depression in primary and secondary care", Clinical Guideline 23, http://www.nice.org.uk/nicemedia/live/10957/29592/29592.pdf, page. 7. This edition of the United Kingdom medical guidelines was in force until 2007.

203 ID 1497, page 28.

204 For instance if initial treatment with a SSRI had failed to produce the desired results.

205 ID 9, page 30.

206 NRIs include mirtazapine (Organon's brand Remeron) and reboxetine (Pfizer's brand Edronax/Davedax), and were launched in the second half of the 1990s (ID 1053, page 138).

used on the market: Cipramil is the most selective SSRI, it is well tolerated, has simple kinetics without active metabolites, it is not likely to interact with other drugs because of its minor influence on the metabolic enzyme systems of the liver, and it is easy to administer, only once a day. These advantages over other SSRIs are especially important as regards elderly patients. This group of patients often has problems of tolerance and frequently receives other medication concurrently with antidepressant treatment. In addition, they need a simple medication scheme."[207] As of 2002, Lundbeck launched in EEA markets a successor SSRI to citalopram, called escitalopram, which is the S-enantiomer of citalopram. In 2004 Lundbeck described escitalopram as "more than just the active enantiomer of citalopram. The originally thought "inactive" part of citalopram, R-citalopram, has been shown to counteract S-citalopram and has consequently masked the full efficacy potential of S-citalopram."[208]

5.3. Lundbeck's patent rights on citalopram

(109) Lundbeck's earliest citalopram patent, filed in 1977 in Denmark (DK 143275) covered the pharmaceutical compound of citalopram and two processes to produce citalopram, referred to by Lundbeck as the cyanation 2002-1 process and the alkylation 2002-2.[209] Patents for the product or the processes were granted in most Western European countries between 1977 and 1985. In certain countries at that time, notably Austria, Denmark, Finland, the Netherlands, Norway and Sweden, patents could only be granted for processes for preparing pharmaceutical products, not for the pharmaceutical compound itself.[210] In these countries, only the original processes for producing citalopram were protected, thus offering only indirect protection for the compound.[211] In principle, if an API producer managed to develop an industrially efficient non-infringing process, market entry of generic citalopram in those countries would be possible as soon as data exclusivity had expired at the latest on 30 January 1999[212] and the necessary marketing authorisations had been obtained. Lundbeck expected that this would be the case by the year 2000.[213]

(110) The same was in principle possible in some other countries in the EEA where Lundbeck neither had any patent protection for the citalopram compound nor for the manufacturing processes. This was the case notably in Greece, Italy, Luxemburg and Portugal.[214]

(111) In Germany, due to the absence of an SPC[215], protection on the compound expired already in December 1994. Nevertheless, in this Member State the citalopram compound was still protected to the extent that it enjoyed data protection until 30

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207 ID 163, page 982.
208 ID 9, page 30; for 2007 see also ID 5394, page 80.
209 ID 823, page 3 and ID 5394, pages 34-35. The year refers to the date of expiry of patent protection in most countries in the EEA.
210 ID 9, page 300. See also ID 869, page 27.
211 ID 869, page 27.
212 ID 280, page 1. In certain Member States, such as Denmark, data protection had already expired on 30 January 1995, depending on whether they granted six or ten years of data protection. See also ID 1053, page 166.
213 ID 9, page 304.
214 ID 9, page 36.
215 ID 280, page 1.

January 1999.[216] In Spain patent protection expired in February 1998.[217] In Sweden, patent protection on the original process expired in December 2001; in Belgium (compound), Denmark (original process), Finland (original process), France (compound), Ireland (compound), the Netherlands (original process), Norway (original process) and the United Kingdom (compound) in January 2002; and in Austria (compound) in April 2003.[218] These periods include the extended protection offered by SPCs.

(112) By the mid-1980s, Lundbeck had developed a new and more efficient process for purifying citalopram, referred to by Lundbeck as the diol process, which allowed Lundbeck to manufacture citalopram efficiently on an industrial scale.[219] In 1985, Lundbeck obtained patent protection in the EEA for this process under patent number EP 0171943[220] (and in those countries where this was allowed also for the intermediate produced by the process).[221] These patents expired in 2005.[222] From approximately 1986 to 2003, Lundbeck used this process to manufacture citalopram.[223]

(113) On 13 March 2000, two years before the expiry of the original citalopram patent covering the compound and cyanation and alkylation processes, Lundbeck filed a priority patent application[224] for the so-called crystallisation patent in Denmark, covering a process for the preparation of purified salts of citalopram through crystallisation of the base.[225] An application was made under the Patent Co-operation Treaty (PCT) of the World Intellectual Property Organisation (WIPO) in April 2000 (WO 01/68627: Crystalline base of citalopram). The international filing date was in February 2001 and the patent application was published in September 2001. A number of national patents or utility models were granted in the EEA, starting with a utility model (basically a 6-year patent granted without examination) in the Netherlands on 6 November 2000.[226] The national United Kingdom patent

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216 Germany was among those countries that granted 10 years of data exclusivity under Directive 2001/83. See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 143.

217 ID 9, page 36. Spain was among those countries that granted 6 years of data exclusivity under Directive 2001/83. See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, page 143.

218 ID 9, page 36. See also ID 869, page 23 and ID 9, page 300.

219 ID 280, page 1, ID 282, pages 1 to 9 and ID 5394, page 36.

220 ID 5394, page 36.

221 In Austria, Portugal and Spain, the patent covered the process only. In all other Contracting Parties to the EEA Agreement where Lundbeck registered the patent, it also covered the intermediate. See ID 869, page 28.

222 ID 869, page 28.

223 See ID 823, page 4, footnote 3 and ID 5394, page 36.

224 The priority application is the first patent filing in any country for the invention concerned. Under the Paris Convention for the Protection of Industrial Property, if within 12 months following the first application in any of the member states to the Convention an applicant makes further patent applications for the same invention in other member states, then, for the purpose of the patent examination, these subsequent applications will be regarded as if they had been made on the date of the first application (the "priority date"). See Sector Inquiry Report, footnote 218.

225 See ID 823, pages 3-4 and ID 5394, page 36.

226 Information based on Espacenet (NL1016435) and register.octrooicentrum.nl (1016435). See also ID 847, page 62. This Dutch utility model was granted without examination for a period of 6 years, see ID 4817, page 140 and ID 4817, pages 175, 194 and 219. Amongst others, an Austrian utility model was

application was published on 4 July 2001 and granted on 30 January 2002[227] (GB 2 357 762[228]), followed by several other European countries in the first half of 2002.[229] A European patent application was applied for by Lundbeck on 28 February 2001, published by the EPO on 9 January 2002 and granted on 4 September 2002 (EP 1 169 314 and national equivalents).[230] […]* [231]

(114) The crystallisation patent and other process patents which Lundbeck filed close to the expiry of the compound patent are described further below in section 6.3. That section provides additional information on Lundbeck's process patents in connection with its strategy against generic entry, including Lundbeck's objective to create a 'window of opportunity' for the introduction of escitalopram. These process patents created considerable uncertainty for potential generic entrants and were at the heart of the generic companies' struggle for market entry.

(115) In the 1980s, Lundbeck also started the development of a successor product to citalopram that would be patent-protected for an additional number of years. This product became escitalopram, the S-enantiomer of citalopram. Patent protection for the escitalopram compound, with priority date of 14 June 1988[232], was accepted in most European countries in 1989, albeit not in Denmark (where the application was rejected) and in Finland, Greece, Norway, Portugal and Spain (where compound protection was not possible at that time). The corresponding process patent was granted in all European countries applied for. Patent protection for escitalopram expires in most European countries in June 2014 (including SPC).[233]

5.4. Lundbeck marketing of citalopram in the EEA

(116) Lundbeck first filed a patent application for the citalopram compound in 1977 in Denmark. However, the original production processes it had developed as part of the original invention worked in the laboratory, but were not well suited to economically produce a pure product on an industrial scale. It was only in 1985 that Lundbeck developed the more efficient diol manufacturing process and prepared to market citalopram as a medicine. Lundbeck obtained its first marketing authorisation in the EEA in January 1989 (in Denmark).[234] The product was launched in Northern Europe at the beginning of the 1990s, but introduced in the larger EEA markets only in 1994-1996.[235] In Germany, for instance, the single largest market in the EEA in

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published on 25 June 2001 (AT004364 (U1)) and two German utility models on 31 August 2000 (DE 20007303 (U1)) and on 8 August 2002 (DE 20121240 (U1)). Information based on Espacenet.

227 Information based on Espacenet. See also ID 723, page 19. Lundbeck's information in ID 5394, footnote 77, that the application for the crystallisation patent was published in the United Kingdom on 7 January 2001 appears incorrect.

228 ID 610, pages 9 and 28.

229 For instance, the patent for Denmark was granted on 11 February 2002, the patent for Sweden was granted on 16 April 2002. See ID 846, page 46. For the patent situation in Germany, see footnotes 226 and 390.

230 Information based on Espacenet. See also ID 1713, page 1 and ID 2773, pages 1 to 4.

231 See ID 823, pages 3-4 and ID 5394, page 37.

232 ID 280, page 1, ID 286, pages 1 to 17.

233 ID 844, page 8.

234 ID 823, page 3, ID 673, page 26, ID 621, page 3.

235 According to one study, additional safety data had to be provided to obtain marketing authorisation in those larger markets in the EEA. See ID 9, page 370.

terms of number of inhabitants, citalopram was not approved for marketing until June 1996.[236]

(117) By 1993, four years after citalopram's first market introduction in Denmark in 1989, Lundbeck had become fully aware of the enormous commercial potential of citalopram for the company. In its Strategic Plan for 1993 Lundbeck wrote:

"CIPRAMIL, although still in the introductory phase, is by far the most important Lundbeck product, accounting for 65% of the antidepressant business and 22% of total turnover in 1993. CIPRAMIL is marketed with great success in Denmark, Finland, Switzerland, Greece, Luxembourg, Austria, Belgium and Sweden. It is expected that half of Lundbeck's turnover in 1997 will come from the sales of CIPRAMIL and that its sales will have grown with about 800% by the year 2000."[237]

(118) By 1996, Lundbeck's sales of citalopram in the EEA (at EUR [50-150]* million) had come to represent [50-60]* % of the undertaking's effective total sales in the EEA. By 2002, Lundbeck's sales of citalopram in the EEA (at EUR [400-600]* million) represented [80-90]*% of the undertaking's effective total sales in the EEA.[238]

(119) At the same time, the product was also highly profitable for Lundbeck:

"As the CIPRAMIL profit per daily dosis is often five times as large as the profit per daily dosis of older products, and as the potential market volume is up to three times the volume for the old tricyclic antidepressants, the majority of Lundbeck's marketing activities aim to ensure CIPRAMIL's market penetration."[239]

(120) Thus, while in 1993 Lundbeck's profit before tax (on revenue from all products) had been 7%, by 2002 this had grown to 22%, largely due to booming sales of citalopram.[240] Lundbeck internally referred to citalopram as its "golden egg".[241]

(121) As already mentioned, citalopram was promoted by Lundbeck as the SSRI with the least side-effects, having the least interactions with other medicines, and easiest to administer. A Lundbeck document from 2000 stated that "since the launch of citalopram in Denmark for a good ten years, the main argument in the marketing has been that citalopram is the most selective SSRI."[242] In 2001, Lundbeck reported that "Citalopram is the fastest growing product within the SSRIs."[243]

(122) The first marketing authorisation for escitalopram, Lundbeck's successor product to citalopram, was granted in December 2001 (in Sweden). Due to delays in approval, Lundbeck did not meet its original objective of launching escitalopram in the first Member State by May 2001.[244] The Swedish approval was the basis for a mutual

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236 Marketing authorisations for citalopram were issued in France in December 1994 and in the United Kingdom in March 1995. See ID 280, page 1, ID 283, pages 1-2.

237 ID 163, page 981.

238 ID 972.

239 ID 163, page 982.

240 ID 1499, page 60.

241 ID 230, page 193.

242 ID 9, page 587.

243 ID 1498, page 18.

244 ID 163, page 447. Lundbeck had expected that escitalopram would be launched in Sweden already in May 2001. See ID 9, page 675. See also ID 815, page 45. Lundbeck informed the Commission that it had filed an abridged application based on Article 10(1) of Directive 2001/83 considering that Lundbeck could rely on the pre-clinical data originally submitted for the registration of citalopram. The

recognition procedure by the other Member States.[245] By May 2002, Austria, Belgium, Denmark, France, Ireland, Luxemburg, Norway, Sweden and the United Kingdom had approved escitalopram for the treatment of depression and panic disorder. However, Lundbeck had to withdraw its application in Finland, Germany, Greece, Italy, Portugal and Spain after these national authorities raised public health concerns.[246] By December 2002, escitalopram had also obtained marketing authorisations in Finland, Germany, Italy, Portugal and Spain.[247] Lundbeck introduced escitalopram in most EEA markets between April 2002 (Sweden) and April 2003 (Belgium). Escitalopram was launched in the United Kingdom in June 2002.[248] Lundbeck markets escitalopram in the EEA mainly under the brand names Cipralex, Seroplex and Sipralexa.

6. LUNDBECK'S STRATEGY AGAINST GENERIC ENTRY INTO THE CITALOPRAM MARKET[249]

6.1. Lundbeck's overall strategy against generic entry on citalopram

(123) Because Lundbeck had managed to introduce citalopram, first patented in 1976, in the larger European markets only by the mid-1990s, the available time for Lundbeck to fully exploit the product commercially before patent expiry of the compound, by January 2002 for a number of European countries and earlier for certain other European countries[250], was comparatively short.

(124) As early as 1997, therefore, Lundbeck started planning for possible generic entry in the coming years. An internal planning document of 14 February 1997 on Cipramil sales forecasts for the coming years stated:

"We are assuming that Citalopram generics will gain 40-70% of total substance volume in year five after introduction (at a 40% price discount to the original) (emphasis in the original)."[251]

Later on, the document stated: "The negative impact of generic citalopram on Lundbeck's own original sales will vary by market according to independent variables such as reimbursement, generic substitution regulations, the existence of a JHQHULF HQYLURQPHQW RU VXSSOLHUV« WKH FXUUH IRU WKH WRWDO SKDUPD PDUNHW« SURILW PDUJLQV substance following patent expiry is forecast as shown in ***figure 6***. The end-point for the volume market share of Citalopram substance is assumed to be year 5 after patent expiry. The end-points for UK, Germany, Italy & Spain (realistic scenario)

Swedish authority, however, required the submission of all the pre-clinical and clinical data requested under the normal procedure. See ID 5394, page 238.

245 ID 280, page 2, ID 287, pages 1 to 2.

246 ID 5394, footnote 930.

247 ID 1499, pages 10-11. Cipralex was launched in Spain only in April 2004. See ID 163, page 141.

248 ID 1499, page 10.

249 The Commission's factual description in this chapter of Lundbeck's strategy against generic entry into the citalopram market does not prejudge the question of the legality of those practices of Lundbeck which are not legally assessed in this Decision.

250 See section 5.3 above.

251 ID 9, page 282.

are assumptions taken from IMS who forecast that original fluoxetine[252] will keep only 30%, 40%, 50% and 60% respectively of substance sales; generics will gain the remainder at a price/day 40% lower than the original. Historic experience from the patent expiry of fluoxetine shows that in Finland, [two countries outside EEA] & Denmark generics have gained a 25-30% volume share of total substance in the first year after patent expiry. In Finland, 4 years after patent expiry original fluoxetine only has 30% of substance volume [emphasis in the original]."[253]

Figure 6 of this document showed the following:

countries	impact	scenario	year 0	1	2	3	4	5+
DK, UK, IRE, NL, [not EEA]	VERY HIGH	PESSIMISTIC	[90-100]*%	[65-75]*%	[40-50]*%	[30-40]*%	[20-30]*%	[15-25]*%
		REALISTIC	[90-100]*%	[65-75]*%	[45-55]*%	[35-45]*%	[25-35]*%	[25-35]*%
		OPTIMISTIC	[90-100]*%	[75-85]*%	[60-70]*%	[55-65]*%	[50-60]*%	[45-55]*%
F, S, SF, N, D, B, A, GR, [not EEA]	HIGH	PESSIMISTIC	[90-100]*%	[65-75]*%	[40-50]*%	[30-40]*%	[25-35]*%	[20-30]*%
		REALISTIC	[90-100]*%	[70-80]*%	[50-60]*%	[45-55]*%	[40-50]*%	[35-45]*%
		OPTIMISTIC	[90-100]*%	[80-90]*%	[65-75]*%	[60-70]*%	[55-65]*%	[55-65]*%
ITALY	MED	PESSIMISTIC	[90-100]*%	[70-80]*%	[55-65]*%	[45-55]*%	[40-50]*%	[35-45]*%
		REALISTIC	[90-100]*%	[75-85]*%	[60-70]*%	[55-65]*%	[50-60]*%	[45-55]*%
		OPTIMISTIC	[90-100]*%	[80-90]*%	[65-75]*%	[60-70]*%	[55-65]*%	[55-65]*%
SPAIN	LOW	PESSIMISTIC	[90-100]*%	[70-80]*%	[55-65]*%	[45-55]*%	[40-50]*%	[35-45]*%
		REALISTIC	[90-100]*%	[80-90]*%	[65-75]*%	[60-70]*%	[55-70]*%	[55-65]*%
		OPTIMISTIC	[90-100]*%	[80-90]*%	[75-85]*%	[70-80]*%	[65-75]*%	[65-75]*%

Source: ID 9, page 290.

[252] Fluoxetine (best known under its brand name Prozac) is another anti-depressant in the SSRI class. In this document, Lundbeck uses the development in generic sales of fluoxetine which IMS expected to occur in the years following patent expiry of fluoxetine as a proxy for the expected development of generic sales of citalopram after patent expiry of citalopram.

[253] ID 9, page 284. See also ID 9, page 303.

Note: These figures assumed that Lundbeck would maintain its price for Lundbeck citalopram at the original level and would not launch its own generic product.[254]

(125) By the end of 1997, Lundbeck identified the following "sales risk and uncertainty" in its Budget and Activity Plan for 1998 :

"With an attractive, worldwide SSRI market estimated at a value of more than DKK 30bn [over EUR 4 billion][255] in 1996, generic SSRI competition poses a major threat to Lundbeck.

About 60% of Lundbeck's 1998 turnover is expected to come from CIPRAMIL. It is to be foreseen that generic competition will limit CIPRAMIL's growth rate in the antidepression market in the years to come."[256]

Consequently, Lundbeck listed as one of the company's key expectations for 1998: "Implement generic strategy for citalopram."[257]

(126) The following year, in its Budget and Activity Plan 1999 of November 1998, Lundbeck listed for this expectation of "Implement a generic strategy for citalopram" the following "results achieved"

"Initial steps have been taken towards cooperation with generic manufacturers and towards the establishment of local co-marketing agreements with generic companies in order to postpone generic competition on a short-term basis. S-citalopram is considered to be the long-term weapon against generic competition, and the development has been accelerated accordingly."[258]

(127) Later on in the same report, Lundbeck provided more specifics on this strategy:

"Generic citalopram represents a serious risk to Lundbeck because CIPRAMIL accounts for a high percentage of Lundbeck's turnover in all markets and is essential to the company's continued growth. Generic competition is foreseen on markets where the product patent has expired or where generic suppliers may invent a new manufacturing process. In some EU markets the patent has already expired. However, Lundbeck expects only minimal generic competition on CIPRAMIL in Europe before year 2000.

Lundbeck currently strives to identify potential generic chemical manufacturers of citalopram. The aim is to reach agreements with such manufacturers that will postpone or stop the manufacturing of generic citalopram in the short-term, such as:

- Lundbeck outsources individual steps in the citalopram manufacturing process to the generic manufacturer under a secrecy agreement
- Lundbeck purchases the rights to the generic manufacturer's production method

254 ID 9, page 284.

255 Using an exchange rate of 7.45 DKK to one EUR.

256 ID 163, page 640.

257 ID 163, page 635.

258 ID 163, page 599. An example of a local co-marketing agreement as referred to in this statement is the agreement Lundbeck concluded in 1999 with Nycomed authorising Nycomed to launch a generic version of Lundbeck citalopram in Denmark before expiry of Lundbeck's compound patent there.

- Lundbeck purchases large quantities of citalopram from the generic manufacturer

Another defensive strategy is to strike up alliances with some of the important generic marketers. Such alliances must be formed when launch of hostile generics is imminent and will ensure that Lundbeck receives a part of the profits made by the generics.

The development of S-citalopram is the strategic measure which will enable Lundbeck to protect the income from its antidepressant portfolio in the long term."[259]

(128) In a report to its Board of Directors of 8 February 1999, Lundbeck wrote:

"When generic citalopram is launched on a market, there is enormous price competition with the maker of the original product to begin with, until a sort of equilibrium is attained where the generic producers are satisfied with their market share."[260]

(129) Lundbeck's "Goal, Activity and Budget Plan 2000" of December 1999 stated:

"During the nineties Lundbeck has seen substantial growth in sales, primarily due to Cipramil and geographical expansion. Cipramil will continue to be the main driver behind Lundbeck's sales in the coming years. However, generic citalopram is expected to have appeared on the market in several countries by the end of 2000. But because of Lundbeck's 2002 patent in some major markets and the limited tradition for generics in southern Europe, sales should nevertheless increase in both 2000 and 2001. By 2002, however, generics are expected to have captured a substantial share of Cipramil sales. The launch of Lu 26-054 [Cipralex, escitalopram] is foreseen to prevent a decrease in sales."[261]

(130) An undated internal Lundbeck strategic analysis stated under "Assumptions":

"Priority number one is to keep the market price of citalopram as high as possible before launch of Cipralex. Th[is] because of price as a competitive advantage on Cipralex, but first and foremost the threat of an influence on the reimbursement price.

Priority number two is not to lose more sales to generics than we have to."[262]

(131) A Lundbeck Business Development document with the title "Generic citalopram update 22 11 02" stated:

"It is like a poker game

- We have been dealt a mediocre hand ± two aces, a couple of queens and some small uneven cards
- But we have a large pile of $$$ at our side
- We call it ±"the art of playing a loosing hand ***slowly***"

Our strategy

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259 ID 163, page 601.
260 ID 9, page 316.
261 ID 163, page 550.
262 ID 903, page 150.

- Our objective : To create a window of opportunity for the Cipralex switch
- Focus on EU and particularly the northern European markets the generic markets
- Three main tactics:
  - Influencing the authorities
  - Patent defence, mainly process patents
  - Deal making".[263]

Lundbeck defined "window of opportunity" as "time difference from Cipralex launch to generic entry [on citalopram]".[264]

(132) The same "Generic citalopram update 22 11 2002" also stated:

"Value of delayed generic entry

- Besides the value of "sales not lost to generics"
- Additional value from impact on
  - Cipralex price
  - Cipralex penetration!
  - Staff morale".[265]

(133) From these quotes above it may be deduced that by 1997[266] Lundbeck had concluded that generic entry on citalopram, which it deemed realistically possible as of the year 2000 in a number of European countries[267], represented the greatest threat to the company's future profitability, given the company's strong dependence on sales of citalopram. By the end of 1998, Lundbeck had come to consider the earliest possible market launch of its successor product escitalopram as the company's most important strategy to ensure continued high turnover and profitability for the company in the future.[268] Ideally, the market launch of escitalopram would take place before generic entry on citalopram, thus creating a "window of opportunity" for Lundbeck to switch a maximum of new patients to escitalopram. Lundbeck apparently believed that patients that had started taking escitalopram were unlikely to switch in the course of their treatment to generic citalopram, given that Lundbeck marketed escitalopram as being a different and better product than citalopram.[269] Every month gained in enlarging this window of opportunity was therefore of significant commercial value to Lundbeck. The worst case scenario for Lundbeck would arise if massive generic entry on citalopram took place long before escitalopram was launched in the market.

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263 ID 847, pages 50-51. Emphasis in the original. As concerns Lundbeck's view of this document see footnote 1479 below. See also ID 904, page 290, Concerning Lundbeck's general strategy dated 11 December 2001 to aggressively defend itself against any breach of patent rights, see ID 815, page 85.

264 ID 163, page 251.

265 ID 847, page 75.

266 See recital (124) above.

267 See recitals (127) to (129) above. See also ID 847, page 52, which indicates that Lundbeck expected generic entry to occur in a number of Contracting Parties to the EEA Agreement as early as the beginning of the fourth quarter of 1999.

268 See recital (126) above.

269 See recital (108) above. See also section 6.2 below.

In that case, there could be significant negative consequences for Lundbeck's turnover and profitability on citalopram (and therefore for the turnover and profitability of the company as a whole), for the price and reimbursement level of escitalopram[270] and for Lundbeck's chances to gain a large customer base for escitalopram (and therefore for the future turnover and profitability of the company as a whole). It thus became very important for Lundbeck to delay as much as possible the entry of generic citalopram in European markets.

(134) The sections below will describe in greater detail, based on contemporaneous documents, several policies Lundbeck pursued as part of its strategic defence against generic entry on citalopram.[271] Such policies will be described to the extent that they were relevant for the agreements which are the subject of this Decision. These policies were:

- Creating a window of opportunity for escitalopram;
- Patenting processes to manufacture citalopram;
- Intervening in marketing authorisation procedures for generic citalopram;
- Eliminating the competitive threat of upcoming citalopram API producers;
- Persuading generic suppliers to stop their efforts to enter the citalopram market.

In order to understand the rationale behind Lundbeck's agreements as covered in this Decision and to evaluate their legality under Union competition law it is important to realise how these agreements fitted into Lundbeck's overall strategy against generic entry.

6.2. Creating a window of opportunity for escitalopram

(135) Already in its Strategic Plan for 1993 Lundbeck considered:

"In 1994 it will be decided whether Lundbeck should initiate development of the enantiomer to replace the CIPRAMIL (citalopram) racemate whether for safety reasons (registration authority requirements) or for patent reasons, or both."[272]

(136) A document prepared for a H. Lundbeck A/S Board meeting of 24 April 1998 stated:

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[270] See section 4.3 above. See also section 6.2 below.

[271] In its reply to the Statement of Objections, Lundbeck claimed that the Commission "mischaracterize[s] Lundbeck's actions by focusing on isolated statements in selected documents rather than on the relevant facts and the evidence." See ID 5394, page 76. The Commission notes that many of the contemporaneous statements reported in this chapter 6 originate in documents that were distributed to the board of directors of H. Lundbeck A/S. The quotes mentioned in this chapter speak for themselves and constitute facts and evidence regarding the intentions of Lundbeck. Lundbeck did not supply the Commission with quotes from cotemporaneous documents that would significantly contradict the policy statements reported in this chapter, which together lead to the conclusion that Lundbeck did everything it could to delay generic entry on citalopram, its most important product by far. At most, quotes reported by Lundbeck in its reply to the Statement of Objections complemented the intentions of Lundbeck, in the sense, for instance, that Lundbeck's acquisition of VIS served not only to avoid generic competition from citalopram products manufactured with the production process of VIS, but also to obtain additional production capacity for Lundbeck's own citalopram. The Commission simply notes, in this respect, that of course the one does not exclude the other.

[272] ID 163, page 999.

"The two developing projects[...]*" and "S-Citalopram" have been evaluated to see if they could be included as part of a generic strategy[...]*. The projects should therefore alone serve the purpose to prevent or slow down generic companies in introducing Citalopram or slow down the loss of market share to the generic competitors."[273]

The same document stated:

"The S-Citalopram project can lead to the launch of a patent protected product in year 2002. When this happens, Lundbeck's protection against generic competition will be prolonged until 2012 or later in the UK, Ireland, Belgium, Netherlands and France. On top of this a shift from Citalopram controlled release to S-Citalopram will further secure Lundbeck's market share in the other countries where generic competition already exists."[274]

According to Lundbeck, a decision to initiate the development of escitalopram for the European market was taken in 1998.[275]

(137) Lundbeck's Budget and Activity Plan 1999 of November 1998 stated:

"The enantiomer of citalopram, S-citalopram, is expected to become Lundbeck's most important defence against generic competition on the citalopram racemate. The enantiomer has certain therapeutic advantages over the racemate and will be protected by product patents until year 2012 as well as by clinical data protection.

The development of S-L W D O R S U D P Z L O O E H D F F H O H U D W H G « 6 X file is scheduled for year 2001 with subsequent launch in year 2002."[276]

(138) A Lundbeck document of 24 September 1999 listing the company's goals and their status of implementation stated as the company's third goal (after profitability and strengthening citalopram's commercial position):

"Speed up the development of S-citalopram"

The business rationale given for this goal was:

"Launching a new version of citalopram will prolong Cipramil's [citalopram's] life-time and minimise losses caused by generic competition".[277]

(139) Lundbeck's "Goal, Activity and Budget Plan 2001" of December 2000 stated in the Executive Summary:

"The major challenges in the medium-term will be to:

- Successfully switch patients from Cipramil/ Celexa [citalopram] to escitalopram"[278]

Later on in the same document, Lundbeck wrote:

"The immediate goal after launch will be to switch loyal Citalopram prescribers into loyal escitalopram prescribers."[279]

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273 ID 9, page 100.
274 ID 9, page 100.
275 ID 5394, page 81.
276 ID 163, page 601.
277 ID 9, page 599.
278 ID 9, page 654.

(140) Lundbeck's "Goal, Activity and Budget Plan 2002" of December 2001 stated:

"Launch and promotion of Cipralex (escitalopram) have the highest priority in Lundbeck in 2002. The citalopram franchise should be converted into escitalopram WR WKH OD U J H V W S R V V L E O H G H J U H H «

«

The continued growth of Cipramil is pivotal for an optimal market penetration of Cipralex (escitalopram) once introduced, and an effective strategy to counter generic erosion of Cipramil sales is of utmost importance in maintaining Cipramil's sales base."[280]

(141) Handwritten notes to a Lundbeck strategy presentation probably dated early 2003 stated:

"Lundbeck fight generics to create a window of opportunity to switch to escitalopram."[281]

(142) The situation in Spain illustrates well the importance to Lundbeck of delaying generic entry of citalopram in order to obtain a higher price for escitalopram. A Lundbeck Business Development document with the title "Generic citalopram update 04 09 2002" stated with respect to the Spanish market:

"We are trying to obtain an injunction against Tifi [Tiefenbacher], Cipla & Matrix. If successful the generic will not be included in the reference price list. Important for the Cipralex price."[282]

(143) A later Lundbeck document of December 2003 shows that the arrival of the first generic citalopram on the market in Spain led the authorities, firstly, to establish a reference group with a price for citalopram (including for Lundbeck) which was 29% lower than Lundbeck's previous price for citalopram. Secondly, with respect to escitalopram, where Lundbeck had originally hoped to get a price of [5-15]*% above the previous price for Lundbeck citalopram, the introduction of lower-priced generic citalopram led the Spanish authorities to offer Lundbeck the generic reference price (the one 29% lower) also for escitalopram. Lundbeck hoped at that time it could negotiate up to a price equal to the previous price for citalopram (but not any longer [5-15]*% higher).[283]

6.3. Patenting processes to manufacture citalopram

(144) Between 1997 and 1999, with the expiry of patent protection for the citalopram compound in many European countries looming, Lundbeck launched an avalanche of patent applications for all processes for manufacturing citalopram Lundbeck was able to identify. A Lundbeck press release of 16 May 2000 stated that "The PDQXIDFWXUH RI FLWDORSUDP « LV SURWHFWHG E\ Q however all known production methods."[284] At least seven patent families for processes for manufacturing citalopram were filed. According to Lundbeck, "The purpose of these

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279 ID 9, page 663.
280 ID 163, page 375.
281 ID 844, page 45.
282 ID 904, page 274.
283 ID 9, pages 723 to 726. See also ID 9, page 722.
284 ID 8, page 521, translation from Danish. See also ID 5394, footnote 257.

patent applications is to protect alternative methods and thereby to prevent that generic companies circumvent the above-mentioned process patents".[285]

(145) A Lundbeck Business Development document with the title "Generic citalopram update 22 11 2002" stated:

"Process patent defence

- From 1997 we patented some 30 different citalopram processes
- In addition, we have some use patents on citalopram within special indications."[286]

(146) Lundbeck also filed patents for different intermediates of citalopram (including 5-cyanophthalide and 5-carboxyphthalide), as well as for particle sizes, processes to make tablets, and different formulations of citalopram.

(147) According to information from GUK, in the period from July 2000 to January 2002 – the 18 months before the expiration of Lundbeck's compound and basic processes patent in a number of Contracting Parties of the EEA Agreement[287] – Lundbeck applied for 14 new process and related patents for citalopram, of which it withdrew or allowed to lapse eight before December 2006.[288] These new process patents Lundbeck was obtaining made it more difficult for generic competitors to produce citalopram, once the compound patent had expired, without potentially infringing one or the other Lundbeck patent (application) on different production methods. The uncertainty this created for potential generic competitors was further increased by the fact that several of Lundbeck's patent applications had not been granted or even published yet shortly before expiry of the compound patent.[289]

(148) Lundbeck used its process patents in an effort to deter API producers from producing generic citalopram. In an internal e-mail entitled "India visit postponed" of 12 January 2001, Lundbeck wrote:

"This week we have been sending out a "warning" letter with a listing of all our citalopram process patents and other related IP rights. This letter has been sent t

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285 ID 869, page 28. These "above-mentioned process patents" were the Lundbeck patents covering the diol process, which Lundbeck had been using in its production of citalopram since the mid-1980s, see recital (112) above. Lundbeck wrote in its third quarter 2002 financial statement: "Lundbeck is still convinced that citalopram is protected against generic competition beyond the date of expiry of the original compound patent via, among other things, a large number of process patents" (ID 611, page 7).

286 ID 847, page 56.

287 In January 2002, Lundbeck's last national patents in Contracting Parties of the EEA Agreement on the citalopram compound and original process expired, with the exception of Austria, where the original process expired in April 2003. See ID 9, page 300.

288 ID 1013, page 3.

289 See ID 673, pages 96 to 99, including a list of Lundbeck patents and patent applications Lundbeck sent to API producers and certain generic suppliers in January 2001. In a number of instances the list indicates "Unpublished application" or "To be published soon". See also recital (1113) below, where Ranbaxy mentions the risk that claims may be amended before the patent is granted. As another example, Tiefenbacher wrote to Arrow on 28 January 2002, after Lundbeck's patent covering the compound and the two original production processes had expired in most European countries and generic entry had in principle become possible: "As you know Lundbeck is still publishing a lot of patents and nobody can give guarantees. We are currently checking the situation regarding one SDWHQW«,W V HYHQ QRW FOHDU ZKHWKHU VRPH RI WKHLU FODLPV DUH DOUHDG\ SXEOLVKHG RU QRW through or not." See ID 631, page 3.

companies which we believe are involved with citalopram, and amongst others the letter has been sent to Natco, Max, Herero, Cipla, Ranbaxy-Vorin, Dai-ichi, Sun and RPG Life Science."[290] This letter also mentioned the crystallisation patent as granted as a utility model in the Netherlands.[291]

(149) According to Lundbeck, Lundbeck's "enemies" labelled the crystallisation patent "high school chemistry" and considered that it was not novel.[292] Lundbeck itself admitted: "[…]*"[293] This process patent immediately became Lundbeck's main legal weapon to fight generic market entry in the EEA with infringement litigation.[294] According to Lundbeck, use of the original cyanation 2002-1 process or the original alkylation 2002-2 process left chloro- and bromo-impurities that crystallisation of the free base of citalopram could reduce in a very efficient and cost-effective manner to levels below regulatory requirements in the EEA. It is this patent in particular that was at issue in the disputes and litigations with generic companies that led to most of the agreements that are the subject of this Decision, as Lundbeck argued that generic citalopram offered for sale in the EEA had been purified by the API producers concerned through crystallisation of the free base.

(150) Indeed, in its reply to the Statement of Objections, Lundbeck went so far as to argue that "No commercially viable processes, apart from the Crystallization Patent and the other processes patented by Lundbeck, existed at the time."[295] However, earlier in the proceedings before the Commission, Lundbeck had stated to the Commission:

"In early 2002, (just after expiry of the Citalopram Product Patent), Generics were preparing to enter the market. They could have entered the market using the Cyanation and Alkylation method, or any other method the Generics could invent (e.g. the Matrix "Washing Method" or Sumika's process). But: the method identified in the Crystallization of Free Base Patent was a more efficient method to achieve

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290 ID 681, page 111.

291 See recital (248) below.

292 ID 847, page 62. On 12 February 2002, Merck (GUK) stated in an internal e-mail: "I can't believe that WKLV SDWHQW KDV EHHQ JUDQWHG LQ WKH 8.« WKH H[DPLQHU the crystalline free base has been disclosed in the prior art" (ID 673, page 326). Merck added on 25 February 2002: "the patent is considered to be weak. Thus some generic companies try to invalidate the patent DQG ZRUN WRJHWKHU (See ID 675, page 25). Considering these assessments, it is not clear why Merck KGaA argued, in reply to the Statement of Objections, that the possibility that the patent would be revoked, if challenged, was not "distinct" but only "theoretical". (See ID 5960, pages 121-122.)

293 ID 904, page 251.

294 A generic citalopram update of Lundbeck of 28 June 2002 called the crystallisation patent "Currently the most important patent". See ID 848, page 18. According to Ranbaxy in its reply to the Statement of Objections, "Lundbeck's claim was very broad because any process whereby citalopram base in solution was treated with a reagent and yielded even an infinitesimally small amount of crystalline citalopram would be a target for an infringement attack" (ID 5176, page 23).

295 ID 5394, page 39; ID 6814, page 4. In its reply to the Statement of Objections, Lundbeck argued infringement of the crystallisation patent, at least initially, by Natco (API supplier to Merck (GUK), Cipla (API supplier to Arrow and Alpharma) and Matrix (potential alternative supplier to Arrow and Alpharma). As for Ranbaxy, Lundbeck at the time mainly argued infringement of two other process patents, namely Lundbeck's iodo and amide process patents (European patents EP 1159274 and EP 1015416 respectively), as reflected in the agreement with Ranbaxy. See recital (564) below. Similarly, in its reply to the Statement of Objections Merck KGaA claimed (without producing further evidence) that it was "impossible or at least extremely difficult to avoid" the crystallisation patent. See ID 5960, pages 11, 12 and 26. It moreover claimed that Lundbeck invoked patent EP 1015416 also against Merck (GUK). See ID 5960, page 151.

commercial volumes of sufficient quality quickly. The Crystallization Patent could not prevent generic competition as non-infringing processes to produce citalopram existed, although these were less efficient. The Generics opted to infringe Lundbeck's Crystallization of Free Base Patent in order to boost their potential profits (emphasis in the original)"[296]

Therefore, according to Lundbeck, « J H Q H U L F H Q W U D Q W V F R X O G citalopram by using the process described in Lundbeck's original compound patent filed in 1977, albeit with a different and potentially less efficient method of purification, or they could have invested to invent an entirely new process. The Crystallization of Free Base Process, however, was a significant improvement over other known processes used to manufacture pure citalopram, enabling more efficient production, and several of the early suppliers of generic citalopram thus chose the lower-cost option of infringing Lundbeck's Crystallization of Free Base patent."[297]

Lundbeck had also earlier explained to the Commission that "In the 2002-2004 timeframe, there were several processes available to produce citalopram. Instead of using one of the several processes available, generics freely chose to use the process described in the Crystallization patent because it was more efficient than the othe processes"and had listed the following processes which generic companies could have chosen to use in the period 2002-2004 instead of (allegedly) infringing the crystallisation patent:

- the original cyanation and alkylation processes;
- the Matrix washing method;
- Sekhsaria's process;
- Sumika's process;
- other process, including processes of the API producers Max Pharma, Natco and Cipla, which these API producers claimed to be non-infringing.[298]

Moreover, on 2 March 2002, Lundbeck's patent experts concluded: "SPE has shown that it is possible to make an active pharmaceutical ingredient (API) that very probably does not require crystallisation of the free base."[299]

Consistent with these latter explanations is also a contemporaneous statement of 9 November 2002 that Lundbeck's Senior Vice President gave to the press: "It would

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296 ID 1944, page 16.

297 ID 823, page 4. See also ID 723, page 19.

298 ID 2773, pages 14 and 15. Regarding this list, Lundbeck clarified: "Given the number of potential processes to produce citalopram, it is not possible to provide an exhaustive list." In reply to the Letter of Facts, Lundbeck pointed out that it did not intend to imply that all these processes would have been available already at the beginning of 2002. With respect to Sumika, Lundbeck claimed that the process became available only in 2004. Regarding Max, Lundbeck alleged that "Lundbeck had already established that [… Max] infringed the Crystallisation patent" and that Max's citalopram would have only become available in 2004, although it was being advertised with a regulatory file and registration already in February 2003. See ID 6814, pages 24-27.

299 ID 681, page 113 (translation from Danish, emphasis in the original). For the relevant context of this statement see further recital (281) below. "SPE" was a research unit within Lundbeck, which according to Lundbeck had developed an alternative process for the preparation of citalopram (for laboratory purposes); the process had been patented by Lundbeck in 1997. See ID 6814, page 27.

be naïve to think that it is ***not*** possible for producers of generic copies to produce Cipramil without breaking our patent."[300]

(151) With respect to Lundbeck's crystallisation patent, it should be noted that as published in September 2001, Lundbeck's PCT patent application WO 01/68627 also contained several claims to the crystalline base of citalopram itself with a purity of more than 99.8% as well as claims to pharmaceutical compositions. After the application had entered into the regional phase, the EPO communicated to Lundbeck on 10 January 2002 that these claims lacked novelty. As requested by the EPO, Lundbeck deleted these claims from the patent application and decided to pursue the claims regarding the crystalline base of citalopram separately in a divisional application. Lundbeck did later manage to obtain from the EPO a product patent on the crystalline base of citalopram itself (EP 1 227 088). This patent was opposed before the EPO and subsequently revoked by the EPO in 2007.[301] Crystallisation patents applied for at a national level, including GB patent 2357762 in the United Kingdom, also contained claims relating to the crystalline base of citalopram itself and to pharmaceutical compositions.[302] The claims regarding the crystalline base of citalopram in particular led to considerable uncertainty on the part of API suppliers and generic companies, because, if valid, they meant that irrespective of whether the precise method of production, the creation of highly pure crystalline base of citalopram could in itself amount to a patent infringement.[303] In January 2001, Lundbeck sent a warning letter to API suppliers and generic companies which it suspected of wanting to sell generic citalopram. This letter listed the Dutch utility model 1016435 which covered not only a process to purify citalopram through crystallisation of the free base, but also, in the words of Lundbeck in the letter: "The crystalline base of citalopram is claimed pr. se."[304]

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300 ID 1789, page 6.

301 See ID 307, page 2 and Espacenet.

302 It appears that the British patent GB 2357762 was granted including the product claims and pharmaceutical composition claims. Source: Espacenet and United Kingdom Intellectual Property Office IPsum online databases. In its reply to the Commission's Letter of Facts of 12 April 2013, Lundbeck stated: "With respect to the UK patent, there were simply no opposition claims filed, and therefore the patent remained in force in unamended form." See ID 6814, page 28. There is no indication in the file that Ranbaxy opposed the British patent, as it had intended in March 2002. See recital (555) below. In the Netherlands, utility model 1017413, granted on 13 September 2001 and similar in nature to utility model 1016435 already granted in November 2000 (see recital (113) above) was challenged by a generic company (different from the ones subject to this Decision) before the Industrial Property Office. In the proceedings, Lundbeck stated that it wished to limit the patent rights to the method claims only. The Office advised in a ruling of 5 September 2002 that only the process claims 3 to 5 (out of a total of 16 claims, of which three related to the crystalline base of citalopram and three more to pharmaceutical compositions) could be maintained in the two patents and then only if they were reformulated to significantly narrow the scope of the claims. See ID 5409. In the United Kingdom, Ranbaxy intended to oppose the product claims in the crystallisation patent, but apparently no longer pursued this after having reached its agreement with Lundbeck.

303 For examples, see recitals (382) and (505) and (555). This meant that the United Kingdom patent was on the one hand more likely to be infringed than without these claims, but on the other hand also more likely to be found at least partially invalid. Merck KGaA argued in its reply to the Statement of Objections that the wide scope of the crystallisation patent took several API producers by surprise. (ID 5960, page 11).

304 See, for example, ID 903, pages 66-68. The letter stated: "Lundbeck has used substantial resources in investigating new processes for the manufacture of citalopram. Lundbeck has, of course, protected such new processes in addition to the earlier patented processes). Accordingly, we now have a large

(152) In the United Kingdom the crystallisation patent was most notably invoked by Lundbeck in court in October 2002 against the generic company Lagap, after Lagap had started to distribute in the United Kingdom citalopram sourced from Matrix in the United Kingdom.[305] On 15 March 2002, Lundbeck had sent a warning letter to Lagap informing Lagap about Lundbeck's patents, which it intended to enforce.[306] Having obtained a marketing authorisation on 1 August 2002[307], and prior to entering the United Kingdom market, in September 2002, Lagap sent an independent expert to inspect Matrix's manufacturing process at Matrix's manufacturing facility in India for four days. The expert reported that the inspected process, which used a washing method to purify citalopram[308], did not involve crystallisation and was, in his opinion, able to operate on an industrial scale. He found that Matrix had the facilities, equipment and raw materials to conduct the process at an industrial scale. In light of this report, Lagap informed Lundbeck on 9 October 2002 that it intended to enter the United Kingdom and started selling Matrix citalopram in the United Kingdom on 11 October 2002.[309] In that context, Lagap also provided Lundbeck with a full process description for Matrix's method of production and the report prepared by its expert. Lundbeck, however, issued legal proceedings on 14 October 2002 and sought directions in respect of an application for an interim injunction.[310] Lagap in turn challenged the patent's validity, denied infringement and stated to the press that it "had every confidence that it would win".[311]

(153) At a hearing for directions before the United Kingdom patent judge in charge of the case, on 18 October 2002, the judge remarked that Lundbeck's expert should view Matrix's production facility to confirm what Lagap's expert had seen before any application for an interim injunction was to be heard. The judge told Lundbeck: "If your expert goes out and sees what [Lagap's expert] did, and is satisfied in the same way, you had better turn on your toes. If [Lagap's expert]'s report is right, then that

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portfolio of patents and other intellectual property rights relating to the preparation of the compound including special know-how useful to obtain the required purity, formulation of the compound and crystal forms of the compound".

305 On 26 July 2002, Lagap, a United Kingdom subsidiary of the pharmaceutical undertaking Sandoz (in turn part of the Novartis group), had received a United Kingdom marketing authorisation for the distribution of citalopram tablets of 10, 20 and 40 mg, see ID 682, pages 4-5. A Lundbeck document of 14 October 2002 stated: "Lagab [sic] (Novartis) launched with Matrix in the UK Friday 11 Oct – it seems as if they are only selling to retail pharmacists and not yet to wholesalers – price is relatively high £12.40 – Lundbeck has requested an injunction to-day – probably a November hearing". See ID 846, page 34. On 7 March 2003, Lundbeck reported the following press article to its Board of Directors: "Lagap has sold a generic version of Citalopram in the UK since October 2002. The latest information we have is that Lagap's generic Citalopram is priced on a par with branded Citalopram from Lundbeck. According to our information, Lagap has not been very aggressive in its marketing and thereby not gained much sales. The reason for this cautious behaviour is that if Lagap loses the court case – so far set for October 2003 – it will be fined a penalty according to the damage Lundbeck has suffered. Lagap has not been willing to comment on its position in the suit". See ID 891, page 36.

306 See ID 5394, page 59.

307 ID 1239.

308 Matrix made a patent application under the PCT for its washing method, see ID 640, page 2.

309 ID 5394, page 68.

310 ID 239, pages 497-523 (501-502); ID 234, pages 34 to 36 (which states as entry date 9 October), and ID 5394, pages 68-69 and 206. That Lundbeck had at least considered the idea of concluding an agreement instead of litigating with Lagap is shown by recital (203) below, where a contemporaneous Lundbeck document is quoted as saying: "May [2002]? MAs [marketing authorisations] for Lagab (Novartis) and Ratiopharm Lu [Lundbeck] requests injunction or settles". See ID 847, page 4.

311 ID 1789, page 36.

will be the end of the case."[312] With the consent of Matrix[313], an inspection by Lundbeck of Matrix' production facility in India took place in November 2002, during which the main proceeding was stayed.[314] In the course of these investigations, Matrix admitted that it had used base crystallisation to manufacture citalopram from December 2000 to July 2001 (when Lundbeck's United Kingdom patent application was published and allegedly without having exported such product to the EEA), but claimed that it had been using the non-infringing process since September 2001 (including for product that had been exported as of March 2002 to the EEA).[315]

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312 ID 234, page 37. On 23 October 2001, the same judge had issued an interim injunction in the United Kingdom proceedings Smithkline Beecham PLA v Generics (UK) Limited (2002) 25(1) I.P.D. 25005 Official Transcript) (also referred to as the Paroxetine case) against GUK because it had failed to do the necessary "for clearing the way": "The defendants could, ***so soon as they settled upon the product they were intending to sell, have caused the litigation to start***. They could have done a number of things: First, they could have launched a petition for the revocation of the patent and started a claim for a declaration of non-infringement. Or, since there are certain difficulties with the latter (for example RQXV RI SURRI JRHV WKH RWKHU ZD\ URXQG WKH\ FRXOG VLPS are not saying when but it is a settled intention) to launch our product within the next five years. If you LQWHQG WR VXH XV VXH XV QRZ´ ,I WKH\ KDG WDNHQ VXFK D intended to sell, the whole of this dispute would have been got out of the way before their date of intended launch[…] They knew perfectly well the issue of infringement was likely to arise. If they wanted to be sure of their position they could and would have made sure that all their experimental data was properly in place and vouched for by an independent expert. And they would have presented this evidence to the patentees[…] The commercial position was that they did not take the steps necessary to show exactly what the product they were intending to sell was." (emphasis added) Source: Westlaw.uk 2001 WL 1346930. Lagap's efforts to clear the way have to be analysed against this background.

Lundbeck argued in its reply to the Statement of Objections that "The Paroxetine ruling created powerful incentives for both Lundbeck and generic companies to settle instead of litigating. With respect to the UK, Lundbeck hesitated to rely entirely on one important, but isolated, first instance judgment, even though it was favourable to its position. At the same time, generic companies took this judgment as a negative signal that UK courts would be inclined to grant preliminary injunctions to originators absent sufficient action taken by the defendant to resolve the dispute before launch" (ID 5394, page 58). However, Lundbeck itself stated that before the Paroxetine ruling, "a preliminary injunction had not been granted in a patent case in the pharmaceutical sector for a long time" (ID 5394, page 57). It is therefore difficult to see how the Paroxetine ruling, which according to Lundbeck "was favourable to its position" in that "UK courts would be inclined to grant preliminary injunctions to originators absent sufficient action taken by the defendant to resolve the dispute before launch" could have made Lundbeck less inclined to litigate compared to the situation that existed before the Paroxetine ruling. For Merck KGaA's and GUK's arguments in respect to this ruling see footnote 498.

313 On November 8 and 18, 2002, the judge issued a consent order granting Lundbeck permission to conduct an inspection at Matrix, but at the same time ordering that any information arising out of these inspections would be confidential and could not be used for any other purpose than for the proceedings in England before the High Court of Justice, except with the written consent of Matrix. Subsequently, by letter dated 3 December 2002, Matrix agreed that the information gathered in the inspection could also be used by Lundbeck for judicial patent proceedings abroad, again on condition that confidentiality was guaranteed. See ID 239, pages 246-251, ID 2785, pages 1-3, ID 8, pages 464-465 and ID 240, page 19. See also ID 234, page 37.

314 ID 222, page 13.

315 ID 823, pages 8 and 16 to 20. See also ID 222, pages 12 to 14, ID 234, page 38, ID 239, pages 497-523 and 1687, ID 5394, page 163. In a witness statement to the United Kingdom court, Matrix stated about its old process (the so-called Matrix I process): "[…]*" See ID 240, page 996. With respect to the Matrix II process, which included the washing step, Lundbeck stated in its reply to the Statement of Objections that "It was only in April 2002 that Lundbeck learned for the first time that Matrix might FODLP D PRGLILFDWLRQ LQ "United Kingdom v Generics (UK) Ltd (trading as Lagap Pharmaceuticals) and Merck KGaA «

(154) Following the inspection, Lundbeck withdrew its application for an interim injunction, a hearing for which had been scheduled in December 2002. […]*[316] […]*[317] However, Lundbeck continued to argue in the Lagap trial that the inspected process was not economically viable and that Matrix's product sold in the United Kingdom was actually produced with a (less cumbersome) infringing process using crystallisation.[318] Lundbeck also accused Matrix of having forged batch data.[319]

(155) In an interim ruling on 14 February 2003, the United Kingdom judge stated:

"[an independent expert on whose views Lundbeck had relied]'s views have not only been used in this country. They were also relied upon by Lundbeck in support of a successful application for an interlocutory injunction in equivalent proceedings in Denmark. No doubt the court there was impressed with the [Lundbeck's expert]'s confidence that the Lagap product could not be made by any other process than that covered by the patent."

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"Lundbeck and [Lundbeck's expert] now had to admit, having examined the process in operation in India, that their firm and unshakeable confidence that it was impossible for Lagap and its suppliers to be operating a non-infringing process was unfounded. The process that they had seen was indeed a non-infringing process and did produce a product which appeared to be Lagap's product."

The judge also stated that "I must say now that I am not persuaded on the material VKRZQ WR PH WKDW WKHUH LV DQ\ FUHGLEOH FDVH F[320]

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market on June 14, 2002, was the first time when Lundbeck learned that Matrix-based citalopram had been launched on the market" and "Generic companies started switching from Cipla's to Matrix's API from the end of September or the beginning of October 2002." See ID 5394, pages 163-164.

On 7 May 2002, Tiefenbacher filed in the Netherlands, the reference Member State, for a Type I variation to its marketing authorisation to cover Matrix's "patent free extraction method for purification of Citalopram". This application was completed positively on 16 July 2002, see ID 1718, page 1. A filing for Cipla's "patent free purification method" was ready for filing on 24 September 2002. According to Tiefenbacher, this application was also approved after around two months after filing, see ID 1713, page 1. See also ID 1359, page 1, an e-mail from Tiefenbacher to Arrow, which explains that the Dutch authorities considered a type I variation was sufficient.

316 Inter alia, patents no GB2375763 and EP1478635. In reply to the Letter of Facts, Lundbeck pointed out that there were probably more than two Matrix processes. See ID 6814, pages 30-41. In the Commission's view, this would only confirm the ability and freedom of API producers to amend their processes, if needed.

317 In December 2002, a Finnish judge lifted an interim injunction that had earlier been granted against a generic company that had sold Matrix citalopram in Finland. In coming to this decision, the court had examined documents of the Matrix inspection from the Lagap litigation. Lundbeck's then CEO claimed to the press, however, that Lundbeck possessed "decisive data" that it had not presented in the Finnish proceedings but would present in the United Kingdom proceedings. See ID 1789, pages 25 and 36.

318 See for instance ID 239, page 389 and ID 241, page 740. Lundbeck relied, in this respect, on an analysis it had made of chloro/bromo impurity ratios of Matrix products sold in the United Kingdom […]*. See ID 823, pages 16 to 20. However, in the course of the Lagap proceedings, Lundbeck withdrew this analysis. See recitals (156) and (158) below.

319 ID 823, pages 8 and 16 to 20. See also ID 222, pages 12 to 14, ID 234, pages 38 and 182, and ID 1789, pages 25 and 36. […]* See ID 247, page 4. […]* See ID 247, page 6.

320 H. Lundbeck A/S v Lagap Pharmaceuticals Claim No HC 02 CO 2978, 14 February 2003, 2003 Westlaw 1822925, page 2. A forensic expert appointed by the Court concluded that […]*. See ID 244, pages 649 and 655-656; and ID234, pages 39 and 188.

(156) In a report of 12 August 2003, Lagap's expert stated that "Some of [Lundbeck's allegations], in particular those concerning so called "fingerprints" for purification PHWKRGV DUH KLJKO\ IODZHG«[321]

(157) In an internal assessment of 29 September 2003, Lundbeck estimated the chance that the United Kingdom judge would hold the crystallisation patent invalid at 60%.[322] At this time, Lundbeck was still optimistic about its chances that if the patent were held valid, it would also be found infringed, estimating the chance of infringement at 80%.[323]

(158) Lundbeck's optimistic assessment on infringement changed radically, however, once the main proceedings started on 3 October 2003. The judge requested marked-up versions of the three expert reports prepared by Lundbeck's expert witness, for the purpose of clarifying what arguments Lundbeck was still relying on and what arguments it had withdrawn. Having reviewed the mark-ups in these expert reports, the judge summed up his impression as follows:

"The impression that I get is that most of the technical, that is the chemical reasons, for alleging that the Matrix November process was a sham when it was shown to your clients and was not used before or since, most of those have gone, subject to small qualifications, may be little bit and pieces left over. That is right, is it not?"

Lundbeck's counsel responded:

"Yes it is. The chloro-bromo ratio has gone. The dimer has gone. The economic benefit has gone. Those are the major items that I think your Lordship is referring to."

Lundbeck's counsel also declared about the Matrix II process:

"I do accept that it can be run economically. It does depend on how you do the cyanation. They [Matrix] do the cyanation more efficiently than we have believed that they could do it."[324]

Lundbeck also admitted:

"That is why the capacity has been deleted from the pleading. We are not saying that they did not have the absolute capacity."[325]

(159) Before any judgment on substance (validity of the patent, infringement of the patent) was reached, the parties settled on 13 October 2003. In the settlement, Lagap's parent company Sandoz agreed to drop all challenges against Lundbeck's crystallisation patent (including before the EPO) in exchange for Lundbeck a) withdrawing its claims of infringement, damages, forgery and perjury and b) granting Sandoz an irrevocable, non-exclusive royalty-free licence to Lundbeck's crystallisation patent

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321 ID 240, page 293 and ID 234, page 40. See also ID 240, page 294, where the same expert reiterated: "I have seen no evidence that Matrix are infringing the Patents. Matrix have developed their own process for purifying Citalopram which V FKHPLFDOO\ YLDEOH DQG FDSDEOH RI SURG VFDOH[…]*:"« @

322 ID 846, page 3. One month earlier, on 19 August 2003, Lundbeck had still estimated that there was a 50% chance that the patent would be held invalid. See ID 9, page 450.

323 ID 846, page 3.

324 ID 244, pages 876 and 913 and ID 234, page 42.analysis ss

325 ID 234, page 106. See also ID 244, page 921.

covering the entire EEA.[326] This licence allowed Sandoz to sell Matrix products in the United Kingdom also via other generic suppliers. In other EEA Contracting Parties than the United Kingdom, Sandoz could, however, only sell the product itself, not via other generic suppliers.[327] Also in other EEA Contracting Parties, a definitive legal ruling finding the crystallisation patent valid and infringed was never made.[328]

(160) An internal Lundbeck document probably dated shortly after the settlement analysed the Lagap litigation. It found that the United Kingdom judge "did not accept our arguments:

– Chloro-bromo relationship

– Dimer

– Lack of capacity

– Economical incentive (no motive)."[329]

This Lundbeck document depicted "The alternative" to a settlement with Lagap as:

"[The UK judge] would have ruled:

– Non-infringement

– Patent invalid

– Vindicated Matrix and completely dismissed any doubt of fabrication

– Lundbeck to pay all costs

– Condemned Lundbeck"[330]

Under the heading "What's in it for us? Damage limitation", the same document stated as a benefit of a settlement with Lagap:

"Avoiding a humiliating defeat which would be used against us in other jurisdictions".[331]

(161) In another, subsequent analysis of Lundbeck's reasons for settling with Lagap, Lundbeck stated: "Lundbeck realized that it was only a matter of time before Lundbeck would not be able to show that the processes were infringing".[332]

(162) Lundbeck later explained to the Commission: "The judge indicated that Lundbeck would win the case if it could be proven that Matrix had forged the documents, but that entailed that the burden of proof of Lundbeck became much more severe as

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326 ID 237, pages 1205 to 1221.

327 See clause 2.6 of the licence agreement, ID 237, page 1218.

328 ID 1713, page 2. See also recital (185) below.

329 ID 903, page 14.

330 ID 903, page 17.

331 ID 903, page 20.

332 ID 823, page 19. Contrary to what Lundbeck argues in its reply to the Statement of Objections, ID 5394, page 74, the sentence is not taken out of context as the full quote shows: "By this stage in the Lagap trial (late 2003) Lundbeck had spent the previous two years defending the Crystallization of Free Base Patent against Lagap and others in courts across the EEA. Lundbeck realized that it was only a matter of time before Lundbeck would not be able to show that the processes used were infringing. Under these circumstances, the benefits of continuing the case against Lagap (and others) seemed increasingly doubtful as time progressed (and attempts by generic companies to invent around Lundbeck's patents continued)."

Lundbeck then had to prove in accordance with criminal law standards that Matrix KDG FRPPLWWHG IRUJHU\ WR REWDLQ D MXGJPHQW hereof Lundbeck was cornered into a situation where it would have to prove that all entries in all batch documentation for all the final stage records of the batches made by Matrix were forged in order for the judge to find infringement. Based on that opinion, Lundbeck agreed to settle the case, which was effectuated by a settlement agreement dated 13 October 2003."[333]

(163) In a separate "clearing the way" proceeding, launched on 11 April 2003[334], the United Kingdom High Court of Justice, Chancery Division, Patents Court granted on 28 July 2003 a declaration of non-infringement to the company Niche Generics for generic citalopram supplied by the Indian API producer Sekhsaria, following an inspection at the latter's premises in India in May 2003. Lundbeck was ordered to pay Niche's legal costs. Niche entered the United Kingdom market in late September 2003.[335]

(164) On 22 December 2003, another generic company, Neolab Ltd, also settled its litigation with Lundbeck.[336] In October 2002, Neolab had launched generic citalopram from the Indian producer Cipla on the United Kingdom market.[337] In November 2002 Lundbeck started infringement proceedings. Neolab lodged a counterclaim that Lundbeck's crystallisation patent was invalid.[338] In December 2002 and February 2003, Neolab accepted voluntary injunctions until judgment was given in first instance in the Lagap litigation on the counterclaim of invalidity of Lundbeck's crystallisation patent or until 30 November 2003, whichever was the earlier.[339] Lundbeck agreed in the Orders that it would have to pay damages if the invalidity ruling were to go against it. Following Lundbeck's settlement with Lagap of 13 October 2003, Lundbeck released Neolab from its injunction on 15 October 2003. Neolab re-started selling in the United Kingdom on 30 October 2003.[340] However, Neolab still had an interest in obtaining damages from Lundbeck for the past through a finding of invalidity of Lundbeck's crystallisation patent. Based on Lundbeck's internal consideration that "They will try to invalidate the crystal patent aQG FODLP GDPDJHV"[341], and because Lundbeck considered it had a "90% likelihood of loosing" the litigation at that time[342], Lundbeck preferred to settle with Neolab. In the settlement of 22 December 2003, which terminated the proceedings, Lundbeck agreed to pay Neolab its incurred damages (for the year that Neolab was prevented from selling in the United Kingdom through the voluntary injunctions) in exchange for Neolab releasing Lundbeck from any claim for damages under the cross-undertakings in the Court Orders. Lundbeck in turn released Neolab from any

333 ID 222, pages 13-14.
334 ID 222, page 15.
335 ID 903, page 169.
336 ID 396, pages 459 to 491.
337 ID 845, page 99. Neolab had received a United Kingdom marketing authorisation for citalopram tablets of 10, 20 and 40 mg on 17 September 2002. See ID 682, page 6.
338 ID 396, page 481.
339 ID 396, pages 473 and 481.
340 ID 903, page 117.
341 ID 903, page 23.
342 ID 394, page 175. See also ID 845, page 99. This latter document shows that Neolab claimed that the second Cipla process did not infringe and that Lundbeck's crystallisation would not hold up in court.

claims under its patents for past sales and future sales until 31 March 2004, reserving its patent rights for the period thereafter.

(165) Because of Lundbeck's settlements with Sandoz and Neolab and the agreements which are the subject of this Decision, the validity of Lundbeck's crystallisation patent was never decided by a United Kingdom court.[343] After the Lagap settlement, Lundbeck continued to invoke the crystallisation patent in courts in other Member States, for instance in Belgium in 2003.[344]

(166) At the EPO level, the crystallisation patent was first revoked in 2006 after opposition by a number of generic companies but was then reinstated in 2009 in amended form after an appeal by Lundbeck. The amendment in particular resulted in the deletion of claims 1, 2 and 5 as granted and in the limitation in the scope of claims 3 and 8 as granted. Claim 3, as finally upheld by the EPO Board of Appeals in 2011, states: "A process for the manufacture of a salt of citalopram characterised in that one or more impurities of the formula [follows the chemical formula] wherein Z is halogen, are removed from a crude mixture of citalopram or from a crude salt of citalopram, by precipitating citalopram base in crystalline form, optionally re-crystallising said base one or more times and/or transferring said base into a salt thereof."[345] This patent, as amended, expires in 2021.

6.4. Intervening in marketing authorisation procedures for generic citalopram

(167) In August 2000, reacting to generic applications based on the Tiefenbacher file in Austria and in the Netherlands, Lundbeck headquarters sent out general instructions regarding action to be taken by Lundbeck national subsidiaries towards the marketing authorisation authorities in all EEA Contracting Parties. These actions included writing letters expressing "serious public health concerns" about the quality of the generic citalopram used for the application in the Netherlands, which would act as reference Member State for the mutual recognition process. According to Lundbeck: "Due to the patent situation, generic applicants have to use methods of synthesis that differ from the method used for the reference product. The samples of the generic products tested by Lundbeck show unknown impurities exceeding the legal limit of 0.1%. These differences raise serious doubts whether the generic versions of citalopram are "essentially similar" to the reference product."[346]

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343 Lundbeck estimated in September 2003 that if the crystallisation patent were invalidated, it would have to pay damages in the United Kingdom of between EUR [0-10]* and [10-20]* and in Scandinavia of between between EUR [0-10]* and [10-20]*, see ID 903, page 32.

344 ID 234, page 2.

345 See Board of Appeal of the European Patent Office, Decision of 2 July 2009 in Case T/1618/06, page 7. The companies that filed opposition were: Biochemie GmbH; Neuraxpharm Arzeinmittel GmbH & Co. KG; Stada Arzeinmittel AG; Ratiopharm; Hexal Pharmaforschung GmbH; Alfred E. Tiefenbacher GmbH; Biomo Pharma GmbH; Egis Gyógyszergyár RT; Merck dura GmbH; and Niche Generics Limited. Merck N.V. intervened later. See ID 2773, page 7. None of the generic undertakings that concluded the agreements with Lundbeck subject to this Decision opposed the patent at the EPO, with the exception of Merck. Lundbeck explained to the Commission that the amendment of the patent at the EPO restricted the list of impurities removed to halogen impurities for the manufacture of a salt – not a base – of citalopram. According to Lundbeck, the claims most relevant for the infringement litigation in the United Kingdom and elsewhere in the EEA were upheld. Halogen elements are: fluorine, chlorine, bromine and iodine. See ID 2773, pages 12 to 14.

346 ID 9, pages 751 to 753.

(168) In October 2001, Lundbeck appealed to the Objections Committee of the Dutch Medicines Evaluation Board against the latter's decision in September 2001 to grant marketing authorisations to Tiefenbacher for generic citalopram sourced from the Indian companies Cipla or Matrix. Lundbeck complained that Tiefenbacher's application file was "partially based on information with respect to the manufacturer of an active substance of which no valid information is available in the file, namely the Italian company VIS." Lundbeck claimed in particular that the stability data and the bioequivalence studies in the registration file were based on citalopram produced by VIS.[347] This objection was rejected on 25 January 2002.[348] Simultaneously in October 2001 Lundbeck had lodged with the court of Amsterdam a request for an injunction against the Dutch marketing authorisations being used, including their further treatment under the mutual recognition procedure. This request was denied on 21 December 2001.[349] Merck (GUK) internally commented: "me thinks that Lundbeck are starting a general war here".[350] In January 2002 Lundbeck lodged an appeal against the decision of the Objections Committee of the Dutch Medicines Evaluation Board confirming Tiefenbacher's marketing authorisation in the Netherlands but lost these proceedings on 11 July 2002.[351] It then appealed to the highest Dutch court, the Hoge Raad, but also lost this appeal.[352] Nevertheless, Lundbeck's intervention in the Netherlands delayed by more than half a year, until after Lundbeck had lost its appeal for an injunction in the Netherlands in July 2002, the issuing of marketing authorisations by the United Kingdom Medicines Control Agency to generic companies whose application in the United Kingdom was based on Tiefenbacher's registration file, including Arrow, Alpharma and Lagap.[353] A contemporaneous Lundbeck document of 4 September 2002 stated: "Following the decision [by the appeal court of Amsterdam rejecting Lundbeck's appeal on 12 July @ WKH 0&$ 8.« LVVXHG WKH QDWLRQDO OLFHQFHV 14 days±this licence took more than 7 months!"[354]

(169) In December 2001, Lundbeck intervened with the United Kingdom Medicines Control Agency (MCA) submitting information regarding certain tests Lundbeck had done allegedly showing impurities in the API of the Indian company Natco, on the basis of which Merck (GUK) had filed an application for a United Kingdom

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347 ID 621, page 8. Lundbeck had withdrawn VIS' registration file after it had acquired the company, see recitals (175) to (177) below.

348 ID 844, page 9, ID 846, page 168.

349 See recital (257) below.

350 ID 673, page 182.

351 ID 904, page 280. See also ID 6082, page 34.

352 ID 291, page 4, ID 844, page 9. Lundbeck stressed amongst others in its reply to the Statement of Objections (ID 5394, page 93-94) its strong interest in surveiling the quality of generic citalopram and argued that it had "an ethical obligation to inform the authorities of potentially defective material to safeguard patient health".

353 In reply to the Statement of Objections (ID 5394, pages 94-95), Lundbeck contested the delay in the United Kingdom without, however, having been able to put into question the evidence cited in recitals (170), (171) and (384).
Tiefenbacher informed the Commission that a leading Tiefenbacher representative was invited to Lundbeck's headquarters "on a Sunday (!) morning" and was offered a "significant amount of money in case Tiefenbacher stops the regulatory activities, especially in the UK. Due to the valid contracts with our customers Tiefenbacher saw no option to follow that approach." See ID 280, page 7. However, Tiefenbacher neither indicated the date on which this would have happened nor provided any contemporaneous documents to corroborate this allegation.

354 See ID 904, page 281.

marketing authorisation. Lundbeck argued that the quality of Natco's product was not compliant with relevant guidelines.[355] The MCA nevertheless granted the marketing authorisation on 9 January 2002.[356]

(170) An internal Lundbeck "generic citalopram update" of 28 June 2002 explained that on "26 June [2002] we [Lundbeck] submitted data re Natco impurities to MCA [the United Kingdom Medicines Control Agency …]. Our aim is to try to delay the MRP [mutual recognition process] and to question the UK license."[357]

(171) A Lundbeck Business Development document titled "Generic citalopram update 04 09 2002" summarised:

"Conclusion

We have delayed the issuing of the national licenses in all European countries from few to many months."[358]

6.5. Eliminating the competitive threat of upcoming citalopram API producers

(172) A document prepared for a Lundbeck Board meeting of 24 April 1998 stated:

"Contact with the potential producers of Citalopram is still sought for, for the possibility of stopping them in their attempts to reach the market through independent generic marketing firms. The strategy for these contacts is either to stop the further development of Citalopram with help from Lundbeck's production patents or to enter into partnerships with them, where under they become producers for Lundbeck."[359]

(173) A Lundbeck report to the Board of Directors of 8 February 1999 stated:

"Lundbeck has been contacted by a number of firms who say they have been offered a citalopram registration file but who would instead prefer to cooperate with Lundbeck. Lundbeck is working to localise the generic producers who offer generic citalopram.

VIS, a fairly small Italian chemical manufacturer, have already said that they supply generic citalopram. Lundbeck have therefore begun negotiations on various forms of cooperation with them with a view to preventing VIS from supplying generic citalopram on the world market."

After rumours that Merck Generics are synthesising citalopram, a meeting was held with their top management. At the meeting Merck Generics confirmed the fact, but were not able to confirm whether they were using a Lundbeck patented production method or whether they had developed a new method. A fresh meeting has been agreed."[360]

(174) The first company to which Lundbeck applied this policy of making deals with API producers to prevent them from supplying generic citalopram was the Italian

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355 ID 8, pages 357 to 360.

356 ID 682, page 120. For France, see ID 1021, page 61.

357 ID 848, page 40. Lundbeck undertook a similar approach to the Italian medicines evaluation body in September 2002. See ID 681, pages 119 to 123 and 141 to 143 and ID 356, pages 69 to 72. See recital (337) below.

358 ID 904, page 288.

359 ID 9, page 100.

360 ID 813, page 8. See also ID 9, page 316.

company Norpharma. In October 1998, Norpharma filed a patent application for its process for manufacturing citalopram which was different from Lundbeck's processes and two subsequent patent applications for improvements to that process in May and August 1999. One year later, in October 1999, Lundbeck purchased all three of these patent applications.[361] This purchase entailed that Norpharma's independent process for manufacturing citalopram, the first to become available, could not be used by generic companies to enter European markets with generic citalopram. Following the purchase, after having tested Norpharma's process, "Lundbeck concluded that Norpharma's process patents did not offer an improved alternative to Lundbeck's existing process, and Lundbeck chose not to use the processes covered by Norpharma's patents commercially."[362]

(175) The second API producer to which Lundbeck applied its "deal making" strategy was the small Italian company VIS Farmaceutici S.p.A. ("VIS").[363] Since the late 1990s, VIS had collaborated closely with Tiefenbacher to prepare generic citalopram for intended sale in Europe. Based on VIS' Drug Master File, Tiefenbacher submitted by the end of 1999 an application for a marketing authorisation for generic citalopram in the Netherlands. Tiefenbacher had expected to receive marketing authorisation for citalopram in the Netherlands by the end of 2000. Once this marketing authorisation had been recognised by other Member States[364], this would have put VIS and Tiefenbacher in a position to immediately start supplying citalopram to generic

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361 ID 8, pages 45 to 48.

362 ID 5394, page 98. As reported to the Commission by Norpharma: "The initial contact with Lundbeck A/S in 1999 was by Norpharma. Norpharma s.p.a. was starting-up as a fine chemical company (the company had been established in 1997) and was interested to discuss the possibility of supply agreements on the medium-long term: the active principle Citalopram was one of many products to which Norpharma s.p.a. was thinking, as it had acquired and was further developing certain technologies to produce Citalopram. Actually, Norpharma s.p.a. had manufactured research & development samples, but had not yet scaled-up the method. Some time during the first quarter 1999 Norpharma s.p.a. sent a facsimile to Lundbeck A/S, the originator, in which it set-out that it would be amenable to qualify as a supplier of Citalopram. Lundbeck A/S responded promptly, but showed more interest in Norpharma's technology than on a possible supply agreement" (see ID 995, pages 3-4). Lundbeck stated to the Commission: "A supply agreement with Norpharma would not have been a viable option as Norpharma did not have proper production plant standards or capacity and it would have taken Norpharma at least three years to obtain the necessary government approvals for such production. An acquisition of Norpharma's technology and know-how was therefore considered preferable" (see ID 5394, page 97). While Lundbeck in its reply to the Statement of Objections on the one hand argued that Norpharma's technology "could prove useful" (see ID 5394, page 96), the project group evaluating "whether parts of the process could be used concluded [at the time] that no single part of the Norphama process was applicable in the current Lundbeck process" (see ID 5427, page 9)

363 Despite the contemporaneous quote in recital (173) above that Lundbeck started negotiations with VIS "with a view to preventing VIS from supplying generic citalopram on the world market", Lundbeck has argued to the Commission in its reply to the Statement of Objections that "Lundbeck acquired VIS to obtain additional capacity." (see ID 5394, page 98). It is true that following the acquisition, Lundbeck invested in VIS' production capacity and used VIS as a supplier of intermediates to Lundbeck. A contemporaneous report of a Lundbeck visit to VIS' production site of 9 July 1999 stated: "VIS has Citalopram HBr on its 'menu', which obviously makes Lundbeck prick up its ears. Therefore, there have repeatedly been contacts between VIS and Lundbeck over the last couple of years. VIS tries to push Lundbeck into an agreement and we are trying to enter into the cheapest possible agreement. Our visit to VIS was therefore an attempt to find out how far ahead they are in the development of the process." The same report stated: "If one for a second disregards the purpose of the visit and the ongoing 'matter' between VIS and Lundbeck, VIS is an excellent contract manufacturer of intermediates/material for Lundbeck." (translation from Danish, see ID 5394, page 100; see also ID 673, pages 22-23 and 34).

364 See recital (85) above.

suppliers in those European countries where Lundbeck did not enjoy any patent protection (Greece, Italy, Luxemburg, and Portugal), in those European countries where only Lundbeck's original process was protected (Austria, Denmark, Finland, the Netherlands, Norway and Sweden) as well as in those European countries where Lundbeck's compound patent protection had already expired (Germany, Spain).[365]

(176) However, after Lundbeck had first in September 1999 concluded an agreement with VIS under which VIS agreed to supply citalopram to Lundbeck, containing restrictions on VIS' possibilities to supply third parties[366], Lundbeck actually purchased VIS in October 2000.[367] Immediately following the purchase, VIS/Lundbeck withdrew the VIS Drug Master File from Tiefenbacher's marketing authorisation application in the Netherlands, claiming impurities in the VIS product.[368] With the same argument, Lundbeck also cancelled all of VIS' supply contracts (including, but not only, to Tiefenbacher) and offers of supply VIS had made. Tiefenbacher then switched to the Indian companies Cipla and Matrix as alternative API suppliers and used these companies as alternative suppliers in its applications for marketing authorisation in the Netherlands. According to Tiefenbacher, the withdrawal of the VIS Master Drug File by Lundbeck caused a delay in the granting of the Dutch marketing authorisation of at least nine months, the marketing authorisation being finally granted in September 2001.[369]

(177) Another company which had wanted to market VIS' citalopram was Merck (GUK). Based on the VIS Drug Master File it had expected to receive a marketing authorisation in the United Kingdom in February 2001 and in other European countries, using the mutual recognition procedure, by December 2001.[370] Lundbeck's withdrawal of VIS' Drug Master File forced Merck (GUK) to search for another supplier, which it found in the Indian producer Natco. According to GUK, Lundbeck's withdrawal of VIS' Drug Master File caused a delay of around nine months to Merck (GUK)'s preparation of entry.[371] An internal Merck (GUK) e-mail of 3 January 2001 stated: "The dossiers were originally submitted to the MCA (the UK Medicines Control Agency) on 15/8/2000 (our resubmission with Natco batches was 14/6/01).[372]

(178) CF Pharma, a small Hungarian API producer that was also preparing to produce generic citalopram, became the third target of Lundbeck's API deal-making strategy. […]*.[373] […]*[374], […]*.[375] […]*[376] In October 2002, Lundbeck' increased its

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365 See recitals (109) to (111) above.

366 ID 10, pages 186 to 204.

367 ID 8, page 532. Taking into account the fair value of VIS' assets and liabilities, Lundbeck estimated that it had paid DKK 199 million (around EUR 26 million) for VIS' "goodwill", see Lundbeck's Annual Report for the year 2001, ID 1498, p. 60 and its annual report for the year 2000, ID 1503, page 60.

368 ID 295, page 1.

369 ID 280, page 6. Tiefenbacher explained to the Commission that the forced switch to Matrix and Cipla as API suppliers meant that new real time stability data had to be submitted to the Dutch authorities, which took at least 6 months. Tiefenbacher also claimed that it was approached by Lundbeck with an offer of money in case Tiefenbacher stopped its regulatory activities, in particular with respect to the United Kingdom. See footnote 353 and ID 280, page 7.

370 ID 673, page 23.

371 ID 673, page 85; see also recital (221) below and footnote 446.

372 ID 675, page 17.

373 […]* See ID 5, pages 12-13.

374 ID 5, pages 14-15.

investment and shareholding in CF Pharma. […]*, CF Pharma became a supplier to Lundbeck of intermediates.[377] The result of these actions was that CF Pharma was prevented from selling generic citalopram to the EEA markets.

(179) It is important to realise the timing of Lundbeck's actions in respect of Norpharma, VIS and CF Pharma. It was only in March 2000 that Lundbeck filed a priority application for the crystallisation process of purification. API suppliers that had already been using crystallisation in combination with one of the original Lundbeck manufacturing processes could, based on prior use, claim that they did not infringe either the crystallisation patent or the original compound process once this latter patent had expired.[378] An e-mail of Arrow's [employee function]* dated 5 August 2003 summarised the European citalopram situation over the last couple of years as follows: "Towards expiry of the basic compound patent in Europe there was essentially only [one] source of raw material, VIS. The route that they employed was essentially that shown in the basic patent and this formed the basis for the generic registrations around Europe. In an attempt to restrict generic entry Lundbeck bought VIS and refused to supply material to generic companies. Lundbeck also started to file numerous patent applications aimed at blocking the "old" route of synthesis from being used. Of these by far the most troublesome was WO 01/68627 which covered a method of purifying citalopram base by recrystallization before conversion to the marketed hydrobromide salt."[379]

(180) Lundbeck was also closely monitoring API producers in India, which were now also gearing up to produce citalopram. As mentioned in recital (148) above, in January 2001 Lundbeck wrote to a number of API producers in India warning them of potential patent infringement. With respect to those Indian companies that were not deterred by these threats, that continued to search for non-infringing ways of producing citalopram and that were preparing to sell generic citalopram to EEA markets, Lundbeck pursued its deal-making strategy. For this dual purpose of deterrence and, if unsuccessful, deal-making, a visit to several Indian producers took place later that year.

(181) A first Indian API producer that Lundbeck tried to eliminate in this manner as a competitive threat was the company Natco. This company had developed an allegedly non-infringing method to produce generic citalopram. Lundbeck visited the company in February 2001. According to Natco, Lundbeck was "interested in initiating a commercial relationship with Natco". However, Natco rejected this proposal.[380] Lundbeck subsequently entered into negotiations with Merck (GUK), which on behalf of the Merck Generics Group had a 'preferred' right to purchase Natco citalopram API for distribution in Europe.[381] Through two agreements with Merck (GUK), one for the United Kingdom covering the period between 24 January 2002 and 1 November 2003 and one for the rest of the EEA, covering the period

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375 ID 5, pages 34 to 37.

376 ID 3167, page 1 and ID 178, pages 102 to 104.

377 ID 5394, page 103.

378 In its reply to the Commission's Letter of Facts, Lundbeck stated: "In theory, it may be true that generics that had already been using free base crystallization before could have claimed prior user rights. The reality is, however, that none of them did." See ID 6814, page 46.

379 ID 649, page 2.

380 ID 579, page 2. For further details on this meeting, see recitals (230) to (233) below.

381 See recitals (234) and (330) - (331) below.

between 22 October 2002 and 22 October 2003, Lundbeck indirectly also aimed at preventing Natco from selling citalopram API to the EEA in that period. As these events are assessed in legal terms in this Decision, they are described in detail in section 7.2 below.

(182) In June 2002, Lundbeck made an agreement with a second Indian API producer, Ranbaxy, which was at the same time also a major supplier of generic medicines in its own right in Europe. This agreement entailed that Ranbaxy would not sell citalopram API or citalopram medicines to the EEA. The agreement covered the period between 16 June 2002 and 31 December 2003. As these events are assessed in legal terms in this Decision, they are described in detail in section 7.7 further below.

(183) Finally, in February 2003, Lundbeck was reported in the press to have made an offer to the Indian API producer Matrix to acquire Matrix's process rights for the manufacture of citalopram. According to Tiefenbacher, this offer was made in October 2002.[382] Contemporaneous Lundbeck documents confirm that a meeting with Matrix took place in October 2002.[383] At the time, in a communication to the Bombay Stock Exchange, Matrix stated:

"We would like to confirm that Lundbeck did approach us with a proposal to acquire process rights related to the process developed by us and also to stop production of citalopram. We rejected the offer in the larger interests of the company and to honour the supply commitments made to generic pharma companies in Europe, and thereby continue to service their requirements."[384]

Matrix also told the press that the offer had amounted to "300 million Danish Crowns [… ~EUR 40 million]"[385]

6.6. Persuading generic suppliers to stop their efforts to enter the citalopram market

(184) As described in section 6.5 above, Lundbeck had been quite successful in eliminating the competitive threat from the earliest producers of generic citalopram API, that is to say Norpharma, VIS and CF Pharma, in 1999 and 2000. Lundbeck's efforts in 2001 to persuade Indian API producers not to produce generic citalopram (or at least not to sell it to EEA markets) were, however, markedly less successful, as both Natco and Matrix refused. The Indian companies Cipla and Sekhsaria also continued their preparations to produce generic citalopram. Therefore, following expiry of Lundbeck's compound patent in January 2002 in most remaining EEA Contracting Parties, persuading generic suppliers to refrain from entering citalopram markets in the EEA became Lundbeck's last line of defence against imminent generic entry of citalopram.

(185) Lundbeck tried to achieve this, firstly, by threatening or actually starting infringement litigation (using the process patents it had obtained since 1997 and in particular the crystallisation patent).[386] In total, in response to a request for information of the Commission, Lundbeck listed 85 legal procedures concerning citalopram in 9 different EEA Contracting Parties (Belgium, Denmark, Finland,

382 ID 291, page 4.
383 ID 2673, pages 30-31.
384 ID 290, page 1. See also ID 291, pages 24 to 26 and ID 904, page 69.
385 ID 291, page 29. See also ID 291, pages 15 to 28.
386 See recitals (144) to (152) above.

Germany, Netherlands, Norway, Spain, Sweden, United Kingdom) in which Lundbeck was involved in the period between January 2002 (United Kingdom) and June 2006 (Denmark). Most of these were infringement cases initiated by Lundbeck, launched against generic citalopram originating from Cipla or Matrix.[387] In several of these countries, Lundbeck did manage, at least in an initial stage, to obtain interim injunctions and seizures, in particular against citalopram produced by Cipla. In a number of these cases, after the generic companies in question had switched to citalopram produced with the Matrix II process[388], the injunctions and seizures were subsequently lifted in appeal (and further injunctions and seizures against other suppliers denied) or the case was settled.[389] In Germany, all claims of infringement by Cipla and Matrix citalopram were rejected by the courts from the beginning.[390] In the United Kingdom, all legal proceedings were settled by Lundbeck before a final ruling could be issued, with the exception of Niche's request for a declaration of non-infringement, which was granted.[391] In no Contracting Party to the EEA Agreement was a final ruling that the crystallisation patent was valid and infringed ever made by a court.[392]

(186) In a number of other cases, which are the subject of this Decision, where generic suppliers appeared undeterred by Lundbeck's process patents, Lundbeck offered - and the generic supplier concerned accepted - a transfer of value to the generic

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387 ID 234, pages 2 to 18. See also ID 2774. Lundbeck was also involved in an invalidation/infringement proceeding in Italy in 2005 regarding certain formulations of citalopram which Lundbeck had patented in Italy only.

388 See recital (154) above.

389 ID 234, pages 2 to 18. Examples are:
- an interim injunction of 17 June 2003 against Copyfarm in Denmark was lifted after appeal on 26 January 2004 (ID 234, page 5);
- an interim injunction of 21 March 2003 against United Nordic Pharma in Denmark was lifted after appeal on 26 January 2004 (ID 234, page 6);
- a request for an interim injunction against Ratiopharm in Denmark was denied on 25 April 2003; the denial was confirmed in appeal on 26 January 2004 (ID 234, page 7);
- an interim injunction of 5 July 2002 against Novartis in Finland was declared null and void on 23 December 2002 (ID 234, page 9).
- a request for an interim injunction against Ratiopharm in Finland was denied on 27 December 2002 (ID 234, page 10);
- a seizure granted against Hexal and Multipharma in the Netherlands in a summary procedure initiated on 6 December 2002 was subsequently lifted in the same procedure (ID 234, page 11);
- an interim injunction of 12 March 2003 against Desitin Pharma in Sweden was revoked in appeal on 4 June 2003 (ID 234, page 16).
See also ID 234, pages 119-122 and ID 5394, pages 67-68. See also recital (442) below.

390 ID 234, page 8. With respect to the patent situation for citalopram in Germany, an internal Alpharma document of 12 February 2002 stated: "According to our latest information, the patent situation of Citalopram in Germany seems to be rather different from Holland and UK and Danmark. Obviously there is no patent issued and there will be no patent issued in Germany. Instead of that, Lundbeck got a so called "Gebrauchsmusterschutz" ("legal protection of utility models"). The infringement of the "legal protection of utility models" can not be taken as a basis for a Preliminary Injunction." See ID 4817, pages 38-39. Lundbeck also explained to the Commission that in Germany courts will not grant interim injunctions unless the validity of the legal right in question is beyond any doubt. As utility models are unexamined rights, this is unlikely to be the case. See ID 5394, pages 56 and 180 and ID 5410, page 11. Tiefenbacher reported to the Commission that Lundbeck's utility model 200 07 303 was revoked by the German Patent Office on 5 November 2003. See ID 291, pages 5 and 31 to 35.

391 ID 234, page 18. See also recital (163) above.

392 ID 1713, page 2.

supplier as part of an agreement in which the generic supplier gave up, at least for a certain period of time, its efforts to enter the citalopram market.

(187) As already mentioned, Lundbeck itself summarised this policy of deal-making most strikingly in the following words:

"It is like a poker game

- We have been dealt a mediocre hand ± two aces, a couple of queens and some small uneven cards
- But we have a large pile of $$$ at our side
- We call it ±"the art of playing a loosing hand ***slowly***."[393]

(188) Lundbeck realised - or should have realised - that this policy carried risks under Union competition rules. An internal Lundbeck e-mail reporting on discussions with Ranbaxy regarding a possible deal covering the EEA asks:

"Do we want a deal? I guess a deal will be $10M-$20M or even more. My opinion is that it will be difficult ± D Q W L W U X V W Z L V H F R V W V D Q G Y D O X H I[394]

(189) Some months after Ranbaxy and Lundbeck had concluded an agreement in which Ranbaxy agreed in exchange for a considerable sum of money not to sell citalopram in the EEA during the term of the agreement, Ranbaxy confirmed to Lundbeck that it had not sold any citalopram in the EEA after the agreement had been concluded. The Lundbeck email which distributed this news to key players within the undertaking Lundbeck warned: "Strictly confidential ± please do not forward this e-mail!"[395]

(190) In a Lundbeck Business Development document with the title "Generic citalopram update 04 09 2002", one can read the following:

"Sweden ± NM Pharma

- NM Pharma does not want to talk to us
- (P D L O I U R P « 3 K D U P D F L D R Z Q H U V R I 1 0 3 K D U P D

"Thanks for inviting us to a meeting but no thanks, we have nothing to discuss. Under our Global Standards of Business Conduct and our Antitrust Policy, we cannot engage in further discussion on this topic.""[396]

(191) Also, a Lundbeck Business Development document with the title "Generic citalopram update 22 11 2002" stated:

"Deal making

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393 See recital (131) above. In its reply to the Statement of Objections, Lundbeck explained that "The "mediocre hand" refers to Lundbeck's process patents, which, despite their validity and inherent value, are difficult to enforce, and would ultimately be worked around by generic competitors". See ID 5394, page 81.

394 ID 681, page 88.

395 ID 681, page 151. In reply to the Statement of Objections (ID 5394, page 107), Lundbeck claimed that this e-mail did not intend to conceal a potential antitrust infringement, but rather to protect sensitive business information.

396 ID 904, page 303. One month later, in October 2002, Lundbeck made an agreement with NM Pharma's supplier of generic citalopram Merck (GUK) that Merck (GUK) would stop supplying NM Pharma. See section 7.3 below.

- We have made a number of deals; although it is tricky
  - They fantasize of the value of the generics
  - It is illegal to block competition
  - Worthless taking out one of two or three players
- However some of our deals have been very valuable."[397]

(192) This Decision concerns six agreements which Lundbeck concluded and operated in the period from January 2002 to December 2003 with the following four undertakings:

- **Merck** (first for the United Kingdom, covering the period between 24 January 2002 and 1 November 2003, followed by a second agreement for the rest of the EEA, covering the period between 22 October 2002 and 22 October 2003)[398];
- **Arrow** (first for the United Kingdom, covering the period between 24 January 2002 and 20 October 2003, followed by a second agreement for Denmark, covering the period between 3 June 2002 and 1 April 2003);
- **Alpharma** (for the EEA, covering the period between 22 February 2002 and 30 June 2003);
- **Ranbaxy** (for the EEA, covering the period between 16 June 2002 and 31 December 2003).

(193) In total, for all of these agreements together, Lundbeck transferred a value of around **EUR 66.8 million**, consisting of the following transfers to individual generic undertakings:

- **Merck**: +/- **EUR 31.4 million** (EUR 19.4 million for the United Kingdom agreement and EUR 12 million for the agreement regarding the EEA excluding the United Kingdom)[399];
- **Arrow**: +/- **EUR 11 million** (EUR 10.4 million for the agreement regarding the United Kingdom and EUR 684.000 for the agreement regarding Denmark)[400];
- **Alpharma**: +/- **EUR 11.7 million** for the agreement regarding the EEA[401];
- **Ranbaxy**: +/- **EUR 12.7 million** for the agreement regarding the EEA[402].

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397 ID 847, page 57. Likewise, a Lundbeck strategy document probably dated early 2003 stated:
"Settling is a tricky business
- It is illegal to block competition
- Generics fantasize about the value of their products."

ID 844, page 27.
In reply to the Statement of Objections (ID 5394, page 107), Lundbeck pointed out that the document also lists lawyers specialised in antitrust legislation as parties involved in the settling arrangements.

398 The agreement with Merck (GUK) for the rest of the EEA indirectly also aimed at stopping exports of the Indian API producer Natco. See recital (181) above.

399 See recitals (307) and (370) below.

400 See recitals (447) and (472) below.

401 See recital (547) below.

402 See recital (587) below.

(194) Although these agreements were concluded against the background of patent disputes, none of the agreements finally resolved a patent dispute; the agreements rather postponed generic entry for a certain period of time, leaving open what would happen afterwards. As Lundbeck wrote to the Commission: "Lundbeck's settlements did not remove uncertainty over whether a generic's challenge would eventually succeed, because they did not finally resolve the dispute" "Lundbeck's D J U H H P H Q W V m a t e l y G e c i d e w h e t h e r a n y g e n e r i c company could enter the market."[403]

(195) From these agreements, four of which concern the United Kingdom market, it is clear that Lundbeck focused its efforts to delay generic entry through agreements to a large extent on the United Kingdom market. As Lundbeck stated in its reply to the Statement of Objections, "The UK was both the most important EEA market at the time of the Agreements, and the focus of the dispute between Lundbeck and each of Alpharma, Arrow, GUK and Ranbaxy."[404] Moreover, with its specialised and critical patent court, the United Kingdom is an important Member State for testing patent infringement and invalidation cases. Generic companies tend to select the United Kingdom as one of the first countries in which they try to enter the market with a new generic product. A United Kingdom judgment finding that the manufacturing processes of an API producer did not infringe Lundbeck's process patents or, worse from Lundbeck's perspective, that Lundbeck's crystallisation patent was invalid, would have set a very negative example for Lundbeck which courts in other EEA Member States might well have taken into account in their own judgments. Lundbeck apparently believed that it would be difficult to obtain an interim injunction in the United Kingdom and that United Kingdom courts were "not in general pro-patentee"[405]

(196) The United Kingdom market was also one of the markets most sensitive to generic penetration. On 11 December 2001, Lundbeck wrote in its "Goal, Activity and Budget Plan 2002" with respect to the United Kingdom market:

"The UK is the market that Lundbeck expects to be hit most severely by generic competition. Immediately following patent expiry in January 2002, generic sales are expected to take 60% of the citalopram business.

Cipralex (escitalopram) is planned to be launched in April 2002. The aim will be to convert the remaining part of the citalopram franchise to escitalopram as fast as possible, with strong focus on the first three months after launch. This implies a cannibalisation of the citalopram business, the effect of which is a reduction of citalopram sales of 65% in total on [Expected] 2001."[406]

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403 ID 1683, pages 3 and 2.

404 ID 5394, page 56. See also ID 681, pages 18-19 and ID 904, page 94.

405 ID 5481, page 3. In its reply to the Commission's Letter of Facts of 12 April 2013, Lundbeck stated: « W K H 8 . F R X U W V K D Y H g e n e r a l l y i m p o s e d i n j u n c t i o n s o n t h e p h a r m a c e u t i c a l s e c t o r f o r d e c a d e s, D Q G « R Q O \ D + L J K & R X U W M X G J P H Q W R I 2 F W R E H U K D G Paroxetine matter. This High Court judgment was confirmed by the Court of Appeal only in 2003." See ID 6814, page 46. With respect to Denmark, for which Lundbeck concluded an agreement with Arrow, Lundbeck believed that "Interim injunctions are granted within about 6 months" (ID 5481, page 3) and that it might therefore not be able to prevent Arrow's market entry through an application for an interim injunction. See ID 5394, page 212.

406 ID 163, page 409.

(197) A management report of the same date of 11 December 2001 stated:

"[Lundbeck's] generic strategy in the United Kingdom is complex, but is very important because of the significant impact that generic products have been shown to have on sales of branded products (sales of Prozac [branded fluoxetine] fell by 70% within a few months)."[407]

(198) On 7 January 2002, just two days after Lundbeck lost exclusivity for citalopram in the United Kingdom, an internal Lundbeck document shows that despite still holding or having applied for certain process patents, including in particular the crystallisation patent, Lundbeck expected for the year 2002 in the United Kingdom a reduction in sales "at the hands of generics" of GBP [25-50]* million (EUR [40-80]* million[408]) for citalopram and escitalopram together, from GBP [50-100]* million (EUR [80-160]*million) of expected sales without generic entry) to GBP [25-50]* million (EUR [40-80]* million).[409] In other words, at this time Lundbeck expected to lose 56 percent of its sales of citalopram and escitalopram together in the case of widespread generic entry in the United Kingdom in 2002 alone. That Lundbeck fully expected this scenario to happen is confirmed by the fact that it is reflected in Lundbeck's official budget for the United Kingdom for the year 2002, which shows expected sales of EUR [25-50]* million for citalopram and EUR [0-30]* million for escitalopram (together EUR [25-80]* million).[410] In reality, after having concluded agreements with Merck (GUK), Arrow, Alpharma and Ranbaxy to keep generic citalopram out of the United Kingdom market, Lundbeck achieved sales of citalopram in the United Kingdom in 2002 of EUR [40-150]* million and of escitalopram of EUR [0-20]* million[411], EUR [0-90]* million more than it had expected to sell if widespread generic entry had taken place.[412]

(199) Those agreements operated in the United Kingdom not only in 2002 but also in the first 10 months of 2003. In the first 10 months of 2003, Lundbeck sold EUR [50-100]* million worth of citalopram and escitalopram in the United Kingdom[413], EUR [0-30]* million more than it had budgeted for the same period expecting widespread generic entry as of December 2002.[414] For the year 2002 and the first 10 months of 2003 together, therefore, the four agreements concluded by Lundbeck covering the United Kingdom at a total cost of EUR 54.2 million generated additional budgeted Lundbeck sales of citalopram and escitalopram in the United Kingdom in the period concerned of EUR [40-110]* million (EUR [40-80]* million plus EUR [0-30]*

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407 ID 815, page 85.

408 Using a GBP/EUR exchange rate of 0.61659 in January 2002, source European Central Bank.

409 ID 853.

410 ID 2061.

411 ID 983, page 18.

412 Taking citalopram and escitalopram together, Lundbeck actually sold in the United Kingdom in 2002 EUR [40-170]* million (of which EUR [0-20]* million for escitalopram), compared to expected sales of EUR [40-80]* million in the case of widespread generic entry, a difference EUR [0-90]* million.

413 ID 984.

414 ID 2061. See also recital (206) below. There are no contemporaneous documents in the file showing Lundbeck's budgeted sales in 2003 in the United Kingdom in the absence of widespread generic entry, so the Commission could for the first ten months of 2003 only compare budgeted sales (which assumed widespread generic entry) with actually achieved sales. Those actually achieved sales may, however, have been higher or lower than would have been budgeted by Lundbeck for the United Kingdom market absent widespread generic entry.

million). Additional actual sales were EUR [0-120]* million higher (EUR [0-90]* million plus EUR [0-30]* million).[415]

(200) In any case, once Lundbeck had paid Merck and Arrow to keep them out of the United Kingdom market, these costs would have been sunk and would therefore not have prevented Lundbeck from making additional payments in the subsequent agreements with Alpharma and Ranbaxy to keep them out of the United Kingdom market as well.

(201) Moreover, two of the four agreements in question, those with Alpharma and Ranbaxy, also covered all other EEA Contracting Parties.

(202) Finally, as appears clearly from Lundbeck's strategy documents[416], what was at least as important for Lundbeck as a short term cost/benefit calculation, was the fact that Lundbeck managed successfully to introduce its successor product escitalopram in the United Kingdom in June 2002, six months after generic entry had become possible, four months before the first small-scale generic entry by Lagap actually occurred and 16 months before widespread generic entry in the United Kingdom occurred. Lundbeck itself called this a "top result".[417]

(203) A Lundbeck Business Development document titled "Generic citalopram update 21 05 2002" stated with respect to the United Kingdom:

"UK Strategy

6 Jan	Product patent expired
24 Jan	Merck Generic UK deal for 12 months
24 Jan	Arrow Generics deal till 1 Jan 2003
8 Feb	Injunction against Arrow Generics [voluntary, as stipulated in the agreement]
22 Feb	Alpharma deal till 1 July 2003
15 Mar	Warning letters to Lagab (Novartis) & Ratiopharm
Mar	Injunction against Alpharma [voluntary, as stipulated in the agreement]
May	Cipralex [escitalopram] launch
May?	MAs [market authorisations] for Lagab (Novartis) and Ratiopharm
	Lu [Lundbeck] requests injunction or settles
??	MAs for Norton (Ivax), Sterwin (Sanofi) & Neolab

Oct?? The patent infringement case against Arrows to be heard in court."[418]

(204) After Lundbeck had launched Cipralex (escitalopram) in the United Kingdom on 10 June 2002, a Lundbeck Business Development document with the title "Generic citalopram update 28 06 2002" stated in its conclusions:

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415 In the year 2002, Lundbeck gross profit (net sales minus cost of goods sold) for all products in the United Kingdom was [80-100]*% of net sales and its net profit (earnings) [40-60]*% of net sales. See ID 983.

416 See sections 6.1 and 6.2 above.

417 See recital (204) below.

418 ID 847, page 4.

"Launching Cipralex before generic competition in the UK is a top result."[419]

(205) A Lundbeck Business Development document titled "Generic citalopram update 04 09 2002" stated with respect to the United Kingdom:

"The UK switch window is open and going into the 4th month!"[420]

(206) On December 2, 2002, Lundbeck wrote in its Goal, Activity and Budget Plan for 2003 regarding the United Kingdom market:

"The expected entry of generic citalopram in Q1 2002 was very effectively postponed until October 2002, when the first generic citalopram was made available. Generic sales have been limited so far, but are expected to increase dramatically in December 2002 and to take some 60% of the Cipramil [citalopram] business in 2003 due to substitution by pharmacies. It remains obvious that the absence of generics for 10 months longer than expected in 2002 will continue to have a positive effect on the sales development of Cipralex [escitalopram] in 2003."[421]

(207) On 13 October 2003, one and three quarters of a year after generic entry had become possible in principle in the United Kingdom and following its earlier agreements covering the United Kingdom with Merck, Arrow, Alpharma and Ranbaxy, Lundbeck also settled its only on-going infringement litigation in the United Kingdom with the generic company Lagap.[422] The settlement entailed that Lagap dropped all challenges against Lundbeck's crystallisation patent (including before the EPO) in exchange for an irrevocable, non-exclusive royalty-free licence to Lundbeck's crystallisation patent covering the entire EEA.[423]

(208) This settlement with Lagap basically put an end to Lundbeck's efforts to prevent generic citalopram from being distributed in the United Kingdom.[424] The agreement with Alpharma (EEA-wide, including the United Kingdom) had already ended by 30 June 2003. The agreements with Merck and Arrow for the United Kingdom were terminated on 1 November 2003 and 20 October 2003 respectively following Lundbeck's settlement with Lagap. The agreement with Ranbaxy (EEA-wide, including the United Kingdom) ended on 31 December 2003. Lundbeck's last legal action in the United Kingdom took place in January 2004, as it settled its infringement litigation with the generic supplier Neolab. This settlement included damages to Neolab for the period December 2002 to October 2003 in which Neolab had not sold on the United Kingdom market because of the infringement proceedings Lundbeck had initiated against it. [425]

(209) Following Lundbeck's settlement with Lagap in October 2003 and the termination of Lundbeck's agreements with Merck and Arrow by the end of that same month, prices

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419 ID 848, page 47.

420 ID 904, page 259.

421 ID 163, page 253.

422 See recitals (113) to (159) above.

423 ID 237, pages 1205 to 1221. As part of the settlement, Lundbeck also explicitly withdrew its allegations of forgery and perjury against Matrix, see ID 237, page 1211.

424 Lundbeck claimed in its reply to the Statement of Objections that "Thus, to clarify, Lundbeck was and is still confident that the processes that were at issue in the Lagap litigation were infringing", see ID 5394, page 74.

425 ID 234, page 18, ID 891, page 258. See also recital (164) above.

of generic citalopram finally took on a strong downward trend.[426] By December 2003, intense generic competition had brought the average price level of generic citalopram to 69% of the average price level of generic citalopram in September 2003, amounting to an average drop of 10 percentage points per month.[427] As Lundbeck explained in a report to the Board of Management of November 2003: "in November [2003] both Neolab and Niche Generics began giving considerable discounts on generic citalopram and the generic erosion is occurring very fast."[428]

(210) In January 2004, a Lundbeck management report signalled that "the impact of generic competition in the UK has been significant. Sales are presently at the level of around 10% of the original Cipramil franchise"[429] The same document reported that "this is equivalent to previous expectations and to the impact experienced by other compounds, e.g. fluoxetine."[430]

(211) By April 2004, the average price level of generic citalopram in the United Kingdom had dropped to roughly 31% of the September 2003 level, losing on average 9 percentage points every month between September 2003 and April 2004. By November 2004, prices of generic citalopram had dropped to a low of 10%[431] of the September 2003 price level, still dropping on average 3 percentage points per month between April 2004 and November 2004. After November 2004, generic prices remained stable until well into 2005.[432]

(212) The graph below shows the evolution of the prices of Cipramil and generic citalopram.

Graph: Evolution of the weighted average generic citalopram prices per DDD in the United Kingdom, in GBP, 2002-2005.

Note: The numbers next to the generic citalopram figures represent the monthly percentage change in the weighted average generic citalopram price (base = September 2003).

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426 Contemporaneous sales data show that in the periods when Lagap was alone on the market, Lagap's market price was stable and comparable to the prices of Lundbeck's suppliers. In periods when one or more other generic companies were present on the market – October 2002 to December 2002 for Neolab, from April 2003 for Sanofi, August 2003 for Merck (GUK) and from September 2003 for Niche and Ratiopharm -, the price of generic citalopram began a downward trend. When these companies stopped selling, the generic citalopram price would increase again to previous levels (Neolab's last stocks on the market apparently ran out in March 2003 (ID 394 page 27), while Sanofi sold little or no citalopram in June, August and September 2003 (ID 2457)). See ID 1937 for Lundbeck, ID 1691 for GUK, ID 1721 for Ranbaxy, IDs 1239 and 2614 for Lagap, ID 2629 for Neolab, ID 2457 for Sanofi, ID 678 for GUK, ID 2416 for Niche and ID 2497 for Ratiopharm.

427 The average price level of generic citalopram has been calculated as the weighted average of the prices of generic citalopram and Lundbeck's unbranded citalopram in the United Kingdom. See ID 1937, ID 1721, ID 1691, ID 2416, ID 1188, ID 1352, ID 1239, ID 2457, ID 2497, ID 2532, ID 2499, ID 2629, ID 2614, ID 2616.

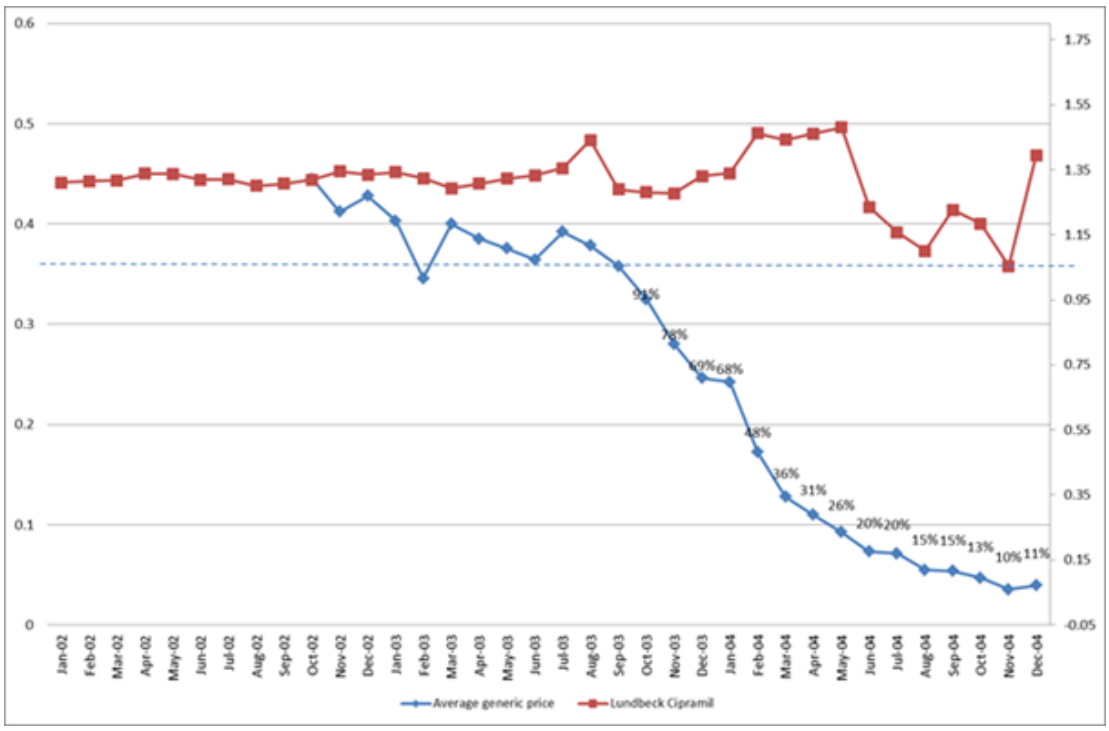
428 ID 891, page 258.

429 ID 892, page 2. The document does not specify whether sales or volumes are meant or what "the original Cipramil franchise" entails.

430 ID 892, page 12.

431 The prices of GUK, Ranbaxy and Lagap dropped to 6% of Lundbeck's September 2003 price, while the price of Arrow dropped to 10% of the same. See IDs 1691, 1721, 1352, 1239, 1937.

432 As shown by ID 1937, ID 1721, ID 1691, ID 2416, ID 1188, ID 1352, ID 1239, ID 2457, ID 2497, ID 2532, ID 2499, ID 2629, ID 2614, ID 2616.



Sources: ID 1937, ID 1721, ID 1691, ID 2416, ID 1188, ID 1352, ID 1239, ID2457, ID 2497, ID 2532, ID 2499, ID 2629, ID 2614, ID 2616, ID 2971[433]

(213) As of April 2004, Lundbeck began changing its citalopram strategy in the United Kingdom, by implementing two strategic commercial decisions for the United Kingdom market: Firstly, it started selling, on average, 60%[434] of its citalopram volumes as unbranded citalopram at very low prices to several generic suppliers in the United Kingdom.[435] Secondly, it started selling over 79%[436] of the Lundbeck-branded citalopram (Cipramil) to a single supplier at a considerably lower price than before.[437] These measures, taken in response to the generic competition, helped to

433 For Sanofi (ID 2457), the prices of June 2003 were replaced with an average of the respective previous and next values. Merck (GUK)'s (ID 1691) price of March 2004 was estimated as an average of the previous and next values. For Neolab (ID 2532), November 2003 sales used for the calculation of the average price comprise sales made until 23 November 2003. Also for Neolab, December 2003 contains estimated sales for the rest of November 2003, and estimated December 2003 sales contain estimated sales for the rest of November 2003 plus estimated December 2003 sales. Lundbeck's (ID 1937) sales of unbranded citalopram to Teva, Colorama, IVAX and Pliva, starting in April 2004, are included in the price calculation for generic citalopram. Lundbeck's calculation does not include sales […]*, and neither sales and prices for the oral formulation, nor sales labelled 'parallel trade'. For Ranbaxy (ID 1721) prices, the monthly European Central Bank GBP/EUR exchange rate was applied for conversion into EUR. Also for Ranbaxy, sales of Niche and Ethigen citalopram made between January and April 2004 (ID 2971) were not taken into account, in order to avoid double counting. For Ratiopharm (ID 2497), no data was available after October 2004.

434 Monthly average until the end of 2004, see ID 1937.

435 In April 2004, Lundbeck started selling its citalopram to Colorama, Pliva and Ivax, and in May 2004 to Teva at prices below GBP [0-10]* per pack of 28 tablets of 28mg (ID 1937). The percentage of these sales in Lundbeck's total sales from May 2004 to December 2004 ranges between […]*% and […]*%, by volume, as shown in ID 1937.

436 Monthly average until the end of 2004, see ID 1937.

437 As of June 2004, Lundbeck started selling [50-80]*% to [70-100]*% of the Lundbeck-branded citalopram in the United Kingdom to the company […]* at a price of GBP [0-15]* per pack of 28

stabilize Lundbeck's declining market share in citalopram, but they meant that Lundbeck's profit margin on citalopram sales decreased considerably.

(214) With respect to the other EEA Contracting Parties, the end of the EEA-wide agreement with Alpharma on 30 June 2003, the EEA-wide Lagap settlement in October 2003, the termination of the EEA-wide agreements with Arrow and Merck in October 2003 and the end of the EEA-wide agreement with Ranbaxy on 31 December 2003 allowed these companies to start selling generic citalopram across the EEA. The table below shows Lundbeck's market shares in EEA countries in the years 2002 and 2003. This table shows that through the agreements with the undertakings subject to this Decision, covering the entire EEA for three of the four generic undertakings, Lundbeck protected significant market positions throughout the EEA.

(215) Lundbeck market shares of anti-depressants in the EEA

Member State	2002	2003
AUSTRIA	[25-35]*	[30-40]*
BELGIUM	[20-30]*	[20-30]*
DENMARK	[20-30]*	[20-30]*
FINLAND	[35-45]*	[25-35]*
FRANCE	[10-20]*	[10-20]*
GERMANY	[0-10]*	[0-10]*
GREECE	[15-25]*	[15-25]*
IRELAND	[15-25]*	[20-30]*
ITALY	[15-25]*	[20-30]*
LUXEMBOURG	[15-25]*	[15-25]*
NETHERLANDS	[0-10]*	[0-10]*
NORWAY	[25-35]*	[20-30]*
PORTUGAL	[0-10]*	[0-10]*
SPAIN	[10-20]*	[10-20]*
SWEDEN	[20-30]*	[5-15]*
UNITED KINGDOM	[10-20]*	[10-20]*

Source: ID2596, ID678, ID1721. In ID2596, neither the hospital channel sales were taken into account nor the citalopram parallel sales. In ID678, Merck's aggregated citalopram sales in the United Kingdom for 2002 and January – October 2003 were provided in GBP, and were converted into EUR using average annual exchange rates

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tablets of 20 mg as opposed to Lundbeck's price of GBP [0-20]*. Compare footnote 556. The NHS reimbursement price of GBP 16.03 was reduced only in January 2005 (ID 1201 page 2).

for 2002 of 1 EUR = 0.62883 GBP and for 2003 of 1 EUR = 0.69199 GBP. Source European Central Bank

Note 1: Lundbeck's market shares have been calculated based on Lundbeck's sales of citalopram and escitalopram in the periods concerned, compared with total sales of all anti-depressants within the ATC3 level group N6A. Sales by Lundbeck of other anti-depressants within this group have not been included in Lundbeck's market share calculation.

Note 2: Lundbeck's sales in the United Kingdom include sales to Merck (GUK) and to Ranbaxy. To avoid double-counting, the sales of Merck (GUK) and Ranbaxy in the United Kingdom market have not been included. Sales by Merck (GUK) and Ranbaxy in the EEA of other anti-depressants within N6A have not been included.

(216) With respect to those generic companies with which Lundbeck had not settled earlier, in particular in other European countries than the United Kingdom, on 5 January 2004, an executive of Lundbeck circulated the following e-mail within the top of the organisation:

"We believe that citalopram has entered its last phase and that it is a matter of time before we in all EU countries will be faced with generic products likely to be non-infringing. We are therefore convinced that we are at a crossroad and we propose that we try to close all ongoing cases re Cipla and Matrix and the infringement of the crystallisation patent in EU.

…

We propose the following settlement terms

– a non-exclusive royalty free licence to the crystal patent

– down payment of 1 million Euro for all European markets. Alternatively down payments of 200K Euro per market for France, Italy and Spain and 100K Euro for each remaining European market

– both parties refrain from claiming costs and damages re products based on Matrix

– Lundbeck will claim damage of period where products were based on Cipla."[438]

(217) As a result, Lundbeck settled in the first half of 2004 with Ratiopharm for the Union and Norway, Desitin for Norway, Sweden and Germany, Eurogenerics for Belgium, Merck Generics for Belgium, Tiefenbacher for the Netherlands, Neurax for the Netherlands and Ratiopharm for Belgium, allowing these generic undertakings market entry.[439]

7. LUNDBECK'S AGREEMENTS

7.1. Introduction

(218) This Decision analyses in detail six agreements which Lundbeck concluded with four different generic undertakings in the course of two years (2002 and 2003). Of these

438 ID 681, page 138.

439 ID 845, page 93.

four generic undertakings, three were medicines suppliers (Merck – two agreements, Arrow – two agreements and Alpharma) and one was API producer and medicines supplier (Ranbaxy). The negotiation, the provisions, the implementation and relevant subsequent events of each agreement are described in detail in the following sections. The order chosen is to start with the earliest agreements (Merck and Arrow for the United Kingdom, concluded on the same day) and end with the most recent agreement, with the proviso that where one generic undertaking concluded two agreements with Lundbeck, the two agreements will be described directly after each other. This chapter will therefore first describe Lundbeck's two agreements with Merck, then its two agreements with Arrow, followed by Lundbeck's agreements with Alpharma and Ranbaxy respectively.

7.2. Lundbeck's agreement with Merck regarding the United Kingdom

7.2.1. The negotiation of the agreement

(219) The description of events leading to Lundbeck's agreement with Merck (GUK) regarding the United Kingdom of 24 January 2002 starts with a meeting between Lundbeck and Merck Generics sometime at the beginning of 1999. In a report to its Board of 8 February 1999, Lundbeck wrote:

"After rumours that Merck Generics are synthesising citalopram, a meeting was held with their top management. At the meeting Merck Generics confirmed the fact, but were not able to confirm whether they were using a Lundbeck patented production method or whether they had developed a new method. A fresh meeting has been agreed."[440]

(220) As described in recitals (175) to (177) above, by the year 2000 Merck (GUK) had come to rely for its intention of selling generic citalopram in Europe on the Italian chemical producer VIS Farmaceutici S.p.A. Based on the VIS Master Drug File, Merck (GUK) expected to receive a marketing authorisation in the United Kingdom in February 2001 and in other European countries, using the mutual recognition procedure, by December 2001.[441] However, in October 2000 Lundbeck acquired VIS and withdrew immediately thereafter VIS' Drug Master File for generic citalopram.

(221) In a meeting with Merck (GUK) on 1 November 2000, Lundbeck representatives, in their capacity as [company function]* of VIS, justified this withdrawal by pointing to an impurity in the VIS material that exceeded the 0.1% regulatory threshold. Lundbeck also talked about its authorised distribution agreement with Nycomed in Denmark. One of the issues on which Merck (GUK) asked for an answer from Lundbeck was "A possible consequential collaboration on the whole product"[442] Following the meeting, Merck (GUK) considered internally that the alleged impurity problem had in fact already been solved by VIS in September 2000[443], shortly before the take-over, or in any case could be relatively easily overcome[444], and that Lundbeck merely used the impurity as an excuse to withdraw VIS' Drug Master File with a view to preventing approval of the generic marketing authorisations based

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440 ID 813, page 8. See also ID 9, page 316.

441 ID 673, pages 7-8 and 23. See also ID 673, pages 17-18.

442 ID 673, page 56, and also pages 54-55.

443 ID 673, page 75.

444 « I U D Q N O \ W K L V Z D V D Q L V V X H Z H F R X O G K D Y H R Y H U F R P H E X W DMF in UK." See ID 673, page 66 and ID 1130, page 1.

thereon.[445] Merck (GUK) estimated that replacing the VIS Drug Master File in Merck (GUK)'s application for a marketing authorisation by the Drug Master File of a new supplier would lead to a delay in obtaining marketing authorisation of around nine months.[446]

(222) Because of the withdrawal of VIS' Drug Master File, Merck (GUK) had to explore possibilities of buying citalopram API from other suppliers than VIS if it still wanted to enter the citalopram market.[447] The material of the Indian company Natco, which was in the process of starting up pilot production, seemed promising. This material was exclusively sold via the Swiss company Schweizerhall.[448] On 18 October 2000, Schweizerhall had sent a first written explanation of Natco's citalopram and the process to make it to Merck's German subsidiary Merck dura.[449] At the same time, Merck (GUK) had hopes that some sort of a deal might still be possible with Lundbeck. In an internal Merck (GUK) e-mail of 6 November 2000, Merck (GUK) wrote:

"We have asked Lundbeck

– when they intend to validate the process they have and provide us with material

– if we can order material from their process as they are now a general supplier of the active to the industry

W K H \ D U H I U D Q N O \ R Q W K H V S R W D Q G F D Q Q R W Z U L J nice deal. We of course asked if they would supply us with their product."[450]

(223) In an internal e-mail of 13 December 2000, Merck (GUK) considered that "the quickest way forward on Citalopram is to persuade Lundbeck to give us their product and help them to protect their backs"[451]

(224) On 11 January 2001 Merck (GUK), acting as raw material support group for the Merck Generics Group, sent a letter to VIS making a last attempt to persuade VIS to supply citalopram API to the Merck Generics Group.[452]

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445 "Clearly a blatant attempt to stop them [VIS] from providing Citalopram for development purposes. […] Anti trust if one saw it. "See ID 673, page 34. "It is obvious that Lundbeck bought VIS to stop generics."See ID 673, page 53. At the time, Merck (GUK) further observed: "there is a marvellous antitrust case in here somewhere" (E-mail of 20 October 2000, see ID 673, page 32) Finally, it considered taking legal action; this idea was abandoned by senior management, because "we would get no direct benefit". See ID 1130, page 1.

446 ID 673, page 85 without reference to any specific country. See recital (175) above, which explains that sales of VIS' citalopram would have been possible already in 2001 in a number of Contracting Parties of the EEA Agreementwhere Lundbeck did not – or no longer – enjoy(ed) patent protection for the citalopram product.

447 See for instance ID 1024, page 7.

448 See for instance ID 673, page 63.

449 ID 670, pages 3 to 14.

450 ID 673, page 53.

451 ID 673, page 83. The reference to "protect their backs" could refer to a situation where Lundbeck would authorise Merck (GUK), several months before generic entry by other companies, to distribute Lundbeck-produced citalopram as a generic product under Merck (GUK)'s brand name at lower prices than Lundbeck's own brand-name citalopram, thereby already gaining a substantial market share in the generic market and protecting Lundbeck against the full impact of subsequent independent generic entry.

452 ID 673, page 95.

(225) On the same day, 11 January 2001, Lundbeck sent Merck Generics/Merck (GUK) a letter warning it of possible patent infringement on citalopram, annexing a list of 22 process patents or patent applications Lundbeck owned on the production of citalopram.[453] This list included the crystallisation patent, as already granted on 6 November 2000 in the Netherlands as a utility model. It did not, however, mention that a patent application for the crystallisation process had been made in the United Kingdom (this United Kingdom patent application was published on 4 July 2001).[454]

(226) In a letter of 16 January 2011 to Lundbeck, Merck (GUK), again in its capacity as raw material support group for the Merck Generics Group, stated: "It is also the policy of the company to make low cost Generic pharmaceuticals available at the earliest opportunity through the global network of Merck Generics Group companies." Merck (GUK) added that it remained available to discuss "any collaboration with Lundbeck".[455]

(227) In an internal e-mail of 30 January 2001, Merck (GUK) wrote: « Z H D U H M X V W D E W R J H W J R L Q J R Q U H S O D F L Q J 9 , 6 Z L W K Z L W K W K H Regarding Z « Lundbeck, the e-mail stated "do you want to approach them about a possible de[a]bncerning supply with Lundbeck's product]".[456]

(228) In an internal memorandum of 5 February 2001, Merck (GUK) recognised that market entry in the United Kingdom with generic citalopram would be possible only after expiry of Lundbeck's basic patent on the compound on 5 January 2002.[457] The same memorandum stated that Natco's process would be using Lundbeck's originally patented bromphthalide process, patent protection on which would expire with the compound patent. The memorandum continued by stating that Natco's process "does not infringe any of Lundbeck's later process patents that we are aware of", including the ones stated in Lundbeck's letter of 11 January 2001, but also pointed out that "there still exists the possibility that Lundbeck may file patents on 2 prior steps where there remain differences between the Natco process and the basic patent. We are not aware of any such patents. However, we will monitor the situation".[458] In

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453 ID 673, pages 96 to 99. In reply to the Statement of Objections, Lundbeck stated that it had sent on 11 January 2001 a warning letter also to Natco (see ID 5394, page 131 and ID 5447, page 1). The content would likely have been similar or identical to the letter sent to Merck (GUK).

454 ID 673, pages 96 to 99. See also recitals (248) to (249) below. In reply to the Statement of Objections, Merck KGaA argued that "it is not clear whether GUK realised the potential impact of that [crystallisation] patent at this early stage, or was even aware of it" (see ID 5960, page 63) However, on 16 January 2001 GUK replied to Lundbeck's warning letter: "thank you for the clarification of your Intellectual Property Rights, we will obviously spend time reviewing our continued work in light of these patents and patent applications" (see ID 5960, page 63) At least since 15 March 2001 GUK was fully aware that Lundbeck had "applied for patents for crystalline forms, cleaning methods and formulae." (See recital (230) below) Moreover, in an e-mail dated 19 November 2001, GUK explained: "We are obviously aware of those patents disclosed in the Lundbeck letter" (see ID 673, page 171) Main utility models or patents of Lundbeck's crystallisation patent group were published or granted between November 2000 and September 2002 (see recital (113) above).

455 ID 673, page 106.

456 ID 673, page 122. In this context, in its reply to the Statement of Objections, GUK stressed that Merck (GUK) struggled "with Lundbeck's obstacles in engaging an API supplier" (see ID 6026, pages 59-61.

457 ID 673, page 124.

458 ID 673, page 124. See also ID 673, pages 128 and 161, ID 682, page 93 and ID 581, page 6. According to Lundbeck, Natco used the original alkylation 2002-2 process, see ID 5394, page 125 and recital (109) above. Lundbeck submitted in its reply to the Statement of Objections that the following quote would show that in Merck (GUK)'s view only the main part, not the entire process used by Natco,

other words, entering the United Kingdom market with Natco's generic citalopram would in principle be legally possible as of 5 January 2002, but not sooner. It was perhaps this time table that led Merck (GUK) to consider on 14 February 2001: "We do have an alternative active supplier, but the quickest way to get a licence would be through Lundbeck."[459]

(229) On 20 February 2001, Merck (GUK) observed: "we may well have to give Schiezerhalle / Natco some kind of guarantees of future purchases if we are to stop Lundbeck from doing what they are currently trying which is to buy up the ZRUOG V VXSSO\« WKH\ DUH FXUUHQWO\ WUR RSLQJ processes and so on."[460]

(230) On 22 February 2001, Lundbeck visited Natco and its exclusive sales agent for citalopram, the Swiss company Schweizerhall, at Natco headquarters in India. According to a contemporaneous meeting report prepared by Schweizerhall and circulated inside Merck (GUK), Lundbeck emphasised, firstly, that escitalopram was soon to be launched in Europe. This was interpreted as meaning: "The message Lundbeck wants to get across is that the racemic product [citalopram] will shortly disappear from the market or play only a minor role."[461] Lundbeck then displayed all the ways known to Lundbeck to synthesise Citalopram and all the patents it had on manufacturing processes of citalopram, including the fact that it had "applied for patents for crystalline forms, cleaning methods and formulas." This was interpreted as: "Lundbeck wishes to create the impression that it is not possible to produce Citalopram on a large scale of sufficient quality for licensing by a non-patent infringing method. The question arises then why Lundbeck bought VIS Farmaceutici."[462] Then Lundbeck explained that it was already using the authorised generic suppliers Bioglan and Nycomed in Denmark. This was interpreted to mean: "Lundbeck wants to show here that the market share for generic product companies independent of Lundbeck will not develop in the way that the generic industry had hoped."[463]

(231) Finally, Lundbeck "said that because of the great demand for Citalopram they would buy material from Natco if the quality were acceptable. In view of the immediately previous descriptions of the expansions of Lundbeck's production capacities and the announcement that the racemic product would shortly be taken off the market, not a very realistic remark"[464] Natco rejected the offer to supply citalopram to Lundbeck, saying it was committed to distribute citalopram through Schweizerhall. Schweizerhall said it did not wish to supply citalopram to Lundbeck. Lundbeck then made an offer to Natco to buy two intermediates for the production of citalopram.

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corresponded to this process: "The main part of the process of Natco is given in the basic compound patent as an example of synthesis of citalopram. All the prior intermediates are also named although they use slightly different reagents for each step. [Name of Merck (GUK) employee] explained that as soon as the compound patent is off we are free to sell the material." ID 673, page 128; see ID 5394, page 127. The quote, however, also indicates that Merck (GUK) had analysed the compound patent, which was about to expire, and that it considered that "as soon as the compound patent is off we are free to sell the material".

459 ID 673, page 126.

460 ID 673, page 130.

461 ID 673, page 138.

462 ID 673, page 138.

463 ID 673, page 139.

464 ID 673, page 139.

This was interpreted to mean: "The enquiry about the two intermediates was certainly an attempt to break the alliance between Natco and Schweizerhall. However, Natco recognised themselves that it was not an offer to be taken seriously"[465]

(232) On 26 February 2001 Merck (GUK) concluded that Natco had the "appropriate synthetic process to allow us to enter these markets at the earliest time."[466]

(233) Within the Merck Generics Group, an email of 2 March 2001 observed, "Lundbeck left [Natco] after 45 minutes not knowing anything about Natco where they are and the quality of their material, which is excellent and good enough to get us through registration. If Lundbeck really knew we could be facing a Lundbeck buy-out of Natco After Lundbeck left they faxed back an "artificial" order which said if Natco had the right quality the [sic] they would order 2 tonnes [of citalopram] for 2 years at 5000USD/kg. Obviously this is a fishing exercise but potential 20 Mio USD which is Natco annual turnover is a significant order as is our project 1000kg order."[467] There is no indication in the file that Natco reacted positively to this offer. Indeed, as Merck (GUK) commented in an internal e-mail on 1 March 2001, "they [Natco] have been offered a fortune by Lundbeck for their output and have refused in our I D Y R X U « O R \ D O W \ Z L O O K.D Y H W R E H U H G X F H G W R [468] That same e-mail further stated: W K R X J K "Z H Z L O O E H F R P P L W W H G W R 1 D W F R Z K H Q Z H P R Y H F D Q Q R W J R E D F N R Q W K L V « « I Z H V K R Z D Q \ V L J Q V going off to another supplier we can kiss the DMF goodbye."[469]

(234) In the same e-mail of 2 March 2001, Merck GUK) confirmed its belief that the Natco process would not infringe any Lundbeck patents: "The citalopram active process is heavily patented but the Schweizerhall process is non-infringing when the compound patent expires (checked out by patents group at Potters [Merck (GUK)'s address]."[470] Merck (GUK) also noted that "Schweizerhall are essentially the furthest ahead of all the potential AIMs [active ingredient manufacturers] (subject to Tiefenbacher separate discussion). We have material from them at Alphapharm that Z L O O D O O R Z X V W R U H I L O H L Q P D Q \ F R X Q W U L H V (8 « lead to a position where we are the only generic in the market place. It will certainly lead to a position of strength versus Lundbeck."[471]

(235) On 15 May 2001, Merck (GUK), on behalf of the Merck Generics Group[472], concluded a Development and Supply Agreement regarding Racemic Citalopram HBr with Schweizerhall Pharma International GmbH.[473] This agreement provided that for Germany, the United Kingdom, France, Finland, Norway, Sweden, Belgium, the Netherlands, Spain and Italy, Schweizerhall became for a period of eight years the preferred supplier of generic citalopram API to the Merck Generics Group, which

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465 ID 673, page 139.
466 ID 670, page 24.
467 ID 1024, page 35. Regarding Lundbeck's limited understanding of Natco's process see recitals (260), (276) and (281).
468 ID 1024, page 37.
469 ID 1024, pages 34-35.
470 ID 1024, pages 34-35. See also Article 9.1 and ID 670, pages 57-58.
471 ID 1024, page 34.
472 ID 1509, page 1.
473 ID 670, pages 52 to 69. In the same month, Schweizerhall was acquired by Aceto Corporation.

would use the API to produce finished dosage forms of citalopram.[474] The Merck Generics Group agreed to apply for marketing authorisations in these designated countries. "Preferred supplier" meant that the Merck Generics Group would, in principle, cover 100 per cent of its annual demand for these countries with Schweizerhall, for a period of at least eight years after launch.[475] The API producer to be used was the Indian company Natco, which confirmed in an annex that they would honour the stipulated supply provisions. Schweizerhall and Natco were, in principle allowed to also sell their citalopram products to other clients in Europe, provided this would not lead to a temporary or complete cut off of supply of the API during the duration of the agreement.[476] Merck (GUK) was a "preferred customer", meaning that its supply needs were to be given priority.[477] Schweizerhall, from its side, indicated that it had only one other client in Europe for Natco's citalopram.[478] Natco confirmed that they would sell only through Schweizerhall.[479] Schweizerhall agreed to indemnify MG-Group in case of "process patent infringement of the API in Germany as far as already published"[480]. The agreement also provided that "To our best knowledge API manufactured by Natco will be non-infringing after these patents/SPCs expire which has been reviewed and confirmed by MG-Group"[481]. The patents and SPCs referred to were Lundbeck's original compound and processes patent and patents of the same patent family as listed in Annex 5 to the agreement and due to expire in most European countries in January 2002. Pursuant to the agreement, MG-Group had "the right to perform a reasonable audit of Natco's manufacturing and quality control procedures, records, facilities as well as all supplements to ensure that Natco complies with the current Rules Governing Medicinal Products in the European Community and other areas"[482]. In a Letter of Guarantee, Natco committed not to change its production/synthesis process of the API without prior written consent.[483] There is no indication in the file that Natco would have changed its production process during the time of the events described in this Decision. The price agreed for the citalopram API was USD 3 900 per kilogram. The Merck Generics Group agreed to buy a minimum of 500 kilograms before the end of 2001 and a minimum of 1 000 kilograms before the end of 2002.

(236) On 4 July 2001, the national United Kingdom patent application for Lundbeck's crystallisation process was published (GB 2 357 762) followed by a publication on 20 September 2001 of the PCT patent application (WO 01/68627).[484]

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474 ID 670, page 55, Article 3.2.

475 See the preamble and Article 2.1 of the agreement.

476 See Article 2.3 and Annex 4 of the agreement.

477 See Article 1.4 of the agreement.

478 This second customer was the German company Hexal, see Article 1.4 of the agreement at ID 670, page 53. See also ID 670, pages 16 and 32. It appears, however, that Hexal subsequently switched to the Indian companies Matrix and Cipla as supplier of its API, see ID 844, page 29 and ID 903, page 4.

479 Natco had appointed Schweizerhall as its exclusive worldwide citalopram sales agent. The Merck Group used its Australian subsidiary Alphapharm to conduct designated product development work and to prepare the drug registration files. See ID 581, page 22 and ID 670, pages 52 and 67.

480 See Article 9.1 of the agreement. In Germany, patent protection for the citalopram compound and two original processes had already expired.

481 See Article 9.1 of the agreement.

482 See Article 5.1 of the agreement.

483 ID 670, page 67. In reply to the Letter of Facts, Merck KGaA explained: "Indeed, the Natco process had to be monitored in detailed in order to avoid any infringement". See ID 6755, page 17.

484 See recitals (113) and (151).

(237) An internal e-mail of Merck (GUK) of 5 September 2001 indicates that Merck (GUK) expected to be able to sell in the United Kingdom about GBP 9 million of Natco citalopram in the first year after launch, of which approximately GBP 7 million would be profit: "Raw material Natco (Indian). This is non-infringing."[485]

(238) Another internal Merck (GUK) e-mail of 5 September 2001 stated that Lundbeck are offering D SRWHQWLDO GHDO IRU WKH 8. PDUNHW « KRZH threat posture."[486] Yet another e-mail of the same day showed that Merck (GUK) was getting ready for entry: "The full 3 month launch stock may not be there on Jan 5th, but it should be there through Jan"[487]

(239) In an internal e-mail of 13 September 2001 Merck (GUK)'s [employee function]* estimated that in a best case scenario, Merck (GUK) expected to make GBP 9.7 million gross profit on its first year of sales of generic citalopram in the United Kingdom. The best case scenario assumed, inter alia, that there would be no other generic competition, that Merck (GUK) would achieve 40% market share from day one and that Merck (GUK) would sell at a price approximately 30% below the NHS list price. In a worst case scenario, Merck (GUK) was expected to make gross profits of GBP 2.2 million. This scenario assumed, inter alia, that there would be generic competitors, that Merck (GUK) would achieve only a 20% market share and that the price would be 50% below the NHS list price. According to the e-mail, the worst case scenario was considered "very pessimistic", in particular because the citalopram market as a whole was still growing and because Merck (GUK) expected that it would be able to negotiate better citalopram API purchase prices from Natco with increased volumes.[488]

(240) Another internal Merck (GUK) e-mail of 13 September 2001 stated:

"Lundebeck [sic] have not really dealt with us on a global basis as such they have tended to do the whole thing a little piecemeal with whoever they see a threat in a given market. They recently "summoned" [the [employee function]* of Merck (GUK)] to one meeting and then followed up with another meeting [with Merck (GUK)'s [employee function]* and the [employee function]* of Merck (GUK)]. They FRPPHQFHG ZLWK WKUHDWV « \RX PXVW EH SDWHQW hHOO « 7KH\ VDLG WKHLU SODQ ZDV WR ODXQFK WKH UHSV DQG WKHQ ZLWKGUDZ WKH &LWDORSUDP « « affect us launching as our file is in and running and so they cannot invalidate our application. So basically we ask for their product in advance of patent off and so RQ «)URP D WHFKQLFDO SRLQW RI YLHZ ZH KRSH W UK."[489]

(241) On 19 September 2001, Merck (GUK) internally rejected the idea of "qualify[ing] a second source for Citalopram" besides Natco, because on the one hand "constant supply [by Natco with citalopram] should not be a problem" and on the other hand "we have potential still for litigation with Lundbeck". Although the document shows therefore that litigation with Lundbeck was a possibility, it also demonstrates that

485 ID 673, page 145.
486 ID 673, page 151.
487 ID 673, page 153.
488 ID 1024, pages 49-50. See also ID 1024, page 53.
489 ID 673, page 155.

Merck (GUK) was so confident in its legal position with Natco citalopram that it considered "adding another source" unnecessary.[490]

(242) A Lundbeck internal e-mail of 28 September 2001 mentioned "Talks with Merck Generics UK" and "Deal with Merck Generics UK?? Tbd."[491]

(243) An internal Merck (GUK) e-mail of 28 September 2001 labelled "RE Lundbeck" transferred "notes from yesterday". Those notes indicated two possible scenarios for Merck (GUK) to follow: The first scenario ("current plans") calculated Merck (GUK)'s expected profits from its own sales of Natco citalopram in the United Kingdom. Merck (GUK) expected in this scenario to sell "1m packs at profit of £9/pack. Worth £9m in year 1". The second scenario, referred to in the notes as "Plan « 6 X S S O L H G E \ ra is ed the question: "How to achieve the same profit figure?" The second scenario was then split into two alternative proposals, one for a Merck (GUK) launch of Lundbeck citalopram prior to Lundbeck's compound patent expiry for citalopram in January 2002 and one for a Merck (GUK) launch of Lundbeck citalopram after the compound patent expiry. The second proposal stated: "COG [cost of goods sold]'s of £5.44 (assume £11 selling price) will deliver £9m profit", and "As selling price falls supply price falls."[492]

(244) An internal Merck (GUK) e-mail of 28 September 2001 sent by Merck (GUK)'s [employee function]* stated "Met twice with Lundbeck in the UK to achieve a deal on Citalopram."[493]

(245) On 12 October 2001 Merck (GUK)'s [employee function]* wrote to Schweizerhall, Aceto and Natco:

« L W L V Q R Z W L P H W R P R Y H I R U Z D U G L Q U H D G L Q H V V This will vary in some markets from having documentation ready for when they try to injunct us, through the use of protective writs. There is the potential to prepare for UK, Sweden, France and Germany. In order to do this we need to provide certain documentation to our lawyers which they will ask us from time to time."[494]

(246) On 24 October 2001, Merck reported to Merck (GUK) that Lundbeck Germany had decided not to follow an early entry strategy for citalopram.[495] Merck observed: "Seems that they [Lundbeck] have reconfirmed their previous strategy to defend their product by all means". Merck (GUK) commented: "and we intend to attack it by all possible means!!!"[496] and "this says to me they will attack even if they are naken and have to throw tennis balls at us."[497] Shortly thereafter, on 12 November 2001 Merck (GUK) noted: "despite the fact that the patent on the compound and the process we are using expires in Jan it is suspected that Lundbeck will try to injunct on the

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490 See ID 1021, page 33. See ID 5960, page 284.

491 ID 903, page 40.

492 ID 1995, pages 2 to 11.

493 ID 1996, page 2.

494 ID 1997, page 2.

495 ID 673, page 159. An early entry strategy generally refers to the conclusion of early entry agreements between the originator and a generic company for authorised generic entry. Such agreements are used by originator companies to anticipate generic competition by providing for a controlled market launch of a generic product generally before loss of market exclusivity. See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, pages 325-339.

496 ID 673, page 159.

497 ID 1998, page 2.

premise that they can confuse the issue in the injunction hearing and hence get a 'status quo' ruling", concluding that "actions to preempt any injunction were agreed to be worthwhile".[498]

(247) On 15 November 2001, German customs authorities seized, upon Lundbeck's request (based on a "customs watch notice"), containers of approximately 75 and 203 kg of Natco's citalopram. The seizure allowed Lundbeck to examine a sample of Natco's API.[499] On the same day, Merck (GUK) internally observed: "the patent litigation with Lundbeck has started today".[500] In reply to the Statement of Objections, Lundbeck argued to the Commission that analysis of this sample showed that the observed low level of 5-Acetyl impurity "necessarily required the use of the Crystallization Process".[501] However, at that time and until the conclusion of the agreement, Lundbeck neither knew which process Natco was precisely using nor had it certainty regarding any possible patent infringement.[502]

(248) On the same day, 15 November 2001, Tiefenbacher sent Merck dura (which was a client of Tiefenbacher) an analysis it had made of the patents and patent applications Lundbeck had mentioned in its general warning letter to API producers and generic suppliers, including Merck (GUK), in January 2001.[503] Merck dura passed the analysis on to Merck (GUK). For Lundbeck's crystallisation utility model in the Netherlands (NL 1016435), which had been granted on 6 November 2000, and the corresponding application in the United Kingdom (GB2357762), Tiefenbacher concluded: "Describes the production of high purity Citalopram through the crystallisation of the base. In principle not applicable, as in our processes the base is not crystallised, but the product is cleaned through re-crystallisation of the hydrobromide. But: in some writings, protection for the production of high purity citalopram (>99.8%) is filed for. Will be monitored."[504] A Merck (GUK) patent expert commented: "In relation to these patents, Tiefenbacher's conclusions are the same as mine in that none of the published patent applications disclosed in the letter constitute a problem".[505] This person did identify one new patent application of Lundbeck on 19 November 2001 that he believed Natco's process would prima facie infringe. However, he considered that this patent application (WO 01/68632A1) clearly lacked novelty and should therefore normally not be granted: "The published search report in fact cites the basic compound patent [...] as a novelty destroying document".[506] A day later, on 20 November 2001, Merck (GUK) observed:

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498 ID 673, pages 161 and 162.

499 ID 5394, page 132. According to a Lundbeck e-mail of 10 January 2002, Merck (GUK)'s lawyer confirmed "that the Hamburg sample constitutes the Natco material of the quality which they have intended to bring on the UK market". See ID 5394, page 124. In reply to the Statement of Objections, Lundbeck pointed out and provided evidence showing that it had internally analysed Natco's citalopram at different points in time throughout the years 2000-2003. See ID 5394, pages 122-127. This does not mean, however, that Lundbeck would have really understood at the time which process Natco was exactly using, see recital (233) and the references in footnote 467.

500 ID 1024, page 60, see also ID 673, page 182 and ID 1114, page 1.

501 ID 5394, page 124.

502 See recital (260) below.

503 See recitals (148) and (225) above.

504 ID 673, page 174, translation from German. The original German text uses the word "Umkristallisation".

505 ID 673, page 171.

506 ID 673, page 171.

"However, the patent in question still applies to the NATCO route and will need to be monitored".[507] In reply to the Statement of Objections, Lundbeck pointed out that although the EPO indicated the patentability in amended form, Lundbeck abandoned the corresponding European patent application EP 1274699 in the spring of 2005 for commercial reasons.[508]

(249) On 16 November 2001, an internal Merck (GUK) e-mail commented: "The fun & games has started already with citalopram as our suppliers [Schweizerhall/Natco] had a sample of raw material stopped at customs in Hamburg [on 15 November 2001] so that Lundbeck could take a sample! I'll call you later today to discuss if that's OK as we now know what patents they may come at us with initially. Therefore we should discuss how to best avoid an injunction in the UK. Lundbeck alleged potential infringement of two patents, an intermediate patent EP 0171948[509] and a utility model DE 20007303[510]. The utility model claims crystalline free base of citalopram and crystalline salts of citalopram prepared from the crystalline free E D V H « 7 K H 3 & 7 D S S O L F D W L R Q D S S H D U V W R E H H Q W H U than the regional phase at the moment. The NL patent is NL 1016435 C1 so it looks like this one has granted but the other national filings in Europe still appear to be applications."[511]

(250) On 19 November 2001, an internal Lundbeck e-mail reported that Merck (GUK) called Lundbeck on that day "and asked if we were interested in a deal" having answered "maybe"; Lundbeck considered internally: "As soon as their UK approval is reality, we must be ready to make an agreement where they drop their registration in return for reduced compensation for the process patent infringement which is quite legitimate – a nice solution on an otherwise complicated problem."[512]

(251) On 27 November 2001, as a follow-up to Lundbeck's letter of 11 January 2001 warning of possible patent infringement[513], Merck (GUK)'s counsel requested from Lundbeck to "let us know" with respect to the large number of patents and patent applications referred to in the letter of 11 January 2001 "which, if any, you consider our clients may infringe".[514]

(252) On 29 November 2001, Aceto wrote to Merck (GUK): "brilliant news from the Hamburg customs. They received instructions from the patent attorneys of the originator today that a.m. batch to be released for our disposal whereas the general procedure of stopping all Citalopram-consignments at the customs should go on (for a period of one year as disclosed by the customs earlier!!!). Of course we will claim

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507 ID 1999, page 2.

508 Regarding these e-mails see ID 5394, page 128, ID 5960, pages 13-14, 74-75, 138-139, 204; ID 6026, pages 38-39, ID 5446, page 1, and ID 171, pages 1687 and 1691. Merck KGaA indicated that "the patent was in fact granted at a later stage in Spain under the reference ES 2159271 (B1) on 11 March 2002". (ID 6470, page 1) There is no indication in the file that the Spanish patent would have ever been legally challenged.

509 This patent covered Lundbeck's diol process. See recital (112) above.

510 See footnote 226.

511 ID 1152, page 1. In the context of the Hamburg seizure, Merck (GUK)'s [employee function]* considered that there was a need to "…check Natco and Alpharma data for validation". Quoted by GUK in ID 6026, page 41. See further footnote 609.

512 ID 682, page 107. See also footnote 518.

513 See recital (225) above.

514 ID 8, page 363. See recitals (249), (256) and footnote 593.

for damages and claim that our consignments should be excluded from above stated procedure as simply no patent infringements are taking place."

An e-mail exchange within Merck (GUK) evaluated the consequences of the customs watch notice and analysed the way forward.[515]

(253) On 3 December 2001, an internal Merck (GUK) e-mail reminded Merck (GUK) staff: "X\V OHW V NHHS LQ PLQG WKDW VWDJH RQH LV[516]

(254) On 9 December 2001, Merck (GUK) internally stated: "now pretty far advanced with GLVFXVVLRQV« , WKLQN D GHDO LV WKH PRVW OLNH to keep everyone apprised of the progress and where the chess game stands."[517]

(255) On 11 December 2001 a meeting took place between Lundbeck and Merck (GUK).[518] The report of Merck (GUK)'s [employee function]* from this meeting stated:

"Met with [Lundbeck] today and they are keen to do a deal. The following points came out during our meeting:

– Currently they are taking legal action with the Dutch HA [Health authority] re the Tiefenbacher [sic] active. If this is successful then we would have the only available product.

– If they 'loose' then Tiefenbacher [sic] will be on the market in March/April 2003. They will be supplying Arrow.

– Lundbeck have sampled our active and their only comment was that it is of poor quality and they may have to take this 'up with the MCA' [the United Kingdom Medicines Control Agency] when we launch.

– They made no reference to our product infringing.

They are very keen to do some sort of deal. I am keen to do this provided the numbers stack up as we will not have a product we could sell in real volumes until 4 « DQG WKDW FRXOG EH WRR ODWH , GR QRW ZDQW

– Lundbeck do not want a generic on the market.

– However they could compensate us for the profit we would have made etc.

– We could sell UK Lundbeck product to target the PI [parallel imports].

– This will give us a good T/O [turnover] as well as the profit.

– I would need some safeguards re generic supply if/when other generics enter the market."[519]

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515 See ID 673, page 190; ID 1124, pages 1-3.

516 ID 2001, page 2.

517 ID 1124, page 1.

518 In reply to the Statement of Objections, Lundbeck argued: "GUK ± not Lundbeck ± proposed the settlement." See ID 5394, page 137. However, in its reply to the Statement of Objections, Merck KGaA claimed: "Lundbeck appears to have called for a meeting" and "roll[ed] out the structure of a deal". See ID 5960, pages 79-80. Relevant in the present context is the fact that both parties participated in negotiating their deal.

519 In reply to the Statement of Objections, Merck KGaA claimed that the latter words of this quote would show that "from GUK's point of view the **deal implied the likelihood of other generic entries**." (ID 5960, page 80, emphasis in the original) The Commission notes that the use in the present context of the

I will go back to Lundbeck with some value/volume expectations (Any thoughts?) but to do a deal we will first need our MA [marketing authorisation]".[520]

The input the author received back from Merck (GUK) on the "value/volume expectations" was:

"Profit value should be as close to our "ideal" i.e., Our estimated net selling price OHVV JURXS FRVW ; YROXPH «[521]

(256) On 13 December 2001, Merck (GUK)'s external lawyers replied to a letter of Lundbeck dated 10 December 2001[522] informing Lundbeck: "Our clients intend to import citalopram into the UK shortly after 5 January 2002 which is the expiry date of the Supplementary Protection Certificate GB95024 extending protection of Lundbeck's UK patent GB 1 526 331 The citalopram is made using a process disclosed in the aforementioned GB patent". The letter explained that the expiry of Lundbeck's product patent including the original process lead Merck (GUK) to assume that they did not infringe any Lundbeck patents: "Our clients have been informed that Lundbeck recently obtained for testing a sample of the citalopram that it is intended Generics will import into the UK. Now that you have completed your tests and released the citalopram, we assume that you do not consider it infringes any patents. However, if this is not correct, please let us know which patents you say are relevant as we asked you on 27 November".[523] In reply to the Statement of Objections, GUK explained: "The aim of the letter is to preserve GUK's legal position by giving notice to Lundbeck that GUK intends to market its generic citalopram and request a statement from Lundbeck".[524]

(257) On 21 December 2001, Merck (GUK) learned that Tiefenbacher (supplying generic citalopram to, inter alia, Merck (GUK)'s United Kingdom competitor Arrow) had completed the mutual recognition process for the marketing authorisations based on the product from Matrix and Cipla and that on that day a Dutch court had refused to issue a preliminary injunction against Tiefenbacher's marketing authorisation in the Netherlands. Merck (GUK)'s reaction to this news was:

«WKLV MXVW DERXW SXWV WKHP EDFN LQ SROH SRV ZKDW ZH FDQ GR WR DVVLVW WKHP««ZLOO WKH\ ????????[that is to say against Tiefenbacher citalopram as to be sold by Arrow]."[525]

Shortly thereafter, on 26 December 2001, Merck (GUK) summed up:

"ERWWRP OLQH«« ZH DUH QRZ QHFN DQG QHFN ZLWK RQ QG 'HF«« EXW WKH\ KDYH WR QRZ ZDLW I

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words "if/when" shows merely that Merck (GUK) wanted to include "safeguards" in the agreement, in case generic entry happened during the term of the agreement, which it considered a possibility. In fact, when a compound patent expires, generic companies will obviously try to enter the market as soon as possible (see recitals (69), (71), (72) and (79) above).

520 ID 673, page 195.

521 ID 673, page 195.

522 ID 904, page 111. See also footnote 546.

523 ID 682, page 93 (same as ID 8, page 362) and recital (251) above. It should be noted that it is possible that this letter could be considered to have expressed "a settled intention [..] to launch" in the sense of the Paroxetine case, see footnote 312 above.

524 ID 6026, page 40.

525 ID 673, page 200.

ZH«««« WKH QHZV RQ WKH OHJDO DFWLRQ LQ +ROOD
JRRG«««« /XQGEHFN ZLOO QRW VXFFHHG DSSDUHQWO\

The document also stated: "we have to start to consider what we are going to do if the licence in the UK is not granted."[526]

In reply to the Statement of Objections, Merck KGaA explained "it was obvious that GUK perceived to be in a close competitive race against Tiefenbacher to obtain a license in the UK" and stressed the "significant competitive advantage" to be the first generic to enter.[527]

Internally, Merck (GUK) reacted in the following way: "[t]he sooner you can tie something up with Lundbeck, the better".[528]

(258) On 28 December 2001, Lundbeck replied to Merck (GUK)'s letter of 13 December 2001 claiming that the expired processes "are not useful in commercial scale production" and that "the product tested by Lundbeck does not comply with the pharmaceutical guidelines". Lundbeck requested more information regarding the process used for the production of Natco's citalopram product.[529]

(259) On 9 January 2002, four days after Lundbeck's basic patent expired, Merck (GUK) received a marketing authorisation in the United Kingdom for 10 and 20 mg citalopram tablets.[530] This was the first approval for a generic company for citalopram in the United Kingdom.[531] Lundbeck had insisted on Merck (GUK) actually having a marketing authorisation before Lundbeck was willing to enter into an agreement with Merck (GUK).[532]

(260) An internal Lundbeck e-mail of the same day, 9 January 2002, analysed Natco's process based on the DMF: "The DMF does not indicate that the product has been purified by crystallisation of the free base. On the other hand the reaction conditions will lead to formation of the 5-acetyl Citalopram impurity (cf. the product marketed in Australia) which may be removed by crystallisation of the free base. However, we are not sure that they purify by crystallisation of the free base. We investigate this further."[533]

(261) Also on 9 January 2002, Lundbeck received the following information from an informed market player in the United Kingdom regarding Merck (GUK)'s planned launch there:

"Generics UK have verbal approval of their licence and are awaiting final written approval which will be in the next week.

Currently their supply of citalopram is on a ship and delivery is therefore confirmed as 30.01.02. The general feeling is that this is very optimistic and that the more likely delivery timescale is middle to end of February.

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526 ID 673, page 198.
527 ID 5960, page 81 (emphasis in the original).
528 E-mail of 31 December 2001, see ID 1024, page 68.
529 ID 8, page 349; see also ID 8, page 359. For Merck (GUK)'s letter see recital (256) above.
530 ID 673, page 343, ID 660, page 8, ID 682, pages 5, 120-121.
531 ID 673, page 343.
532 See recital (250) above. See also Article 2.6 of the Settlement and Supply Agreement between Lundbeck and Merck (GUK), ID 8, page 210.
533 See ID 5494, page 1. See further recitals (276) and (281).

The prices of the GUK product are as follows:

10mg £6.96

20mg £11.55

40mg £19.57

Sterwin who were one of the VIS files (Sanofi) have had difficulty obtaining supply for their DMF and have tied up a deal with GUK."[534]

(262) One day later, on 10 January 2002, Merck (GUK) and Lundbeck met in Copenhagen.[535] At this point, intensive negotiations took place on an agreement between Lundbeck and Merck (GUK).

(263) In an e-mail of 15 January 2002, Merck (GUK) indicated to Lundbeck the price it asked from Lundbeck for selling it 8 million tablets (partially already packed) of the Natco citalopram it already had in stock: "Estimated cost per Kg £14,285 (i.e. £2m/140 kg)."[536] In an e-mail of 17 January 2002 to Merck (GUK), Lundbeck wrote: "As I know you are aware the guys at Head office are very keen to receive the quantities of Products as promised in the initial discussions."[537]

(264) Lundbeck and Merck (GUK) met at least on 15 January 2002[538] and 18 January 2002.[539] Several drafts of an agreement were exchanged in this period.

(265) In an e-mail to Merck (GUK) of 18 January 2002 a Lundbeck representative made the following proposal regarding the envisaged purchasing by Merck (GUK) of Lundbeck citalopram:

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534 ID 904, pages 151-152. These were prices for a 28 tablets pack at wholesale level. The same document explained that the prices to retailers would be around £1.50 higher and that the current average price for parallel imports at the retail level was £13.00 for 20 mg tablets. Merck (GUK)'s initial price of 20 mg tablets to retailers would therefore be at around the same level as that of parallel imports of Lundbeck's own citalopram.

535 ID 904, page 175.

536 ID 682, pages 123-124. From a comparison with Merck (GUK)'s purchase price of the citalopram API from Natco (USD 3 900/kg - see recital (235) above) - it is clear that the price Merck (GUK) asked of Lundbeck for the 8 million tablets reflected (at least) Merck (GUK)'s expected re-sale price in the United Kingdom, including a very significant profit (see recital (237) above), rather than the actual cost of goods sold. For Merck (GUK), the purchase price of 140 kilogram API of Natco citalopram had been 140 x USD 3 900 = USD 546 000 = GBP 377 855 (at an exchange rate on 15 January 2002 of 1 USD = 0.692024 GBP). The re-sale price of the tablets to Lundbeck asked for in this e-mail was therefore more than five times as high (GBP 2 million instead of GBP 377 855), even if one must take into account the cost of producing the tablets and (partially) of packing them. This purchase price of GBP 2 million for 8 million tables was taken over in the agreement as concluded, see recital (267) below.

537 This refers to Merck (GUK)'s Natco material. ID 907, page 129. Compare with the product schedule to the agreement as concluded, ID 8, page 218.

538 ID 682, page 123.

539 ID 682, page 125, ID 907, page 129.

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Strength	*Annual Volume*	*Selling Price*	*Purchase Price*	*Profit*
10 mg	375,000	£ 8.00	£ 5.60	£ 900,000.00
20 mg	1,500,000	£ 11.50	£9.10	£3,600,000.00
40 mg	210,000	£ 23.00	£20.62	£500,000
				£5,000,000.00

"[540]

The reaction from an executive within Lundbeck to this e-mail was "I strongly disagree with the content of this email – we cannot and will not agree selling prices – this is illegal"[541]

(266) In an e-mail of 23 January 2002 to Merck (GUK) explaining the changes Lundbeck had made to the draft agreement with Merck (GUK), Lundbeck wrote:

"Inserted the option for Lundbeck to pay a monthly fee instead of delivery Finished Products in case the market price goes down (this is something I am sure we will discuss more if it happens, ideally it should not happen)."[542]

7.2.2. The agreement

(267) On 24 January 2002, Merck (GUK) and Lundbeck Limited, Lundbeck's United Kingdom subsidiary, concluded a "Settlement and Supply Agreement."[543] The agreement was concluded for one year and covered the United Kingdom only.[544] In its preamble, the agreement stated that Merck (GUK) "had received notice" from Lundbeck that Merck (GUK) might be infringing "certain Intellectual Property" of Lundbeck (Point B).[545] The agreement itself did not specify any specific patent(s) Lundbeck believed Merck (GUK) would infringe.[546] Nor had Lundbeck initiated any infringement litigation against Merck (GUK). The preamble continued by saying:

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[540] ID 682, page 132. In the agreement actually concluded between Lundbeck and Merck (GUK) the two parties agreed that Lundbeck would only sell 20 mg tablets to Merck (GUK), with a "suggested selling price" of £12.00. See recital (271) below.

[541] ID 682, page 132.

[542] ID 682, page 134.

[543] ID 8, pages 207 to 222.

[544] Lundbeck explained to the Commission that "Lundbeck initially concluded an agreement with Generics UK covering only the UK because Generics UK initially had marketing authorization only in the UK." See ID 823, page 51. Regarding the duration, Article 11.1 provided that "this Agreement shall be for a period of twelve months commencing on the Effective Date". The "Effective Date" was defined in Article 1.1 as "the date of delivery of the Products by GUK to the Company" which was determined in Article. 2.2 as "31/1-2002" (note, however, that the Schedule talked about a "January 25th delivery"). Had it not been prolonged, the agreement would have expired on 31 January 2003.

[545] This is presumably a reference to Lundbeck's warning letter of 11 January 2001, see recital (225) above and footnote 546.

[546] The agreement merely said that Merck (GUK) might be infringing "certain Intellectual Property" of Lundbeck, "Intellectual Property" being defined as "patents, trade marks, rights in design, copyright and database rights and all rights or forms of protection of a similar nature in any part of the world." See preamble point B and Article 1.1.

"GUK does not accept that its product is infringing but recognises that there is an inevitable degree of risk in patent litigation plus delays and inconvenience and has agreed not to launch the Products[547] subject to payment in accordance with the terms of this Agreement." (Point C)[548]

"The parties have further agreed that GUK shall purchase its requirements of the Finished Products from the Company and the Company is willing to supply GUK with the Finished Products for resale and GUK is willing to purchase the Finished Products on the terms and subject to the conditions of this Agreement." (Point D)[549]

Article 1.1 defined "Finished Products" as "products containing citalopram in finished pack form to be supplied by the Company to GUK pursuant to this Agreement".

Article 2.1 of the agreement provided:

"The parties agree that there is a risk that certain actions of GUK in respect of the Product and the proposed marketing, distribution and sale of the Products by GUK could give rise to a claim on the part of the Company that GUK's actions may constitute an infringement of the Intellectual Property of the Company."

Article 2.2 provided that "As a result, in consideration of the payment of the sum of £2 million" by Lundbeck, Merck (GUK) agreed to "deliver up" its stock of close to 8 million tablets of Natco citalopram to Lundbeck.[550]

With respect to a possible link of the agreement with the crystallisation patent, Lundbeck argued in its reply to the Statement of Objections that it had at least previously sent GUK warning letters with a list of patents including the crystallisation patent (ID 5394, page 142). In its reply, Merck KGaA argued that the link to the crystallisation patent would have been clear from the context (ID 5960, page 121); similar arguments were made by GUK, which pointed in this context also to the seizure by the Hamburg customs (ID 6026, pages 33-35 and 40-41; see recital (247) above). Internally, Lundbeck did reflect whether Natco might infringe its crystallisation patent. See recitals (150), (247), (260), (281) and (283). Also, Merck (GUK) was aware that Lundbeck might invoke the crystallisation patent (if and when granted in the United Kingdom) against the Natco citalopram, see recitals (248) and (249) above. It is therefore possible that the parties had the crystallisation patent in mind when concluding the agreement. However, at the time when Merck (GUK)'s counsel requested in November 2001 an identification which patents had been infringed by GUK precisely, if any, Lundbeck gave no reply. (ID 904, page 111; see also recital (249) above) Evidence shows that Lundbeck, in fact, did not really know which process Natco was precisely using and could therefore not determine whether GUK was infringing any of its patents.

547 Article 1.1 defined "Products" as "the citalopram products developed by GUK in raw material, bulk product and finished pack form as set out in the Schedule and manufactured in accordance with the specification for Products as supplied by GUK at the date of signature. Attached to Schedule 2 reply to the Statement of Objections, Lundbeck and GUK claimed "6FKHGXOH « UHIHUV WR supplied by Natco", although it did not explicitly mention the name Natco; Lundbeck explained this fact by stating that the Schedule "is redacted to avoid disclosure of Natco's confidential information" (See ID 5394, page 141; ID 6026, page 11) In its reply, Merck KGaA pointed out that the provisions of the agreement clearly referred to Natco based citalopram as "***all of GUK's Citalopram*** products ***were manufactured with Natco's API***, both at the time and also later, due to the exclusive supply clause of GUK's agreement with Schweizerhall until 2008." (See ID 5960, page 134, emphasis in original)

548 ID 8, page 208.

549 ID 8, page 208.

550 It is noteworthy that earlier drafts of the agreement had stated that Merck (GUK) would "deliver or destroy" the products, at Lundbeck's discretion, see for instance ID 673, page 207. Article 2.2 foresees that "[t]his delivery shall take place on 31/1- «" However, the Schedule talked about the "January 25th delivery".

In Article 2.3 of the agreement Merck (GUK) agreed, "in consideration of the payment of £1 by Lundbeck to Merck", to deliver 173 kg of bulk citalopram material still to be received from Natco.

The purpose of these sales of tablets and bulk citalopram, as understood by Merck (GUK) at the time of the conclusion of the agreement, was to take this Natco citalopram "out of circulation."[551] The products were delivered to Lundbeck and later destroyed by Lundbeck.[552]

Article 2.4 provided that the "payments made" and the "delivery up of the Products by GUK" pursuant to Articles 2.2 and 2.3 "shall constitute full and final settlement of any [infringement] claim […] up until this date".

In Article 2.6 Merck (GUK) gave warranty "that it has a marketing authorisation for the sale of the Products", referring to the citalopram from Natco.

Article 2.7 stated that "GUK will not grant duplicates in favour of any third party of its marketing authorisation during the Term for marketing use in the Territory."

Article 3.2 of the agreement provided that "The Company agrees to sell the Finished Products and GUK agrees to exclusively purchase the Finished Products from the Company for resale by GUK and its Affiliates in the Territory during the Term on the terms and subject to the conditions of this Agreement." "The Company" was defined as Lundbeck Limited.[553] "Affiliate" meant any other company in the Merck Generics Group.[554]

Article 4.1 of the agreement provided that Lundbeck would accept all orders placed by Merck (GUK) for Lundbeck citalopram tablets of 20 mg during the term of the agreement for 100% of the quantity forecasted for sale by Merck (GUK). As opposed to what had been envisaged in earlier negotiations between Lundbeck and Merck (GUK), the agreement only provided for Lundbeck sales to Merck (GUK) of tablets of 20 mg, not of tablets of 10 or 40 mg.[555]

(268) Article 6.2 of the agreement provided:

"The Company [Lundbeck] agrees that provided that GUK orders the Volume of Finished Products during the Term, then GUK shall be guaranteed Net Profits of £5 million (or such pro rata figure if GUK orders less than the Volume). If the market price for the Finished Products decreases during the Term, then the Company agrees to reduce the Cost Price accordingly to ensure that GUK is guaranteed to realise Net Profits of £5 million on sales of the Volume (or pro rata if GUK orders less than the Volume) for which the Company is responsible in which the Company sells Finished Products ordered by GUK it shall ensure that GUK is paid such amount as is sufficient to the Net Profit GUK could have realised had the Finished Products been delivered."

(269) Article 12 of the agreement provided:

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551 ID 682, page 133.

552 In reply to a request for information of 12 March 2010, Lundbeck stated that it initially stored the products and following the expiration date, destroyed the stock. See ID 823, page 49.

553 See the preamble, point 2.

554 See the definitions in Article 1.1, ID 8 page 208.

555 See recital (265) above and recital (271) below.

« 7 K H S D U W L H V D J U H H W K D W [of the agreement], GUK may decreases the prices at which it sells the Finished Products such that it makes sales at below the prevailing market price, the guaranteed Net Profits (per clause 6.2) shall not apply in respect of such sales."

(270) The definition of Volume in Article 1.1 of the agreement was:

"the volume of Finished Products notionally to be ordered by GUK from the Company pursuant to this Agreement as set out in the Schedule, it being recognised that GUK shall have no obligation to purchase such volume and that such volume is set out in this Agreement by way of a mechanism to ensure (if and to the extent that such volume is achieved) that GUK receives Net Profits as set out in clause 6.2."

(271) The Schedule to the agreement indicated as "Volume per month" "125,000 packs" at a " > « @ice for the Finished Product "Cipramil 20 mg 28 blisterpack" of "£8.65" and a "Suggested selling price" of "£12.00".[556]

(272) Lundbeck later explained to the Commission that "Under the agreement, Generics UK undertook to deliver its products to Lundbeck in consideration of compensation of GBP 3 million for 7.9 million tablets and 173 kilograms of active ingredients. The agreement also included a supply arrangement whereby Generics UK agreed to exclusively purchase its requirements of citalopram from Lundbeck for resale in the UK."[557]

(273) Lundbeck started delivering these packs as 31 January 2002 and continued to do so for the full duration of the agreement and its two prolongations until 1 November 2003.[558] It is apparent from a comparison of the timing and quantity of products delivered by Lundbeck to Merck (GUK) and those sold by Merck (GUK) that Merck (GUK) did not sell any Natco material in the United Kingdom prior to the agreement with Lundbeck. Merck (GUK)'s first sales in the United Kingdom consist of 125 000 packs of 28 tablets of 20 mg supplied by Lundbeck to Merck (GUK) on 25 January 2002 and sold by Merck (GUK) still in the same month.[559] It is also apparent from sales information provided to the Commission by Lundbeck that when Merck (GUK) ordered more than the 125 000 packs per month agreed, the purchase price was

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556 ID 8, page 218. The quantity of 125 000 packs per month served as the volume basis for calculating Merck (GUK)'s guaranteed profit. In fact, as mentioned in Article 4.1 of the agreement, Merck (GUK) was allowed to order more, in line with expected demand, but in that case Merck (GUK)'s purchase price of Lundbeck's citalopram would increase to ensure that on the whole Merck (GUK) would still make the same amount of profit over the term of the agreement and not more. See for instance ID 850, page 89. See also recital (273) below. As for Merck (GUK)'s re-sale price, this was a suggested selling price to wholesalers. Lundbeck's own official sales price to wholesalers in the United Kingdom at this time was GBP 14.03 for the same pack of 28 tablets of 20 mg, although in practice considerable discounts were given on that price. See ID 1937. The NHS retail price to patients at this time, which served as the basis for reimbursement, was GBP 16.03. See ID 1024, page 51 and ID 1072, page 2. If Merck (GUK) sold for £12.00 to wholesalers, this would mean that the retail price would be around £13.50, which is slightly above the retail price of parallel imports into the United Kingdom of Lundbeck's own citalopram. See ID 904, page 151, which explains that the margin from wholesaler to retailer was around £1.50. See also recital (265) above.

557 ID 823, page 23.

558 ID 841, page 925, ID 823, page 50. For the two prolongations, see recitals (289) and (301) further below.

559 Compare ID 841, page 925 with ID 677, page 3. See also ID 673, page 229, ID 823, page 49, ID 660, page 8 and ID 846, page 168.

adjusted upwards so as to give Merck (GUK) the same amount of total profit per month as if it had purchased 125 000 packs per month.[560]

(274) It may be observed that the financial result for Merck (GUK) of the agreement with Lundbeck came very close to the result Merck (GUK) had expected from one year of selling Natco's product in the United Kingdom. Merck (GUK) had expected to be able to sell in the United Kingdom about GBP 9 million of Natco citalopram in the first year after launch, of which approximately GBP 7 million would have been profit.[561] In another scenario Merck (GUK) expected GBP 9 million of profits in the first year.[562] The best case scenario Merck (GUK) had imagined would have given it a profit of GBP 9.7 million in the first year.[563] Through the agreement with Lundbeck, Merck (GUK) gained GBP 8 million (that is to say GBP 3 million for the sale of citalopram to Lundbeck and GBP 5 million through the distribution agreement) in a year, of which probably around GBP 7 million were net profit.[564]

7.2.3. Events during the implementation and extension of the agreement

(275) On 30 January 2002, Lundbeck's crystallisation patent GB 2357762 was granted in the United Kingdom. As mentioned in recital (151) above, this patent, as granted in the United Kingdom, also contained claims relating to the crystalline base of citalopram itself and to pharmaceutical compositions.[565]

(276) On 2 February 2002, Lundbeck internally discussed the fact that Natco had applied for a patent for 'An Improved Process for High Purity Citalopram and its Hydrobromide Salt'. "What does that mean? That they're probably infringing our crystal patent?" The internal reply to this question was: "We won't be able to see the content of the patent application for another 6 months. It's quite possible that they[Natco] crystallise the base, but we've no way of proving that at the moment."[566]

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560 ID 841, page 925. See also recitals (280) and (295) below.

561 See recital (237) above.

562 See recital (243) above.

563 See recital (239) above.

564 The cost to Merck (GUK) of the Natco citalopram it sold to Lundbeck for GBP 3 million is unlikely to have significantly exceeded GBP 1 million: The quantity of citalopram Merck (GUK) sold to Lundbeck (in the form of tablets) under Article 2.2 of the agreement amounted to 140 kg, see ID 673, page 229. The amount sold under Article 2.3 (in the form of bulk material) was 173 kg, making for a total of 313 kg of API. Merck (GUK) bought the citalopram API from Natco for a price of USD 3 900/kg. The total purchase cost of Merck (GUK) for the quantity of 313 kg API was therefore USD 1 220 700 = approximately GBP 850 000 (at the exchange rate of 1 USD = 0.698241 GBP in January 2002). To this should be added the cost to the Merck Generics group of converting the API into tablets and, partially, of packing them, see ID 673, page 229. An internal e-mail of Merck (GUK) of 11 March 2003 confirms that Merck (GUK) assessed the profit on the sale of stock to Lundbeck at GBP 2 million. See ID 673, page 474. See recital (363) below.

565 This meant that the United Kingdom patent was on the one hand more likely to be infringed than without these claims, but on the other hand also more likely to be found at least partially invalid.

566 ID 681, page 113 and 114 (translation from Danish); see also page 91.
Merck KGaA indicated that the patent in question (EP1368330, which corresponds to WO 02/066453) was never granted (ID 5960, page 143).
With respect to yet another Natco patent application, WO 2004/016602 A1 of 14 August 2002, published on 26 February 2004, hence not the one discussed in Lundbeck's e-mails dating from February 2002, Lundbeck pointed out in its reply to the Statement of Objections that "according to the WIPO International Preliminary Examination Report of October 20, 2003, the invention as defined in at least some of the claims does not appear to meet the criteria mentioned in Article 33(1) PCT, that is to say does not appear to be novel/or to involve an inventive step […].'" Lundbeck claimed that this

(277) On 6 February 2002, Merck (GUK) stated in an internal e-mail: "run a check as to what now iV R XU H [S R V XU H R Q W K H $ 3 , ‹ where Lundbeck ordered for the U Q R Z G H O D \ H G X Q W L O Z H K D Y H U H V R O Y H G S D W H Q W L O L N H O \ W R W D ' N H D \ H D U R U V R «"[567]

(278) On 18 February 2002, Merck (GUK) wrote in an e-mail to Lundbeck:

"Is there any possibility of increasing the volume you supply us (as well as increasing th[e] cost to us to £9.99). We have over 200,000 packs on back order as of today (all at or over £12)."[568]

In the same e-mail exchange, Merck (GUK) asked: "Can we discuss the remainder of the UK active for the next 12 months. Are you interested in purchasing this? This will be in the order of 1000 (ish)". Lundbeck informed Merck (GUK) about its decision "not to purchase any further substance from Merck (GUK) beyond the quantities agreed.[569]

(279) On 21 February 2002, Merck inquired based on a press release, whether GUK had signed an agreement with Lundbeck. In the press release, GUK was reported as having stated to the press that " L W K D G H Q W H U H G D G H D O > « @ L Q V own, cheaper version of Lundbeck's Cipramil. "We have taken a more sensible and commercial view to working with the brand originator rather than face possible legal action'", while Lundbeck was reported claiming that "this agreement means that we now reach certain areas of Britain where we were not present before".[570]

(280) On 25 February 2002, an e-mail from Merck dura to Merck (GUK) stated:

0 H U F N G X U D S O D Q V W R O D X Q F K F L W D G X U D F L W D O R S

As you probably know Lundbeck (Originator) fights very hard against generic competition all over Europe. In Germany the patent situation is different from other European countries and the patent is considered to be weak. Thus some generic companies try to invalidate the patent and work together with Tiefenbacher from whom be bought our registration.

For Merck dura the situation now becomes very difficult. On one side we are together with Tiefenbacher, we get the goods and the registration from them, and we have the same interest in the invalidation of the existing patents, on the other side Generics UK has a contract with Lundbeck and is probably interested in keeping the patent situation as it is. Tiefenbacher knows about the contract with Generics UK and doesn't trust us anymore. In the meantime they would like to keep us out of the business.

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patent application would show that Natco used the crystallisation process as purification method and that Natco therefore infringed Lundbeck's crystallisation patent. (See ID 5394, page 126) However, the Commission notes that at the time Lundbeck was not sure about this (see recitals (281) and (283)). Nor did Merck (GUK) consider to be infringing, see the summary of evidence in footnote 1317.

567 ID 673, page 318.

568 ID 850, page 103.

569 ID 850, page 103.

570 ID 1024, page 72. In reply to the Statement of Objections, Merck KGaA claimed that the agreement itself was not circulated to the parent Merck KGaA. See ID 5960, page 82.

« DUH WKHUH DQ\ LWHPV LQ WKH FRQWUDFW *HQHU to Germany? Do you have any concerns from the view of the Merck generics group if we fight against Lundbeck's patent?

« P\ LGHD LV W Recessary activities to launch the product."[571]

(281) On 2 March 2002, concerning Natco's patent application mentioned in recital (276) above, Lundbeck wondered: "It's most probably a patent on purification, possibly crystallisation of the free base, like ours. Another possibility is an optimum ratio of solvent to base at the alkylation stage."[572] Lundbeck's [employee function]* was still not sure how Natco was manufacturing and stated that "SPE has shown that it is possible to make an active pharmaceutical ingredient (API) that very probably does ***not*** require crystallisation of the free base."[573]

(282) A Merck (GUK) e-mail of 7 March 2002 mentioned that Alphapharm, Merck's Australian subsidiary which produced the citalopram finished dosage forms based on Natco's API[574], had noticed "a potential major problem with the impurity profile of the Natco product. The e-mail concluded by saying: "At this stage, we have to determine the full cause of the discrepancy in the results and until that is done, we have to assume that potentially we have a big problem with regards to impurity profiles, since this impurity is not present in the Lundbeck product. If the level of the impurity is verified, then the necessary steps will have to be undertaken by Natco to reduce the level of the impurity below 0.1%, possibly by an additional recrystallization."[575]

(283) On 8 March 2002, an internal Lundbeck e-mail stated regarding sample "003/L/00" which Lundbeck had taken of Natco citalopram: "This indicates a final crystallisation as stated in the 2005 method."[576] The reference to the year "2005" would mean an alleged infringement of the 2005 patent, not of the crystallisation patent[577] based on which Lundbeck litigated against generic companies.

(284) On 13 March 2002, Merck (GUK)'s patent law counsel sent a letter to Lundbeck to resolve patent law questions,[578] and a reminder on 12 April 2002.[579] A further letter

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571 ID 675, page 25.

572 ID 681, page 113 (translation from Danish). See already recital (150) above.

573 ID 681, page 113 (translation from Danish, emphasis in original). See further footnote 299, recitals (150) above and (283) below.

574 GUK explained to the Commission that "GUK and its affiliates, except Merck dura with respect to FLWDGXUD« VRXUFHG WKH ILQLVKHG GRVDJH IRUP IURP Merck FLWDORSUDP WDEOHWV GHVWLQHG IRU WKH $XVWUDOLDQ PDUNHW entity based in Australia." "In the period 2001 to 2004, Alphapharm produced the following quantities RI FLWDORSUDP WDEOHWV GHVWLQHG IRU WKH $XVWUDOLDQ PDUNHW produced the final dosage product based on raw material supplied by Merck".

575 ID 673, pages 339-340. Lundbeck interpreted this document as admitting that Natco infringed Lundbeck's crystallisation patent. See ID 5394, page 129. However, in its analysis of 15 November 2001, Tiefenbacher had already considered that Lundbeck's crystallisation patent was "In principle not applicable, as in our processes the base is not crystallised, but the product is cleaned through re-crystallisation of the hydrobromide. But: in some writings, protection for the production of high purity citalopram (>99.8%) is filed for. Will be monitored." See recital (248) above.

576 ID 8, page 344. See recital (151) above.

577 See recital (151) above.

578 ID 904, page 115. ID 904, page 114 contains a letter dated 6 March 2002 with identical wording as the letter of 13 March 2002, but without signature. Lundbeck apparently considered in its reply to the Statement of Objections that the first letter of 6 March 2002 was sent (ID 5394, page 136), whereas Merck KGaA did not claim that (ID 5960, page 85). It should be noted that the letter of 13 March 2002

was sent on 15 November 2002 related to the EEA Agreement.[580] Apparently, Lundbeck never responded to any of these letters.

(285) On 5 July 2002, Merck (GUK) received six new United Kingdom marketing authorisations for the distribution of citalopram tablets of 20 mg (five marketing authorisations) and 10 mg (one marketing authorisation).[581] Merck (GUK) had applied for these additional marketing authorisations in the hope that it could license these to other generic companies wanting to sell in the United Kingdom. The supplier for the purpose of these marketing authorisations was Natco.[582] However, as Article 2(7) of Merck (GUK)'s agreement with Lundbeck explicitly prohibited the granting of duplicates of Merck (GUK)'s marketing authorisation to third parties, nothing came of this during the term of the agreement.

(286) A Lundbeck Business Development document with the title "Generic citalopram update 04 09 2002" stated:

"What have we spent out of the pocket?

Company	Market	Time	Cost	M DKK
Merck Generics	UK	24.1.03	£3M	40
Arrow	UK	31.12.02	£5M	65
Alpharma	EU	30.6.03	$12M	100
Arrow	DK	15.5.03	$0.7M	5
Ranbaxy	EU	10.6.03	$5M	40
Out of the pocket				250

"What have we spent totally?

Company	Market	Margin	Cost	M DKK
Out of the pocket				250
Distribution	UK	£419K per mth	£5M	65

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did not refer to any letter sent on 6 March 2002. It is therefore likely that the letter dated 6 March 2002 remained a draft that was never sent. In any case, the letter of 13 March 2002 reiterated Merck (GUK)'s position that it was not infringing and pointed to the fact that 12 months were now available to resolve the issue: "Our clients do not consider that their Citalopram product will infringe any valid and subsisting Lundbeck patents, but understand that Lundbeck may take a different view. Our clients would like to resolve this issue entirely and although the settlement effectively affords 12 months for the matter to be resolved, there seems no merit in waiting too long to assess the issues.

579 ID 904, page 113.

580 See recital (359) below.

581 ID 682, pages 5-6.

582 ID 1509, page 3.

Merck Generics				
Distribution Ranbaxy	UK	10% vol at 40%	£1.5M	20
Less UK discount anyway			?	(35)
Total spend				***300***

"[583]

These tables show that Lundbeck considered that its purchase of Merck (GUK)'s citalopram tablets and citalopram bulk as well as its distribution agreement with Merck (GUK) amounted to a "Cost" for Lundbeck of GBP 3 million and GBP 5 million respectively, in exchange for which Lundbeck had bought "Time" until 24 January 2003.

(287) In an e-mail to Lundbeck of 28 November 2002 Merck (GUK) proposed to extend the agreement, which was due to expire by the end of January 2003, until the end of July 2003 in exchange for a guaranteed profit of GBP 500 000 per month.[584]

(288) On 20 December 2002, Merck (GUK) internally observed:

"I also spoke to [employee name]* about the position in the UK and he said that he wants to continue the agreement to sell Lundbeck's product until after the trial judgement. I explained to him that we had an excellent case and that we shouldn't get injuncted if Lundbeck sued if we launched in Jan but he seemed happy to wait and not disturb what he sees as a steady market at the moment.

[…] Doesthis mean that the validity of the patents will be contested fully?

It would be better for us if the patents are declared invalid as if only infringement is argued, with a cursory argument on validity which is not proved, we may have to prove our non-infringement at some stage as well if we were to launch our own product in the future".[585]

(289) On 10 January 2003, the two parties agreed to extend their Settlement and Supply Agreement until 31 July 2003 and to slightly vary it.[586] Merck (GUK) was guaranteed net profits of GBP 400 000 per month and a clause was added saying that either party had the right to terminate the agreement if another generic company launched competing generic citalopram in the United Kingdom and Lundbeck did not challenge it through the courts.

(290) On 17 January 2003, Merck (GUK)'s counsel wrote: "we have received no response at all from Lundbeck in response to our various letters to them. That is clearly useful".[587]

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583 ID 904, pages 305-306.
584 ID 673, pages 407-408.
585 ID 1111, page 1.
586 ID 8, pages 223-224.
587 ID 1112, page 1.

(291) On 27 January 2003 Merck (GUK) sent a draft of a supply agreement to the United Kingdom company Ivax Pharmaceuticals UK.[588] According to this draft, the two parties were considering to enter into an agreement under which Merck (GUK) would supply citalopram to Ivax Pharmaceuticals UK for re-sale in the United Kingdom for a period of two years. The draft does not mention when the agreement would enter into force. A Merck (GUK) e-mail of 5 February 2003 explains that the "problem" with the draft agreement is that "Ivax will be expecting imminent delivery whereas GUK do not want to supply before a key court case takes place (not involving GUK) which could take place in about September."[589]

(292) On 9 February 2003, Merck (GUK)'s [employee function]* received the following e-mail: "The court case that was scheduled for Jan which would end our contract has been moved out. This is Know is a pain in the Arse but I have no control over this. Rather than build up a stock mountain I have asked the orders to be pushed out."[590]

On 10 February 2003, Merck (GUK)'s [employee function]* replied and explained in an internal e-mail to the Merck Generics Group:

– "I was expecting a court case to resolve the patent issues in Jan. We intended to launch straight after this[591] as we were confident that the patents would be overturned.

– This case was delayed first until July and now October.

– I intend to launch once the patents have been removed but this is a bit of a moveable feast.

– The last thing I want to do is to mess you guys up but at present I do not think we will launch before Q3/4."[592]

(293) On 21 February 2003, Merck Generics sent a letter to Natco trying to explain why it had entered into agreements with Lundbeck for the United Kingdom and the remainder of the EEA promising not to sell citalopram. With respect to the United Kingdom market, Merck Generics wrote that according to recent United Kingdom jurisprudence, generic companies had to ""clear the undergrowth" by making a F R Q F H U W H G H I I R U W W R G H P R Q V W U D W H W K D W W K H \ decided at the time to come to an arrangement in the UK for one year to allow us time to "clear the undergrowth". This timing has expired however we have continued to stay the watch what happens as Lundbeck are suing other parties. This trial is scheduled for June." It also disclosed its strategy to "wait until June in the hope that Lundbeck succeed and we can enter the market with limited competition. Rest assured that should Lundbeck be unsuccessful we will be vigorously marketing the product".[593]

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588 ID 673, pages 419 to 430.

589 ID 1113, page 1.

590 ID 673, page 434.

591 In reply to the Statement of Objections, Merck KGaA claimed that "GUK was able to build up stock because the Agreements contained a clause in which Lundbeck agreed not to assert its patent rights during the operation of the Agreements." (ID 5960, page 105; a similar argument was made in GUK's reply, ID 6026, page 14) In relation to this comment, which is related to Merck KGaA's argument of "clearing the way", see footnote 593.

592 ID 673, page 434.

593 ID 673, pages 437 to 445.

(294) An internal e-mail of Merck (GUK) of 11 March 2003 summarised the profit Merck (GUK) realised from the two agreements with Lundbeck (regarding the United Kingdom and the EEA excluding the United Kingdom) as follows:

"

	Lundbeck UK	Lundbeck Europe
First Deal	£,000	Eur 000
Profit on sale of stock	2,000	
Guaranteed Profit Feb 02-Jan 03	5,000	
Second Deal		
Guaranteed Profit Feb 03-Jul 03	2,400	
Payments Oct 02-Sept 03		12,000
Total	9,400	12,000

"[594]

(295) On 7 April 2003, a Merck (GUK) employee made the following remarks in an internal e-mail to Merck (GUK)'s [employee function]*:

"Am analysing our Mar results which aren't looking great!

I think we are fooling ourselves with Cipramil. Whilst it is great for turnover we are really only generating extra business for Lundbeck unless we can get something more tangible than their goodwill. It also ties up a great deal of cash which we don't have not to mention warehouse distribution customer service etc.

I know it's a bit negative but it is disguising some underlying issues. With good sales our shareholders will expect good profit which as you can see below is not likely to happen.

	Sales	Margin	%
Sales from Reports	11,941	2,975	25%
Cipramil	4,391	583	13%
[other product]	1,572	1,114	71%
Core Business	5,978	1,278	21%

[594] ID 673, page 474.

Given that we make some £400k in each of Cipramil and [other product] (once everyone had had a piece of it!) and our overheads are close to £2m per month we are struggling to make a profit pre R&D and NTR."[595]

The reaction of Merck (GUK)'s [employee function]* was:

"This only supports my view that we should change tack re citalopram post July. We should also look at slowing the rate of sale to say 150k ish a month to improve the gross margin."[596]

(296) An internal Merck (GUK) e-mail of 2 July 2003 stated regarding "Citalopram 20 mg": "I cannot stress how important this is. I must be able to sell this on the 1st Aug."[597]

(297) An internal Merck (GUK) e-mail of 20 July 2003 shows that Merck (GUK) was preparing itself to start selling Natco citalopram in the United Kingdom as soon as the United Kingdom agreement with Lundbeck expired at the end of July 2003.[598]

(298) On 16 July 2003, Lundbeck sent a draft of a second extension agreement to Merck (GUK), proposing an ensured profit of GBP 250 000 per month to Merck (GUK), instead of the GBP 400 000 per month agreed in the first extension.[599] The justification for this decrease in ensured profit was that there were now "several members in the "club".[600] Lundbeck had calculated internally that "Given an expected monthly turnover of £3M we can go up to more than £1M per month since the other agreements "only" involve a cost of ~£400k together."[601]

(299) A Merck (GUK) internal e-mail of 1 August 2003 said:

"Launched ± first orders out +/- £3mio ± [final offer wasn't good enough!!]."[602]

(300) A Lundbeck document entitled "Generic update citalopram 13 08 2003" stated:

"Deal with Merck Generics UK (MGUK) prolonged

- Initially Lundbeck did not succeed in prolonging the deal with MGUK before its expiry on July 31
- Between August 1st and 4th, MGUK sold generic citalopram corresponding to £3.3M sales into the market
- On August 5th, Lundbeck managed to re-establish the deal with MGUK, effective to the end of the year
  - One month notice
  - £750K per month.[603]

595 ID 673, page 479.
596 ID 673, page 479.
597 ID 673, page 482.
598 ID 673, pages 482 to 485.
599 ID 903, pages 47 to 51.
600 ID 682, page 47.
601 ID 682, page 47.
602 ID 2008, page 2.
603 ID 845, page 103. See also ID 682, page 68.

The citalopram sold by Merck (GUK) between 1 and 4 August 2003 was Natco generic material.

(301) The second extension was agreed on 6 August 2003.[604] Guaranteed net profits to Merck (GUK) were increased to GBP 750 000 per month. The extension was to run until 6 January 2004, but each party had the right to terminate it if Lundbeck failed to initiate legal proceedings against generic entry by another company or in the event that judgment was given against Lundbeck in the Lagap litigation.[605]

(302) On 2 September 2003, Lundbeck wrote an e-mail to its external patent counsel in the United Kingdom: "As discussed several times during the last two years, we believe that it is most likely that the generic citalopram marketed by UK-Generics inf[r]inges our process patents, in particular GP pat no 2357763 (desmethylcitalopram removal process) and EP Patent No 1169314 and the corresponding GB Patent No 2357762 (purification by crystallisation of citalopram free base)." The e-mail continued by explaining the evidence, on which Lundbeck based its belief: "Unfortunately, the process description in the DMF does not describe the purification process in details. As you know, following to the seazure of bulk material in Hamburg, UK-Generics asked us to tell which patents they infringe. However, since the product was out of specifications we justed answered that we could not determine from a product which could clearly not be marketed in Europe and we asked UK-Generics to inform of their process. However, they have not accepted to reveal any details regarding the proc[ess]. Copies of certificates of analysis of Natco bulk samples and Merck samples are attac[hed]. In at least one of the bulk samples we have identified the citalopram desmethyl a[mi]de. This impurity is indicative of the purification process covered by our GB pat no 2357763. […] The 5-acetyl citalopram impurity is present in all samp[les]. Though this impurity may be reduced to the (5-hydroxyethyl)-citalopram, crystallisation of free base is considered as the only likely industrial proc[ess]. In addition to efficient removal of the impurities formed during the alkylation process, the crystallisation of citalopram free base would also make purification of earlier intermediates, such as the 5-cyano-phthalane, superfluous, thus increasing the yield. The 5-cyanophthalane will comprise the corresponding 5-Cl and 5-Br impurities which will be converted to 5-Cl- and 5-Br-citalopram, respectively. These impurities may be removed efficiently by recrystallisation of the free base. I understand from our conversations over the years that it is your view that based on the above it is likely that the UK-Generics product will infringe our process patents if marketed in the UK. Please let me have your written comments."[606]

(303) On 29 September 2003, Merck (GUK) observed in an e-mail: "We have not been sued by Lundbeck. We agreed between us (Lundbeck and Merck Generics) to a voluntary suspension of the selling of our product in UK and Europe for 1 year with the aim of clarifying the issues without resorting to litigation. We wrote several letters to Lundbeck without a response. Lundbeck have had a full opportunity to discuss things but have not responded. We launched in UK recently at expiry of the

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604 ID 8, pages 225-226. Apparently the agreement was backdated: An e-mail between Merck (GUK) and Lundbeck was still exchanging a draft of the agreement on 14 August 2003, see ID 673, pages 497 to 499.

605 See recital (152) above.

606 ID 8, pages 340-341. See also recital (284) above.

UK agreement, we were not sued. (Others have been though). The European agreement expires end of October this year. As a result we believe we cannot be injuncted by Lundbeck in any jurisdiction because of their lack of any attempt to resolve litigation during our voluntary withdrawal from the market"[607]

(304) Between 29 September and 1 October 2003, an exchange of e-mails inside Merck (GUK) discussed a citalopram analysis made by Aceto, Natco's exclusive sales agent. The exchange showed some uncertainty inside Merck (GUK) about whether Natco citalopram might infringe Lundbeck's crystallisation patent.

On 29 September 2003, Aceto sent the following e-mail to Merck (GUK) with the subject line "Claim 3 EP 1169314" (the EP crystallisation patent) containing an analysis of the concentrated mother liquor in form of "Chromatograms":

"The carboxylic acid derivative plays indeed no role as already assumed. [process description]*[608]

[process description]*. Shall we try to collect more data to support this?"

Merck (GUK) internally commented:

"With claim 3 [stating that the impurity is] removed from a crude mixture of citalopram or from a crude salt of Citalopram by precipitating Citalopram base in crystalline form, optionally re-crystallising said base one or more times and /or transferring said base into a salt thereof.

[process description]*. I would interpret that as infringement of the above claim. What is your opinion on this?

To my understanding, the only way that non infringement would be proven is if the said impurity was either not possible due to the synthetic route (as per most of those cited in the claim) or not detectable (as in the case of the carbosylic acid)."

In reply, the point was made, however, that "All the claims in this patent require the precipitation of crystalline citalopram free base. As the Natco process [process description]*, there can be no infringement of the claims regardless of what impurities are removed." The response within Merck (GUK) to this was: "I would just like to understand how do you know that Natco process [process description]*"

The discussion was concluded by the following remarks: "Natco tells us that the citalopram base is not isolated in a crystalline form but we have no evidence other than the batch records. We have left it at that point with the knowledge that the Natco process follows the prior art and if Lundbeck allege the process infringes then their claim must be invalid." It was also observed that "We have launched the product in the UK a few months ago and Lundbeck have not attacked us."[609]

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607 ID 1117, page 1; see also ID 846, page 168.

608 It should be recalled that claim 3 of Lundbeck's crystallisation patent, as finally upheld by the EPO Board of Appeals in 2011, restricted the list of impurities removed through the patented process to halogen elements. See recital (166) above.

609 ID 673, pages 503 to 509. The reference to "the product" concerns Natco's generic citalopram, which Merck (GUK) briefly sold in the United Kingdom market in the first days of August 2003 (see recital (300) above), not the Lundbeck-branded citalopram Merck (GUK) was distributing for Lundbeck. See also ID 1024, page 79 and ID 675, page 36.
In reply to the Statement of Objections, Merck KGaA claimed: "It had to rely on what Natco said", which would have added to its uncertainty regarding potential patent infringement. ID 5960, page 212.

(305) On 29 September 2003, Lundbeck internally considered the strategy it would follow in case of a "Total victory" in the Lagap litigation. A total victory would mean a "Court case outcome: Patent validated; Matrix infringes":

"Agreements

Merck Generics (Natco) – seeks to prolong agreement

Arrow (Cipla & Matrix) and [«]* (Cipla) – agreements terminate automatically, do nothing

Alpharma (Cipla & Matrix) – agreement has terminated, do nothing

Ranbaxy (Ranbaxy) – agreement terminates 31 Dec 2003 – do nothing or consider prolonging the agreement"[610]

(306) On 10 October 2003, while Lundbeck was preparing its settlement with Lagap, Lundbeck told Merck (GUK) it wanted to terminate the agreement with Merck (GUK) as of 1 November 2003. Merck (GUK) therefore decided the time had now come to offer other companies active in the United Kingdom, including Ivax Pharmaceuticals UK, supply contracts for Natco citalopram for delivery as of 1 November 2003.[611] Following Lundbeck's conclusion of the settlement with Lagap on 13 October 2003, Lundbeck formally terminated the agreement with Merck (GUK) on 22 October 2003 with effect from 1 November 2003. In its letter to Merck (GUK), the Lundbeck representative wrote: "I know that both companies have E H Q H I L W H G I U R P Z R U N L Q J W R J H W K H U «[612]

(307) In total, over the entire period of operation of the agreement from 24 January 2002 to 1 November 2003, Lundbeck transferred a value to Merck (GUK) of GBP 12.65 million (corresponding to approximately EUR 19.4 million)[613] under the agreement regarding the United Kingdom, consisting of:

– GBP 3 million for Merck (GUK)'s stock of Natco material;

– GBP 5 million of guaranteed profit in the first year;

– 6 times GBP 400 000 in the first extension between February 2003 and July 2003 = GBP 2.4 million;

In its reply, also GUK submitted that it faced uncertainty given that it had "no evidence other than the batch records" (claiming that it "did not have the data to verify") and "there were many indications in the data provided by Aceto that Natco was potentially infringing". ID 6026, pages 35, 41, 46-48. However, the e-mail exchange also shows that Merck (GUK) decided "We have left it at that point". This means that all in all Merck (GUK) did not consider it necessary to request any further data. Furthermore, it should be recalled that according to Article 5.1 of Merck's agreement with Schweizerhall, Merck had inspection rights, which it could have exercised had it considered that necessary: "MG-Group shall have the right to visit Natco's plant where the API is manufactured on any business day upon reasonable prior written notice to Schweizerhall". During such visit, Merck was entitled to "perform a reasonable audit of Natco's manufacturing and quality control procedures, records, facilities as well as all supplements to ensure that Natco complies with the current Rules Governing Medicinal Products".

610 ID 846, page 7.

611 ID 673, page 513.

612 ID 682, page 81.

613 Using an average annual exchange rate for 2002 of 1 EUR = 0.62883 GBP and for 2003 of 1 EUR = 0.69199 GBP, source European Central Bank.

– 3 times GBP 750 000 in the second extension between August 2003 and end of October 2003 = GBP 2.25 million.

7.2.4. Subsequent events

(308) An internal Merck (GUK) e-mail of 12 November 2003 shows that Merck (GUK) kept meticulous track of whether the amount of profit actually received from its sales of Lundbeck citalopram in the United Kingdom corresponded to the ensured profit amounts agreed in the main United Kingdom agreement and its two extensions. These calculations show that at that point in time Lundbeck still owed Merck (GUK) slightly over GBP 1 million for the three agreements together. The figures were sent to Lundbeck "to finish off Cipramil."Over the entire period, Merck (GUK) had sold close to GBP 50 million worth of Lundbeck product in the United Kingdom. [614]

(309) When Merck (GUK) re-started selling Natco citalopram in the United Kingdom as of 1 November 2003, Lundbeck did not start infringement proceedings against it.[615]

7.3. Lundbeck's agreement with Merck regarding the EEA excluding the United Kingdom

7.3.1. The negotiation of the agreement

(310) As Lundbeck explained to the Commission, "Lundbeck initially concluded an agreement with Generics UK covering only the UK because Generics UK initially had marketing authorisation only in the UK.[616]"

(311) An internal Merck (GUK) document of 21 June 2000 indicated in the Commission's view that once GUK would have obtained a marketing authorisation for citalopram in the United Kingdom, which at that time it expected in February 2001 based on raw material supplies from VIS[617], it intended to use the mutual recognition procedure to submit applications in April 2001 for marketing authorisations in Germany, Spain, Austria, Sweden, Belgium, Finland, France, Denmark, the Netherlands, Ireland and Norway. In all these countries, Merck (GUK) expected to obtain marketing authorisation by December 2001. The same document mentioned that "Iceland, Luxemburg, Italy and Greece are also interested.[618]"

(312) An internal Merck (GUK) e-mail of 19 March 2001 also shows that Merck (GUK) was planning for market entry into other EEA Contracting Parties than the United Kingdom, partly via the Swedish generic supplier NM Pharma: "The registration strategy of UK, Sw and France allows each of these 7 months to get a licence, prior to patent off.[619]"

(313) On 15 May 2001, as already explained, Merck (GUK) concluded a Development and Supply Agreement regarding citalopram with Schweizerhall based on Natco's citalopram. Merck (GUK) contractually committed itself to file for marketing

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614 ID 673, pages 515 to 519.

615 ID 660, page 8, ID 823, page 49.

616 ID 823, page 51.

617 As described in recital (177) above, Merck (GUK) suffered a loss of about ten months in obtaining United Kingdom marketing authorisation due to Lundbeck's withdrawal of VIS' Drug Master File. Merck (GUK) re-submitted the application, now with Natco as raw material supplier, to the United Kingdom Medicines Control Agency on 14 June 2001.

618 ID 673, page 23.

619 ID 675, page 2.

authorisations in Germany, France, Finland, Norway, Sweden, Belgium, Netherlands, Spain and Italy. For further details see recital (234) above.

(314) An internal Merck (GUK) e-mail of 12 June 2001 shows that Merck (GUK) was co-operating with the Swedish company NM Pharma to sell the citalopram Merck (GUK) would buy from Natco in Sweden.[620]

(315) On 14 June 2001, Merck's German subsidiary Merck dura concluded a supply agreement for citalopram with Tiefenbacher for sales in the German market.[621]

(316) A Merck (GUK) e-mail of 21 June 2001 stated the following:

"With respect to the filing of the Citalopram dossier in Sweden in the name of NM Pharma at this time we perceive the following potential interaction with Lundbeck:

There is a very high risk that Lundbeck will issue a threatening letter (100%), if for no other reason than to gain more information about our product.

There is also a high risk (75%) that they will sue us on the grounds of process or quality or both.

Purchase of VIS allowed them to publicly question quality with the Health Authority.

If we are sued we perceive there will be a low risk (15%) of being injuncted based on the fact that we clearly follow the synthetic process as disclosed in the basic patent.

If we are injuncted we believe we have a high potential of winning (90%).

The whole process will involve lawyers, expert witnesses and Merck Generics extend their full support, co-operation, and experience in fighting any litigious action brought about by Lundbeck."[622]

(317) On 12 October Merck (GUK)'s [employee function]* wrote to Schweizerhall, Aceto and Natco:

«LW LV QRZ WLPH WR PRYH IRUZDUG LQ UHDGLQHVV This will vary in some markets from having documentation ready for when they try to injunct us, through the use of protective writs. There is the potential to prepare for UK, Sweden, France and Germany. In order to do this we need to provide certain documentation to our lawyers which they will ask us from time to time."[623]

(318) An internal Merck (GUK) e-mail of 3 January 2002 indicates that the national Swedish submission for marketing authorisation was made on 21 August 2001 and the French on 20 September 2001.[624]

(319) An internal Lundbeck e-mail of 13 February 2002 indicates that Lundbeck had become aware that the Swedish company NM Pharma expected a marketing authorisation in Sweden, based on Natco material from Merck (GUK).[625] Moreover, NM Pharma had a strong distribution network in Norway.[626] Around this time,

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620 ID 673, page 143.

621 ID 1267, page 15. See also ID 1272.

622 ID 675, page 6. With respect to Merck (GUK)'s awareness of a possible infringement risk posed by the crystallisation patent, see recital (113) and footnote 454 above.

623 ID 1997, page 2.

624 ID 675, page 17.

625 ID 723, page 66.

626 ID 681, page 130.

Merck (GUK) was in fact shipping Natco citalopram to the Merck subsidiary[627] Gerard Laboratories in Ireland. Some of this material was destined for sale in Sweden, Norway, Denmark and Finland.[628] An e-mail from Gerard to Merck (GUK) of 6 February 2002 states in this respect: "Sweden to launch in March, Norway, Denmark and Finland 3 months later."[629]

(320) In reply to the Statement of Objections, Merck KGaA argued that the injunction proceedings against Tiefenbacher in the United Kingdom and elsewhere lead Merck (GUK) to believe "the risk of injunction to be similarly high". In support, Merck KGaA quoted the following e-mail of 18 February 2002: "the obvious outcome we would like is that all get injuncted and this then spreads into Europe in some ZD\«6ZHGLVK OLFHQVH LV RQ WKH ZD\ DQG 05 LV LQ that ZH KDYH WKH XVXDO ORQJ OHDG"[630] However, even anything, this e-mail shows that Merck (GUK) saw a unique opportunity for launching its own generic with limited competition, if generic companies relying on the Tiefenbacher file were to be injuncted throughout Europe.[631] While Merck (GUK) observed that Lundbeck litigated against other generic companies across Europe, it also quoted an e-mail showing that Merck (GUK)'s case differed from those litigated by Lundbeck in Sweden: "We also have to bear in mind that for our product Lundbeck is searching for a specific intermediate which we do not have because we changed to the other basic process. So they cannot use the same arguments as they used first time against Ratiopharm and Biochemie."[632] Nevertheless, the litigation, in Merck KGaA's view, showed legal uncertainty in the market.[633] Merck KGaA submitted that "[g]iven Lundbeck's all-out-attack on several European fronts", "on the one hand, [Merck (GUK) …] prepared for generic launch at risk and widespread litigation; on the other hand, it began discussions with Lundbeck. This dual strategy was also the result of increasing uncertainty."[634]

(321) For the e-mail of 25 February 2002 exchanged between Merck dura and Merck (GUK) see recital (280) above.

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627 ID 1509, page 3.

628 ID 673, pages 275-276, 318, 322. Probably all of this material was to be distributed in these countries by the Swedish company NM Pharma. See recital (326) below.

629 ID 673, page 318.

630 ID 1021, page 2; ID 5960, page 87.

631 See ID 1021, page 29 and ID 673, page 439 and recital (293) above.

632 ID 5960, pages 83-111; ID 1021, page 31 (e-mail of 9 August 2002 related to Sweden). Pointing to certain proceedings in the Netherlands (ID 5960, page 88), Merck KGaA claimed that the Statement of Objections did not sufficiently acknowledge the risk that national court proceedings might have been suspended until completion of EPO opposition proceedings. A similar argument was made by GUK in reply to the Statement of Objections in particular with respect to Germany (ID 6026, pages 54-55). The Commission notes that it is clear that the suspension of proceedings in view of EPO opposition proceedings in a Member State is only one of many possible steps that may be considered by a court.

633 In relation to "uncertainty", Merck KGaA pointed to the patent law doctrine of equivalents. According to Merck KGaA, this doctrine requires that "the meaning of the invention", that is to say not just the wording, is considered to determine any possible infringement. The doctrine therefore potentially extends the scope of the patent beyond its literal interpretation. See ID 5960, pages 25, 89-90, 206-211, 290, 300 and 303.

634 ID 5960, page 88.

(322) An internal Merck (GUK) e-mail of 7 March 2002 mentioned Natco product destined for "Europe, initially Sweden/France."[635]

(323) On 29 April 2002 Merck Generics' Swedish subsidiary reported to Merck (GUK) that Lundbeck had obtained approval of its crystallisation patent in Sweden and had sent a letter to Swedish pharmacies announcing actions against companies which Lundbeck considered involved in an infringement of this patent. Lundbeck's letter referred to Ratiopharm and Biochemie, which "have been informed about the patent application but have choosen to market their copies of Cipramil".[636]

(324) The first mention of a possible agreement between Lundbeck and Merck (GUK) regarding the EEA (excluding the United Kingdom for which an agreement already existed) was made in an internal Merck (GUK) e-mail of 1 May 2002: "I XQGHUVWDQG « \RX DUH VWLOO GHDOLQJ ZLWK /XQGEHFN The e-mail also mentioned the need to think about "compensating" Aceto (Natco's exclusive sales agent).[637]

(325) On 3 May 2002, NM Pharma received a national marketing authorisation in Sweden for Natco citalopram from Merck (GUK).[638] Sales by NM Pharma in Sweden started on 21 May 2002 and were "very encouraging".[639]

(326) In a contact with Lundbeck, on or shortly prior to 28 May 2002[640], Merck (GUK) informed Lundbeck that NM Pharma had launched the Natco product on the Swedish market[641] and that NM Pharma would use the mutual recognition procedure to obtain additional marketing authorisations in Finland, Norway, Denmark, the Netherlands, Belgium and Spain. Merck (GUK) further said that on 6 June 2002, Merck (GUK) would start a mutual recognition procedure based on its own United Kingdom marketing authorisation for "the remaining countries": Ireland, France, Germany, Austria, Italy, Portugal and Greece. Merck (GUK) also told Lundbeck [incorrectly] that it held "exclusive rights for Natco".[642] According to Lundbeck's report, Merck (GUK) had said: "The UK deal has been very beneficial for Lundbeck." Lundbeck reported that Merck (GUK) was "interested in a new deal." Lundbeck replied in

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635 ID 673, page 339.

636 The reaction from Merck (GUK) was: "I'd just like to remind everybody we have already in our possession a signed ekU W UHSRUW « DERXW RXU SURFHVV 7KH FRQFOX Notwithstanding this we have also arguments against the Lundbeck 'position' if needed." ID 673, pages 347-348. See also ID 1024, page 79, ID 675, page 36 and ID 1021, page 7 (where Merck (GUK) mentioned that it expected a warning letter from Lundbeck as a result of NM Pharma's citalopram approval in Sweden).
In relation to this expert report, in reply to the Statement of Objections, GUK clarified that GUK had commissioned the Expert Report at the end of 2001. "[The expert …] advised only on whether the Natco process fell within the scope of the original compound patent GB1526331 or the EP patent ZKLFK SURWHFWV /XQGEHFN¶V F\DQRSKWDOLV but not whether the Natco process follows the process as set out in the original compound patent. However, his Expert Report does not assess potential infringement of patents other than the two patents GB1526331 and EP 0171943 and its conclusions are therefore limited accordingly." See ID 6026, pages 34-35.

637 ID 673, page 350; see also page 352. Aceto was mentioned here in the United Kingdom context, not the EEA context.

638 ID 847, page 31.

639 ID 1022, page 4.

640 ID 907, page 167.

641 See also ID 848, page 38.

642 See recital (235) above.

these negotiations that it believed Natco was infringing and that it would be forced to start legal action in Sweden very soon. Lundbeck then asked for a "valuation of a deal" for:

- "Sweden 12 months
- UK 6 months extension
- Remaining EU 12 months."

(327) In an internal e-mail to other Merck Generics subsidiaries in Europe, Merck (GUK) wrote on 28 May 2002: "We are currently in discussion with Lundbeck regarding the best strategy for Europe for Citalopram. In order to progress these discussions we URGENTLY need an annual forecast from you"[643].

(328) Internal Merck (GUK) sales forecasts of Natco citalopram in Europe, dated 5 June 2002, show that Merck (GUK), partly via NM Pharma and partly via other Merck Generics subsidiaries, intended to sell in:

- Austria (as of January 2003)[644];
- Denmark (as of March 2003);
- Finland (as of May 2003);
- France (as of June 2002);
- Germany (as of December 2002);
- Ireland (as of February 2003);
- Italy (as of January 2004);
- Netherlands (as of December 2002);
- Spain (as of May 2003); and
- Sweden (as of May 2002).

The amount of sales estimated for one year of sales after market entry was EUR 21 million, of which almost EUR 14 million was profit.[645]

(329) On 6 June 2002, Lundbeck sent to Merck (GUK) a draft of an agreement for the EEA excluding the United Kingdom. The draft mentioned that Merck (GUK) was the exclusive supplier of Natco in this territory. The draft proposed that Lundbeck would pay EUR 7.5 million to Merck (GUK) "in consideration of the settlement arrived at."[646]

(330) In an internal e-mail of 6 June 2002, a Merck (GUK) employee clarified:

«LW PXVW EH XQGHUVWRRG WKDW ZH GR QRW KDYH Natco. We have an exclusive agreement as far as purchase price is concerned but if we did not agree to purchase at the proposed Natco price they can go elsewhere so clause 3 page 2 of the draft EEA agreement under negotiation with Lundbeck,

643 ID 675, page 34.
644 In fact, Lundbeck enjoyed patent protection in Austria until April 2003, see recital (111) above.
645 ID 675, pages 38 to 44.
646 ID 682, pages 181 to 186.

talking about Merck (GUK) being exclusive supplier for Natco; this is actually clause 4 on page 2 of the draft agreement – the word "exclusive" was deleted in the final agreement] L V Q R W D F F X U D W H « X Q O H V V Z H J H W D Q D effectively purchase (or be compensated enough by Lundbeck to allow us to purchase) all the forecasted RM [raw material] from Natco for this 1 year.

I also feel the value in the contract is far too low and should be probably 3 times higher (plus RM [raw material]). If Merck and Natco are Lundbeck's worst nightmare they can afford to pay more for the advantage they get. Our patent position is strong and Lundbeck have so far not responded in the UK to our letters etc. This must bode well and make it extremely difficult for any future attempts by Lundbeck to get an injunction in UK.

I also presume that if we do sign any agreement at a fair price there will be no attempt at 'circumventing it' although that it seems to be possible with the contract as it stands.[647]

(331) The reaction of a second Merck (GUK) employee on the same day to this e-mail was:

On the lack of an exclusive supply agreement with Natco:

1 % S R L Q W « D Q G / X Q G E H F N Q H H G W R X Q G H U V W D Q G W

On compensation for Natco and the settlement amount:

« E H D U L Q P L Q G W K D W W K H U H D U H W Z R Z D \ V W R O R we are fearful that we may not U H Y D L O L Q W K H F R X U W V « L Q Z K L F K V H O O D Q \ P D W H U L D O D Q \ Z D \ « D Q G D W O H D V W L Q D Q \ V W U R Q J O \ D E R X W Z L Q Q L Q J W K L V « E X W W K H V H W K L Q J to make something out of this, [even tho we would not be on all Eu markets in any H Y H Q W « L W L V O R J L F D O W R O R R N D I W H U 1 D W F R « D Q this cost on to Lundbeck as far as is possible. If we cannot do this fully (or at D O O « Z H Z L O O Q H H G > I R u c h a s f o r a n y t h i n g e l s e] t o s h i f t D V of the settlement compensation."[648]

(332) In an e-mail to Lundbeck of 10 June 2002, Merck (GUK) wrote with respect to the draft agreement:

"We clearly will require further input from you in relation to our raw material commitments. We have just over 2,000 kgs in stock or in transit for launch requirements at US$5,500 per kg. The future of this material needs to be agreed. Ideally, Lundbeck should purchase this from MGG [Merck Generics Group].

NM Pharma in Sweden market our product but on their licence. Their profit S U R M H F W L R Q V D U H ¼ P L R I R U[649] W K H S H U L R G X Q G H U G

(333) On 18 June 2002, Merck (GUK) sent an e-mail to Lundbeck with the following content:

"Original 7.5 for MGG [Merck Generics Group] stands

Additional 2.5 for NM [NM Pharma]

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647 ID 673, page 365. For a possible meaning of the "circumventing" aspect, see recital (351) below.

648 ID 673, page 374.

649 ID 682, page 190.

API +/- US$5"[650]

(334) An exchange of internal Merck (GUK) e-mails of 19 June 2002 related to "French citalopram" raised a problem in France:

"According with a patent problem on the active ingredient, citalopram dossier is blocked at the French authorities. The dossier was assessed, he received a favourable unformal agreement, but the formal agreement is delayed according with the decision on the patent"

A Merck (GUK) manager replied:

"7KH EDVLF FRPSRXQG DQG 63& LQ)UDQFH KDV H[SLU have a patent problem at all[651]. Please can you explain the situation [to Merck employees] because they are defending this allegation from the brandleader.

Please can you explain what the issues are relating to the patents. We even have expert statements available about our process. We are selling in Sweden and the brand has not injuncted us yet"[652]

(335) An internal Lundbeck document of 20 June 2002 stated:

"Deal with Merck Generics has been turned down because they doubled the price we will now pursue NM Pharma in court and try to make a deal with NM Pharma at the same time."[653]

(336) An e-mail of Pharmacia (NM Pharma's owner) to Merck (GUK) dated 26 June 2002 informed:

"No WC semifinal for none of us but we all have a mutual winner in Citalopram.

I have just received some additional sales figures for Citalopram Sweden, which is encouraging.

In May the AIP turnover was 86 tEUR, the figures for June until today is 312 tEUR.

Not only that, GEA the last competitor to Citalopram for the moment on the Swedish market has withdraw[n] theirs product. They have probable received a 40 pages greeting from Lundbeck."[654]

(337) An internal Lundbeck "generic citalopram update" of 28 June 2002 mentioned that "NM Pharma received a national Swedish registration 3 May based on Natco and Merck Generics" and that Merck (GUK) "Has also filed a national French

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650 ID 683, page 1.

651 GUK claimed confidentiality for the text in square brackets. ID 673, page 124 compared "Natco's proposed synthetic process" against the processes claimed in Lundbeck's compound patent and concluded that it infringed those processes as long as the compound patent was not yet expired.

652 ID 675, page 63. With respect to the "expert statements" to which this document refers, in its reply to the Letter of Facts (ID 6812, page 11), GUK claimed that the same reservations may apply as for ID 673, pages 347-348 (see footnote 636 above). However, ID 675, page 63 speaks about "statements", apparently several expert opinions. In any case, on 24 October 2002, Merck (GUK) internally concluded again: "ZH VWLOO GRQ¶W LQIULQJH Natco's patent" (see recital (757) below. For further details with respect to Merck (GUK)'s patent assessments, see recital (754) below.

653 ID 846, page 36. An internal Merck (GUK) e-mail of 19 June 2002 confirms that at this point in time negotiations broke down. See ID 673, page 384.

654 ID 1021, page 13.

application"[655] This document expected launch dates for Natco material distributed via Merck (GUK) in June 2002 in France, August 2002 in Austria, October 2002 in Germany, the Netherlands, Spain and Ireland, November 2002 in Belgium, December 2002 in Denmark, March 2003 in Finland and October 2003 in Italy.[656] On the envisaged agreement with Merck (GUK), the document explained:

"- $JUHHG SULFH ¼ 0

- 6XGGHQO\ WKH SULFH WDJ GRXEOHG WR ¼ 0

¼ 0 ¼ 0 1M (Natco)

- No thank you.[657]

The same document explained that, following the break-down in negotiations with Merck (GUK), "26 June [2002] we submitted data re Natco impurities to MCA [the United Kingdom Medicines Control Agency] and we allowed MCA (at their request) to disclose the data to Merck Generics. Our aim is to try to delay the MRP [mutual recognition process] and to question the UK license."[658]

(338) On 11 July 2002, an internal Merck (GUK) e-mail stated: "… we are waiting and preparing for Lundbeck to attack us around the world and inquired about invalidity arguments.[659] At the same time, Merck (GUK) internally considered: "we need to discuss the status of some of the more material cases across the group to assess criteria for: (a) Initiating action [as oposed to responding] (b) Continuing or settling disputes. You will note that some of the legal fees are significant and we therefore need to look at the ROI of this and what actions are needed to manage and to reduce these amounts if they cannot be avoided altogether."[660]

(339) An internal Lundbeck document of 20 August 2002 indicates that Lundbeck intended to invoke its crystallisation patent against Natco citalopram sold by NM Pharma in Sweden as soon as the EPO would have granted it (which occurred on 4 September 2002).[661]

(340) An e-mail exchange of 26 August 2002 between Recordati, Lundbeck's co-marketing partner for Lundbeck-produced citalopram in Italy, indicates that Merck (GUK) had lodged an application for a marketing authorisation in Italy under the mutual recognition process, based on its United Kingdom marketing authorisation. Recordati inquired after Lundbeck's intentions and stated: "There is no need to stress the business at risk."[662]

(341) In an internal Lundbeck e-mail of 29 August 2002, Lundbeck reported to its subsidiary in Ireland on a contact that had just taken place with Merck (GUK): "They

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655 ID 848, page 37.
656 ID 848, page 38.
657 ID 848, page 39.
658 ID 848, page 40. Lundbeck undertook a similar approach to the Italian medicines evaluation body in September 2002. See ID 681, pages 119 to 123 and 141 to 143 and ID 356, pages 69 to 72.
659 ID 1021, page 27.
660 ID 675, page 66.
661 ID 816, page 100.
662 ID 903, page 142. See also Recordati's e-mail of 2 September 2002: "We do not have too much time." See ID 681, page 118.

[Merck (GUK)] say that the MRP [mutual recognition procedure] is finalised on 4 November 2002 and that they expect to launch [in Ireland] in March 2003.[663]

(342) On 4 September 2002, the EPO granted Lundbeck's crystallisation patent, which covered a purification manufacturing process.[664]

(343) An internal Lundbeck "generic citalopram update" of 4 September 2002 stated:

"Merck Generics and Natco

- MRP [mutual recognition procedure] for IRL, GER, I, B, LUX, B & POR will have day 90 on 4 Nov 2002
- It is expected that NM Pharma has a similar MRP for FIN, N, DK, NL & ESP with day 90 in Oct or Nov 2002
- Generic Natco citalopram is expected to hit the market in Q1 2003."[665]

(344) A Lundbeck Business Development document with the title "Generic citalopram update 04 09 2002", stated the following:

"Natco

[…]

- Merck Generics is based on Natco and is on the market in Sweden
- Potential problems with impurity levels
- Possibly crystallising and infringing
- We are building a case against them

[…]

Sweden±NM Pharma

- NM Pharma does not want to talk to us
- (PDLO IURP «3KDUPDFLD RZQHUV RI 10 3KDUPD

"Thanks for inviting us to a meeting but no thanks, we have nothing to discuss. Under our Global Standards of Business Conduct and our Antitrust Policy, we cannot engage in further discussion on this topic.""[666]

(345) On 9 and 10 October 2002, an exchange of Merck (GUK) e-mails discussed the issue of existing stocks (API and tablets) and orders of API in relation to the proposed deal with Lundbeck.[667]

Regarding the proposed deal with Lundbeck, considering the internal evaluation of API on stock and on order, Merck (GUK) concluded:

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663 ID 723, page 3.

664 See recital (113) above.

665 ID 904, page 278.

666 ID 904, pages 255 and 303. One month later, in October 2002, Lundbeck made an agreement with NM Pharma's supplier of generic citalopram Merck (GUK) that Merck (GUK) would stop supplying NM Pharma. See section 7.3 above.

667 ID 673, pages 386-389.

"We have an "agreed offer" on the table at the moment which substantially offers us a "bird-in-the-hand" situation which ***I feel gives us a strong result even taking the below into account.***

I have already put Alpha on hold[…]

The deal is for 12 months which means that, depending on a possible further lucrative extension, we could start manufacture again mid-2003 and use up most of the existin[g raw material].[668] (Highlighting added)

Merck (GUK) did not expect any problems with extending the shelf life of the citalopram raw material, as the product was considered stable.[669]

With respect to existing stocks and orders, the e-mail exchange listed in total US$ 9,234,000 worth of API, of which around 20 per cent was "on hand" and around 80 per cent "on order" (half of which related to Alpha). However, these numbers were apparently not finalised: "As things stand now, we have this supplier gearing up for NLORV IRU « DQG ORRNLQJ DW WKH DERYH Q where the 3000 comes from [although accept that no monthly figures are in for (XURS".H[670] « @

Regarding "manufactured tablets", the e-mail commented: "…we either sell them± or find a place to sell± RU LWV ".DConcerning orders, the e-mail concluded: "Where orders are in for manufacture[…] your call as to whether these are put on KROG QRZ ".RU ODWHU «[671]

The same e-mail asked whether USD 1 million was enough to compensate Natco, which was confirmed as probably being sufficient given that there were "many options for the discussion with Natco."[672] As part of the e-mail exchange, Merck (GUK) considered that "The supplier will need some explaining [and probably something more tangible] if they are to understand any serious reductions to our forecast ± which will be needed as the lower orders are made or are delayed/cancelled."[673]

(346) In an e-mail of 11 October 2002, Lundbeck confirmed to Merck (GUK): "OK to the 12 mill euro."[674] The settlement amount having thus been agreed, the two parties exchanged a number of drafts of a full-fledged agreement in the following days. At this time, as of 7 October 2002, in anticipation of the conclusion of an agreement

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668 ID 673, page 387. A similar content has a different Merck (GUK) e-mail of 9 October 2002 commenting on the "deal": "which means re-scheduling production mid-2003 […]". See ID 1021, page 35.

669 ID 673, page 386. With respect to tablets, the e-mail exchange considered: "The shelf life of a finished product only starts from the time of manufacturing of the tablets".

670 It should be noted that moreover, the numbers in that e-mail do not appear to add up, because under "1.", the e-mail listed "API on hand at Alpha" as 397 Kgs and "API on order by Alpha" as 575 Kgs, whereas the summary just counted these latter 575 kgs. Moreover, some figures had unresolved comments such as, for instance, API allocated to "Alpha": "most of these are 'reject' status± which I understand Alpha has to resolve with the supplier [otherwise a very expensive write-off is coming up]". See ID 673, page 388.

671 ID 673, page 388.

672 ID 673, page 386.

673 ID 673, page 389.

674 ID 903, page 129.

with Lundbeck, Merck (GUK) stopped making deliveries of Natco material to NM Pharma.[675]

(347) By the time Merck (GUK) and Lundbeck entered into an agreement for the EEA excluding the United Kingdom on 22 October 2002, Merck (GUK) had obtained one marketing authorisation for generic citalopram based on Natco's Drug Master File in the territory covered by the agreement, namely in Sweden (3 May 2002).[676] After concluding the agreement with Lundbeck, and during its operation, Merck (GUK) obtained further marketing authorisations based on Natco's Drug Master File in Austria (10 December 2002), Belgium (16 December 2002), Norway (17 January 2003), Denmark (26 February 2003), Luxemburg (26 February 2003), Germany (29 April 2003), Finland (16 May 2003), Portugal (17 May 2003), Ireland (3 June 2003) and France (30 September 2003).[677]

7.3.2. The agreement

(348) On 22 October 2002, H. Lundbeck A/S and Merck (GUK) concluded a "Settlement Agreement" for a year, covering the EEA excluding the United Kingdom.[678]

The preamble to the agreement stated that "GUK is a supplier in the Territory of pharmaceutical products containing Citalopram manufactured by or on the basis of deliveries from Natco Ltd. ("Natco")" (preamble, Point D). The preamble also stated that Lundbeck had performed laboratory analyses of Merck (GUK)'s citalopram and believed that Natco's production method to produce Merck (GUK)'s citalopram infringed Lundbeck's patents or patent applications in different European countries, as listed in appendix A to the agreement. (Point F) This appendix listed the different national equivalents of Lundbeck's crystallisation patent "(the validity of which is not admitted by GUK)." The preamble then continued by saying that "GUK has disputed that the production method used by Natco Ltd. and/or GUK infringes Lundbeck's intellectual property rights" but that "Lundbeck and GUK have arrived at a settlement in order to avoid costly and time-consuming patent litigation, the outcome of which cannot be predicted with absolute certainty" (Points G and H) At the time of conclusion of the agreement, no litigation was taking place between Lundbeck and Merck (GUK) anywhere in the territory covered by the agreement.

In Article 1.1 of the agreement, Merck (GUK) agreed that, "subject to payment of the Settlement Amount", it "shall cease the sale and supply of pharmaceutical products containing Citalopram in the Territory to its Affiliates and/or to any third party (including, without limitation, ceasing to sell and supply NM Pharma AB) during the term of this Agreement and shall use all reasonable efforts to ensure that Natco ceases to supply Citalopram and products containing Citalopram in the Territory for the term of this Agreement."

"Affiliates" should be understood to mean other companies in the Merck Generics Group.[679] An appendix B listed all the citalopram sales Merck (GUK) had made

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675 ID 683, pages 60 and 62. See also ID 675, pages 84 to 89 and 90 to 97.

676 On 18 April 2002, Merck dura obtained a marketing authorisation in Germany. However, this marketing authorisation was based on Tiefenbacher's Drug Master File (using Matrix and Cipla as API suppliers), not on Natco's Drug Master File. See ID 1273 and ID 1267, page 23.

677 ID 1273.

678 ID 8, pages 227 to 233.

679 See the definition of "Affiliate" in Article 1.1 of the agreement.

between 1 January 2002 and 17 October 2002 in the territory (the EEA excluding the United Kingdom). All sales listed had been to NM Pharma in Sweden. Article 1.1 further confirmed that:

"GUK and GUK's Affiliates have made no further sales of products containing Citalopram since 1 October 2002 in the Territory."

Article 1.2 of the agreement stated:

"In consideration of the settlement arrived at between the parties hereto Lundbeck shall pay to GUK EUR 2 million within one month of the Effective Date." Three million euro was to be paid immediately and the remainder in monthly instalments until the expiry of the agreement. The article ended with the following provision:

"Notwithstanding the foregoing, it is expressly understood and agreed that Lundbeck shall not be required to make any payment pursuant to this Article 1.2 which has not yet fallen due in the event that Natco supplies Citalopram or products containing Citalopram in the Territory during the term of this Agreement."

Article 1.5 of the agreement stated:

"The parties will during the term of this Agreement use all reasonable efforts to seek to resolve their disagreement of the issues set out in the Recitals."

Article 4 provided: "…upon the effective date of termination of this Agreement for whatever reason, any party shall be entitled to exercise and prosecute any intellectual property rights owned by or licensed to such party as such party sees fit."[680]

(349) In the light of their wording, the provisions in Article 1.1 and 1.2 appear to have had a dual purpose for Lundbeck: Firstly, Merck (GUK) committed itself not to sell any citalopram in the EEA excluding the United Kingdom, including to group companies and third party suppliers, from whatever supplier the citalopram came. Secondly, Lundbeck would only continue paying the settlement amount as long as the API supplier Natco refrained from selling in the territory, to whatever buyer, whether within or outside of the Merck Generics Group of companies.[681] Lundbeck therefore

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680 In reply to the Statement of Objections, Merck KGaA argued that Article 4 of the EEA agreement was only a standard formality. See ID 5960, page 155. Moreover, Merck KGaA went so far as to claim that "the fact that Lundbeck allowed GUK to prepare the launch immediately after expiry of the EEA Agreement even indicates that Lundbeck had objectively and implicitly waived its right to assert its patent rights against GUK post expiry" (ID 5960, pages 301 and 310) GUK argued that Article 1.5 "was intended to protect GUK against litigation from Lundbeck upon expiration of the Settlement Agreements" (ID 6026, page 25) The Commission notes that Article 1.5 coexists with Article 4. The latter determines that no party waives any of its intellectual property rights, in particular also not any right to request interim injunctions. In fact, to avoid any misunderstanding Article 4 explicitly reserves each parties' right to prosecute any patent right "upon the effective date of termination of this Agreement". GUK's and Merck KGaA's argument is therefore in plain contradiction to the wording of Article 4 of the agreement. In this respect, Lundbeck clarified that the agreements "did not finally resolve the disputes" (see recital (80) above). Moreover, Merck (GUK) internally stated at the time for the (rest of the) EEA: "[I]f and when the time comes to discontinue the agreement we will be ready to defend our rights". (See recital (355) below; Merck (GUK) made a similar statement for the United Kingdom: see recital (288) above.) This shows that Article 4 in the EEA agreement was not just a formality, did not "protect GUK against litigation" and that Merck (GUK) knew very well that the agreements did not resolve its patent dispute with Lundbeck.

681 Lundbeck later explained to the Commission that it believed "that Generics UK had an exclusive agreement with Natco and therefore, to Lundbeck's knowledge, [Natco] could not deliver citalopram in

aimed for the agreement to have effect both towards Merck (GUK) and (indirectly) towards Natco.

(350) With respect to the settlement amount, one may observe that the amount of EUR 12 million agreed with Lundbeck comes very close to the profit projections Merck (GUK) had prepared on 6 May 2002 for one year of sales of Natco citalopram after market entry in the EEA.[682] Those projections had shown close to EUR 14 million of profit for Merck (GUK). However, from this amount should be deducted sales that would start only after the agreement with Lundbeck had ended, such as in Italy where sales would not start before January 2004. Italy accounts for almost EUR 2.5 million of profit. It would therefore seem that the settlement amount of EUR 12 million was based on the estimated profits Merck (GUK) could have made in the EEA in the year covered by the agreement if Merck (GUK) had entered the market.[683]

(351) The 'circumventing' loophole in the agreement Merck (GUK) referred to internally earlier[684] might be that Article 1.1 imposed the obligation to cease the sale and supply of pharmaceutical products containing citalopram only on Merck (GUK), including, in the final agreement, "to" affiliated companies within the Merck

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API form to any other company". See ID 823, page 57. In Lundbeck's view this should influence the interpretation of Article 1.1 of the agreement, see ID 5394, pages 159-160. However, as indicated in recitals (330) and (331), based on a draft of the EEA agreement of 6 June 2002 which said that "Natco /WG KDV DSSRLQWHG 0HUFN DV H[FOXVLYH GLVWULEXWRU LQ V (see ID 673, page 368), Merck (GUK) had taken the view that Lundbeck needed to understand that Merck(GUK) did not have an exclusive supply agreement with Natco and the implications thereof. The agreement actually concluded only mentions that "8. LV D GLVWULEXWRU RI Natco (see ID 8, page 228). This implies that Merck (GUK) informed Lundbeck that it was not the exclusive distributor for Natco in the EEA before Lundbeck concluded the agreement with Merck (GUK) related to the EEA (excluding the United Kingdom). This also explains why the agreement as actually concluded contained the wording in Article 1.1 that Merck (GUK) "shall use all reasonable efforts to ensure that Natco ceases to supply Citalopram and products containing Citalopram in the Territory for the term of this Agreement" and the wording in Article 1.2 that "Lundbeck shall not be required to make any payment pursuant to this Article 1.2 which has not yet fallen due in the event that Natco supplies Citalopram or products containing Citalopram in the Territory during the term of this Agreement", neither of which was part of the draft agreement of 6 June 2002 and which would have been superfluous if Merck (GUK) had been the exclusive distributor of Natco in the EEA (see ID 673, pages 367 to 372). Finally, this observation is consistent with the purpose of Lundbeck's visit at Natco as described in recital (181) above. See also recitals (229)-(232) above. Regarding the interpretation of Article 1.1 see also section 12.3.5.2 below.

682 See recitals (327) and (328) above. In reply to the Statement of Objections, Merck KGaA criticised the Commission's calculations claiming that "[t]he SO errs when deducing [...] 2.5 million Euro for Italy as the profit for Italy is clearly not included in forecasted profit of 14 million Euro". See ID 5960, page 318. However, contrary to Merck KGaA, ID 675, page 40, shows that in the overall profit calculation of € 14 million an amount of € 2.5 million was included for Italy (i.e € 1,544,000 for 20 mg and € 926,400 for 40 mg strength). The calculations are therefore correct.
Possibly in view of this claimed mistake, Merck KGaA explained that "GUK expected to make profits RI ¼ PLOOLRQ KDG WKHUH QRW EHHQ". Without any explanation and "market exclusion risk" would therefore explain the reduction of the payment by € 2 million compared to the profit forecast of € 14 million. See ID 5960, page 315. The Commission notes that based on this explanation, the value that Lundbeck transferred to Merck (GUK) reflected also the exclusion value that was represented by avoidance of competition by Merck (GUK).

683 A draft of 6 June 2002 of the agreement has a settlement amount of EUR 7.5 million. See ID 675, page 49. This amount is comparable to Merck (GUK)'s estimated profit before May 2003 of EUR 6.4 million and Merck (GUK)'s alternative estimated profit, at an assumed market share of 15%, before May 2003 of EUR 7.3 million. See ID 675, pages 40 and 44 and ID 675, page 54.

684 See recital (330) above.

Generics Group, but not strictly speaking on Merck (GUK)'s affiliates themselves. The other companies within the Merck Generics Group were therefore, strictly speaking, free to sell citalopram, at least from other suppliers than Natco, in the EEA. This formulation may have been based on the fact that Merck (GUK) acted as the raw materials supplier for the entire Merck Generics Group. However, Merck (GUK) later stated to the Commission that other companies within Merck Generics were free to license themselves citalopram in finished dosage form.[685] Merck dura, in particular, continued selling Tiefenbacher citalopram in Germany from 15 April 2002 throughout the period of Lundbeck's EEA agreement with Merck (GUK). In an e-mail of 7 November 2002, Merck dura wrote to Merck (GUK) that "Merck dura « K D G L Q W Z R with Lundbeck in Hamburg discussing cooperation opportunities in Hamburg. At the end, Lundbeck denied further negotiations as they believed to get the Es-Citalopram registration to escape generic competition. In the meantime we had several legal proceedings against Lundbeck concerning patent issues. By clever changing the raw material sources we could successfully keep our product in the market."[686]

(352) Natco does not appear to have sold its citalopram to any other suppliers in Europe during the period of the EEA agreement. In a letter to Merck Generics of 14 February 2003, Natco wrote: "Other than MG, there is no other active licence of formulation with Natco as a source" and "After the unexpected shortcut of needs end of last year (forecast figures being decreased in 2 steps from 3.300 kg to 2.200 kg after 1.875 kg being supplied in 2002), there is tremendous uncertainty about when exactly the originally projected quantities will be picked up. This makes us extremely nervous, as you are our only customer."[687] In reply, the [employee function]* of Merck Generics wrote Natco a soothing letter, mentioning in passing Merck (GUK)'s two agreements with Lundbeck but not offering any damage compensation to Natco.[688] It is noteworthy that that letter also announced Merck (GUK)'s intended "vigorous launch" in all European markets following the expiry of the agreements without considering any possibility that Lundbeck's patents, which would still be in

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685 ID 1509, page 1.

686 The reference to "changing the raw material sources" appears to refer to a change from Cipla to Matrix. Merck dura stated in infringement proceedings with Lundbeck in Germany that at the latest since 4 September 2002, Merck dura had been selling citalopram from Matrix only, produced in accordance with the Matrix II process. See ID 235, page 884. In the e-mail of 7 November 2002, it appears that a possible withdrawal of Merck dura from the German market as a result of the Merck (GUK) agreement with Lundbeck was discussed between Merck (GUK) and Merck dura. In the e-mail of 7 November 2002 from Merck dura to Merck (GUK), Merck dura wrote: "Even if Merck dura would withdraw citadura from the market there remain 9 generic competitors still offering a generic version of citalopram. So I can't see the advantage for Lundbeck if only Merck dura leaves the market." See ID 675, page 117. In the end, although challenged by Lundbeck on 16 September 2002 (ID 6814, page 81), Merck dura continued selling on the German market. See ID 677. This, however, does not allow the conclusion, as Lundbeck and GUK apparently considered in reply to the Statement of Objections (ID 5394, page 159; ID 6026, pages 16-17), that GUK was free to sell citalopram not sourced from Natco in the market, as this was prohibited by Article 1.1 of the agreement. Moreover, Merck (GUK) internally concluded that "I also presume that if we do sign any agreement at a fair price there will be no attempt at 'circumventing it'" (see recital (330) above).

687 ID 673, page 490.

688 ID 673, pages 437 to 445. Merck (GUK) argued in this letter towards Natco that "we considered the strategic option of being able to launch without fear of injunction in any jurisdiction in October" 2003 (page 440). See, however, also recitals (288) and (355).

force, could hinder such launch ("We maintain the position we are non-infringing…"[689]).

(353) Contrary to the agreement for the United Kingdom, the EEA agreement did not provide for Merck (GUK) to distribute Lundbeck citalopram.

7.3.3. Events during the implementation of the agreement

(354) On 22 October 2002, Merck (GUK) immediately informed NM Pharma of its withdrawal from the market: "we have decided to temporarily withdraw the product from the Scandinavian market. We have come to this view only after careful consideration and on the basis that we cannot realistically at this stage undertake any legal action to defend our position. We also strongly advise NM not to sell any further Citalopram product and to return existing stocks [...] In the event that you do not return existing stocks, this notice serves to inform NM that we cannot indemnify you…"[690]

(355) On 23 October 2002, an internal Merck (GUK) e-mail explained Merck (GUK)'s rationale for the agreement with Lundbeck as follows:

"They (Lundbeck) hold up to 20 process patents on this molecule and they have made it quite clear through their past actions that they intend, whether they have a case or not to defend their product for as long as possible.

Lundbeck know that when they bought Vis that we started working with Natco and they have somehow managed to get hold of material that they can test. It is there [sic] contention that this material shows evidence through the impurity profile that it infringes one of their process patents. This is not the case as we know, but they don't, that the material is in fact produced by a route contained in patent that has now expired. However as with all these things one faces a choice. Science can be used to both support or pervert the course of justice and in a case like this Lundbeck can adopt delaying tactics which are both expensive, time consuming and frustrating to all involved (including the courts). We are 100% confident that our evidence will show that we do not infringe any of their [IP intellectual property] on this product but in order to do this we undoubtedly will have to take part in some long complex court cases which could delay us for some time to come with regard to full commercial exploitation of the product we now have approved.

As always we are happy to defend our rights in this case but we felt on balance that the collaboration with Lundbeck was the better option for the TIME BEING. The agreement allows us to obtain a return on our investment in this product and does not in any way compromise our ability to launch at a later date and take on any legal actions Lundbeck might care to engage in. All round given the short term nature of the agreement (12 months) we feel this is the option we should choose at this time.

I would stress that in no way is this decision an admission of the validity of the argument that Lundbeck might try to use against us and if and when the time comes to discontinue the agreement we will be ready to defend our rights."[691]

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689 ID 673, page 439.

690 ID 675, page 108. Concerning Merck (GUK)'s obligation to stop supplying citalopram to NM Pharma, see recital (348) above.

691 ID 675, page 403.

(356) On 23 October 2002, NM Pharma answered to Merck (GUK)'s letter of 22 October. "\RX DGYLVH XV QRW WR VHOO DQ\ IXUWKHU The& LWDOR reason for this is, according to your letter, that you 'cannot realistically at this stage undertake any legal action to defend [your] position'. We find this reason very vague and are reluctant to stop the marketing of Citalopram without additional information. We assume that there have been developments in the patent situation, and that new research carried out by you that have prompted your letter.

We ask that you as soon as possible, in accordance with our agreement, provide us with a copy of this recent patent research and any other relevant information that will help us understand the shift in your position. In the absence of an explanation based on disclosed facts, we do not accept your abovementioned letter as releasing you from your obligation to indemnify us according to Article 12 C. of our agreement. For the time being, NM Pharma will continue to sell Citalopram and Merck Generics are under the agreement obliged to continue to supply us with the product.

Please be informed that Lundbeck has not claimed that NM Pharma is infringing any patent rights, nor do we have knowledge of any request for a preliminary injunction or other legal action against NM Pharma."[692]

Subsequent draft letters and letters illustrate that Merck (GUK) tried to provide a plausible explanation to NM Pharma (other than mentioning the EUR 12 million payment from Lundbeck) of why Merck (GUK) had decided to stop supplying NM Pharma with Natco citalopram tablets.

(357) First, a draft Merck (GUK) letter of 24 October 2002, destined for NM Pharma is advising "that it is our intention to withdraw the product from the Swedish market and that we will not be able to supply you with further stocks."[693] No mention is made of any compensation payment from Merck (GUK) to NM Pharma. The draft letter justified Merck (GUK)'s withdrawal from the market by the difficulty and expense of showing that Merck (GUK) did not infringe Lundbeck's patents. An internal reaction from Merck (GUK)'s [employee function]* to this draft stated:

"NM know the patent position; we've shown them our evidence and argued before to them directly that there are a large number of patents and that we still don't LQIULQJH«LQFOXGLQJ WKH FU\VWDOOLQH EDVH SDWH

I've tried a different tac, but I am not going to admit that we were wrong in our assessment of the patent situation."[694]

Another draft (without signature) dated 25 October 2002, which appears to have been sent in that form to NM Pharma[695], stated: "/XQGEHFN >«@ KDYH LQGLFD

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692 ID 675, page 109. Internally, Merck (GUK) wondered the following day: "any idea why it is that Lundbeck have not tried to sue?" See ID 675, page 102.

693 ID 675, page 99.

694 ID 675, page 104. It appears from the exchange of e-mails that Merck (GUK)'s [employee function]* resisted draft language suggesting patent infringement problems. He was "not going to admit we were wrong in our assessment of the patent situation". This meant that he still believed Merck (GUK) was right in its assessment that ZH VWLOO GRQ W LQIULQJH«LQFOXGLQJ WKH FU\ See in particular also recital (355) above. In the end management decided to "modify the whole thing to make it clear tKDW WKLV LV D FRPSURPLVH" See ID 675, page 103, and also page 102.

695 ID 675, page 101.

recent actions that they intend vigorously to "defend" their product and their intellectual property in every way […] It is clear to us that [Lundbeck …] intend[s] to try to use […] tests [of samples] to show that Natco infringe their Intellectual Property on routes of synthesis in some way. We naturally disagree with such assertion, as in our view the process used comes from a patent which has expired, and which therefore cannot be claimed as one on which infringement can be based. However, we are also aware that they have been granted a number of patents, which claim some elements of the same process contained in the not expired patent. This in our view is incorrect as it must now be prior art; however, the European Patent Office does not seem to apply sufficient rigour to the examination to exclude this possibility and therefore the patents are granted and are, prima facie, legally valid. Lundbeck have the ability, resources and desire to sue under these patents […]

As we have previously explained in some detail to you, we could fight any claims Lundbeck may make in this respect in Sweden. However, they are threatening us not just in Sweden, but in a pan-European wide manner and we therefore had to consider all our markets […] The cost in the UK alone for this type of work [injunction, experimentation in front of expert witnesses, legal action] has been over £400,000 per case. This, if translated throughout all European jurisdictions, would be prohibitively expensive especially if injunctions are granted.

In recent contact with Lundbeck we have been given an undertaking from them that we will, in good faith and without compromising our future position, undertake to try and clear all the IP issues as soon as we can. We expect to sort this out without resorting to expensive litigation […] Even if we are temporarily off the market, establishing a modus vivendi for the future must be the right way to proceed, especially since we know the alternative brings with it the certainty of significant and unnecessary costs. Even if we still end up disagreeing we will at least be significantly strengthening our position to ensure injunction could be granted against us in any of the European jurisdictions. Thus at least we should be able to derive income during DQ\ OLWLJDWLRQ SHULRG«"[696]

(358) Second, a letter of 15 November 2002 from Merck (GUK) to NM Pharma persuaded NM Pharma to accept Merck (GUK)'s decision: "suffice it to say that we have looked at the matter at some detail and concluded, as previously stated, that the risk of costly and damaging infringement proceedings from Lundbeck is significant […] to be perfectly honest, I think there is a real risk of our correspondence proving counterproductive if we get bogged down by the minutiae of the Agreement [between Merck (GUK) and NM Pharma]."[697]

(359) On 15 November 2002, Merck (GUK)'s counsel sent a letter to Lundbeck in relation to "… WKH VHWWOHPHQW DJUHHPHQWV HQWHUHG LQW agreement dated 22 October 2002".

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695 See ID 675 page 107. Given that the internal Merck (GUK) e-mail to which this letter was attached circulated "…a trilogy of correspondence relating to our recent communication with NM on our withdrawal of the product Citalopram from the Swedish market", it is likely that this version of the letter was actually sent.

696 ID 675, pages 110-112.

697 ID 675, page 120.

"As noted[«] Lundbeck has made laboratory analyses of Citalopram products made by our clients and believe the production method used infringes the patents set out in Appendix A to the Agreement. Our clients have disputed that the production method used infringes Lundbeck's intellectual property rights.

Pursuant to Article 1.5 of the Agreement, our clients seek to resolve the issues between them and Lundbeck. There seems to be no merit in delaying attempts to assess and resolve the issues. Please let us know what evidence Lundbeck has that leads it to believe our clients' product or production methods infringe the patents set out in Appendix A so that our clients may consider this"[698]

(360) A Lundbeck management report of 2 December 2002 stated that Lundbeck expected the agreement with Merck (GUK) to have the greatest impact on the Swedish market.[699]

(361) On 14 January 2003, Merck (GUK) informed the Austrian Merck Generics subsidiary that it could not use the marketing authorisation it had just been granted (based on Natco material) until October 2003. The Austrian subsidiary had been planning to enter the market in April 2003.[700]

(362) A letter of 21 February 2003 from Merck Generics to Natco indicated that by this date Merck (GUK) had, directly or through NM Pharma, obtained marketing authorisations and had completed all internal issues such as pricing in Ireland, Sweden and the United Kingdom: "Licences gained and marketable". Because of delays in obtaining marketing approvals, Merck expected to be in the same situation by the end of June 2003 in Austria, Belgium, Denmark, Finland, Germany, Italy, Luxemburg, Norway and Portugal and before the end of 2003 in France, the Netherlands and Spain. Tables attached to the letter "show two things: only three markets have generic competition (Sweden, Netherlands and Germany) and only 2536 kilograms have been sold which includes Natco, Matrix, Max, Sumika, Ranbaxy and Fermion material as all those companies are presenting non-infringing material in the market place." The letter mentions the fact that Merck concluded agreements with Lundbeck for the United Kingdom and the EEA, but does not mention any compensation payment from Merck to Natco. With respect to the EEA agreement, Merck Generics wrote: "At the end of October last a further agreement was made with Lundbeck to say that we could not launch for a year and that we would both use this time to resolve any patent issues between us. Strategically we looked at the timings of our licence approval, the cost of litigation in each country (up to £500,000 per jurisdiction) the downside being injuncted for an unspecified period (i.e. at the mercy of court time and the wranglings of lawyers) and the fact that the only market fully genericised was Germany."[701]

(363) The internal e-mail of Merck (GUK) of 11 March 2003 quoted in recital (294) above summarised the profit Merck (GUK) realised from the agreement relating to the EEA (excluding the United Kingdom) "Total": "Eur" "12,000".[702]

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698 ID 2012, page 2.

699 ID 816, page 234.

700 ID 675, page 126.

701 ID 673, pages 437 to 445. See also recital (293) above and recital (367) below.

702 ID 673, page 474.

(364) In a fax of 18 July 2003, Merck (GUK)'s [employee function]* wrote to the French Merck Generics subsidiary:

"Lundbeck took samples of our product as they impounded it in Germany more than 18 months ago and they received samples of the finished dosage in UK in January 2002.

As a result of a court case in the UK; GSK vs Generics UK for Paroxetine a legal precedent was set such that a generic manufacturer was required to prove they did not infringe the intellectual property rights of the originator. Applying this rule Merck Generics wrote to Lundbeck on a number of occasions seeking clarification of any infringement specifically for Citalopram.

It was subsequently agreed between the parties [Lundbeck and Merck (GUK)] that they would work together in good faith and explore the possibility of infringement of Intellectual Property rights. From the samples received by Lundbeck and the data they have on our process, they have not questioned our ability to produce the product by a lapsed basic process and they have not questioned the quality of the product they have tested. Therefore we feel that summarising the details of the discussions should at least demonstrate that in good faith Merck Generics Group has respected the Intellectual Property Rights of Lundbeck in developing and producing a high quality generic pharmaceutical."[703]

(365) An internal Merck (GUK) e-mail of 10 August 2003 mentioned: "Our European deal with Lundbeck ends on 23rd October – they are pressuring us to re-new."[704]

(366) An internal Lundbeck document entitled "Generic update citalopram & escitalopram" of 16 September 2003 stated with respect to Merck in France:

"- Our European deal terminates by 22 Oct

«

- We suggested that Merck stays out [of France] for up to six months against payment

- They are not interested – the opportunity costs are too high – they will be the first generic entrant in F."[705]

(367) On 1 October 2003, Merck (GUK) informed the French Merck Generics subsidiary that it could not sell generic citalopram in France until after expiry of Merck (GUK)'s agreement with Lundbeck in October 2003: "BUT *M*ost importantly, we have an agreement with Lundbeck not to sell in Europe until sometime around the end of 2FWREHU WKLV \HDU« :H DJUHHG QRW WR VHOO FLWD (this was agreed October/November 2002) because of the potential for litigation and the uncertainty of outcome for both parties. As part of the agreement the parties agreed to look into the patent issues. This patent (or its equivalents) [the crystallisation patent] was known about by both parties at the beginning of this agreement. We have written several times to Lundbeck asking for their views and in order to resolve the issue as per the agreement. We have not received a response

703 ID 2009, page 3.
704 ID 2010, page 2.
705 ID 903, pages 24-25.

from them."[706] In this context, Merck (GUK) advised its French subsidiary against now starting an invalidity action against Lundbeck's crystallisation patent. Instead, Merck (GUK) said: «WKHUH LV QR UHDVRQ WR H[SHFW DQ against you in France, provided you launch after the expiry of the agreement. If /XQGEHFN GR WKUHDWHQ \RX LW ZRXOG EH EHVW WR then that any Lundbeck action will then cease."[707]

(368) An internal Lundbeck document of 20 October 2003 reported that Merck Generics had launched generic citalopram in Belgium on 10 October 2003.[708] Lundbeck assessed this action as a breach of its agreement with Merck (GUK).[709] The same Lundbeck document of 20 October 2003 noted that Merck Genericos was the first company in Portugal to receive reimbursement on generic citalopram and was expected to launch late October or beginning November 2003. Finally, with respect to France, the same document remarked that on 30 September 2003, Merck Génériques had had two generic citalopram registrations approved and was expected to launch in January 2004.[710]

(369) The agreement expired on 22 October 2003.

(370) In total, over the entire period of operation of the agreement from 22 October 2002 to 22 October 2003, Lundbeck transferred a value to Merck (GUK) of EUR 12 million under the agreement regarding the EEA excluding the United Kingdom.

7.3.4. Subsequent events

(371) In November 2003, Lundbeck obtained in Belgium a seizure of Natco citalopram that Merck Generics Belgium had started selling there.[711]

(372) When Merck started to re-sell citalopram products in the EEA excluding the United Kingdom after the expiry of the agreement with Lundbeck, Lundbeck did not initiate infringement litigation against it.[712] In January 2004, Merck Génériques became the first company to sell generic versions of citalopram in France.[713]

7.4. Lundbeck's agreement with Arrow regarding the United Kingdom

7.4.1. The negotiation of the agreement

(373) The Arrow Group of companies began its business of developing and marketing generic medicines in the EEA in 2001. Already in a preparatory phase leading up to the start of business, Arrow had identified citalopram "as a major product that it would market shortly after it began trading."[714] Within the Arrow group of

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706 ID 2006, page 2 and ID 673, page 511.

707 ID 2006, page 2. Note the internal change of position resulting from the agreement compared to June 2002 (see recital (334) above).

708 ID 904, page 76.

709 ID 903, page 24. Such breach, however, did not mean that GUK considered itself no longer bound by the agreement as of 10 October 2003, as Lundbeck argued in reply to the Statement of Objections (see ID 5394, page 161), as shown by recital (367) above: "…we have an agreement with Lundbeck not to VHOO LQ (XURSH XQWLO VRPHWLPH DURXQG WKH HQG RI 2FWREH injunction to be granted against you in France, provided you launch after the expiry of the agreemen

710 ID 904, pages 76-77.

711 ID 903, page 97.

712 ID 823, page 55.

713 ID 892, page 19.

714 ID 610, page 5.

companies, the project to develop and launch generic citalopram medicine in EEA markets was led by the United Kingdom company Arrow Generics Limited.[715] Arrow's plan was to launch generic citalopram in the United Kingdom market immediately after expiry of Lundbeck's compound and basic process patent on 5 January 2002, still in the month of January 2002.[716] Following the withdrawal of VIS' Drug Master File by Lundbeck in October 2000, Resolution Chemicals Ltd, another Arrow subsidiary at that time, started its own project to develop generic citalopram API. Arrow recognised, however, that Resolution would not have marketable citalopram products ready by January 2002.

(374) A first indication of contacts between Arrow and Lundbeck dates from 15 December 2000. In an internal e-mail, Lundbeck reported that Arrow did not want to discuss citalopram before Lundbeck had entered into an agreement with Arrow regarding a different product.[717]

(375) On 22 May 2001, Arrow Group A/S, the Danish parent company of Arrow Generics Limited, entered into a contract with the German company Alfred E. Tiefenbacher for the purchase of marketing authorisations from Tiefenbacher and the possible supply of generic citalopram by Tiefenbacher, the API originating from Cipla or Matrix.[718] At that time, Tiefenbacher's request for a marketing authorisation in the Netherlands, mentioning both Cipla and Matrix as suppliers, was nearing approval.[719] Dutch approval would then be followed by Tiefenbacher making requests for approval to other national authorities in the EEA under the mutual recognition procedure or, in the case of France, through a national procedure.[720] Under the contract, Arrow bought copies of (future) marketing authorisations from Tiefenbacher for the Netherlands, United Kingdom, Denmark, Finland, Sweden and France. Under clause 6.1 of the agreement, Arrow had the option upon written notice from time to time to:

– purchase the medicinal products in bulk exclusively from Tiefenbacher for five years after launch in each Member State;

– manufacture the medicinal products itself or through third parties with API purchased from Tiefenbacher (with a (lower) royalty percentage for Tiefenbacher); or

– manufacture the medicinal products itself or through third parties with API sourced from an Arrow affiliate (with a higher royalty percentage for Tiefenbacher).[721]

In reply to the Commission's request for information of 9 March 2011, Arrow interpreted this contract with Tiefenbacher as follows: "The contract did not contain an exclusive purchasing obligation (and indeed no obligation to purchase, only an RSWLRQ WR GR VR «$UURZ *URXS GLG GLVFXVV D

715 ID 610, page 5.
716 ID 610, page 6.
717 ID 681, page 148.
718 ID 619, pages 1 to 8. See also ID 847, page 61 and ID 280, page 5. See also IDs 1630 to 1633.
719 The Dutch marketing authorisation was granted in September 2001, see recital (176) above.
720 ID 619, page 3.
721 See Article 6.1 of the agreement, ID 619, page 4.

Tiefenbacher, but as far as it can ascertain this was never concluded.[722] Under the terms of the contract, Arrow Group was expressly permitted to supply products sourced from third parties, subject to payment of a royalty to Tiefenbacher if it did so [x]% of gross sales if Arrow Group manufactured its own tablets with Tiefenbacher's API (which would have been sourced from Tiefenbacher at [x]% of [«] gross sales if it manufactured its own tablets).[723]

(376) Arrow stated to the Commission that "Arrow Group agreed to purchase tablets from Tiefenbacher, who Arrow understands made the decision to source its API from Matrix (in addition to Cipla) after Lundbeck acquired VIS."[724] According to Tiefenbacher, for the products or API sourced from Tiefenbacher, Arrow was free to specify to Tiefenbacher whether the citalopram should come from Cipla or Matrix.[725] This having been said, initially, at least until the moment when Arrow and Lundbeck concluded their agreement regarding the United Kingdom, the citalopram products supplied by Tiefenbacher came from Cipla.[726]

(377) Arrow has stated to the Commission that by "mid 2001",[727] it became aware of Lundbeck's application for a crystallisation patent. This corresponds to the date of publication of Lundbeck's United Kingdom patent application GB 2357762 on 4 July 2001.[728]

(378) In its reply to the Statement of Objections, Lundbeck has informed the Commission that between July 2001 and January 2002, it performed several analyses of Cipla's citalopram.[729] According to Lundbeck: "The results of these tests were all consistent and indicated the presence of 5-Chloro and 5-Bromo impurities and the absence of 5-Acetyl impurity, which showed that Cipla used the Cyanation 2002-1 Process. The low level of 5-Chloro and 5-bromo impurities and the rate between these two

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722 Clause 6.2 of the agreement of 22 May 2001 provided that Arrow and Tiefenbacher would sign a related Supply Agreement in the course of the duration of the current agreement. However, Arrow reported to the Commission that "Arrow Group considered entering into a supply agreement with Tiefenbacher in Autumn 2002, but as far as it is aware this was not concluded as agreement could not be reached on its terms." See ID 1297, page 24.

723 ID 1297, page 44. That Arrow believed itself free under the contract with Tiefenbacher to buy API from any API supplier is shown by a contemporaneous document of 11 January 2002, which stated that "[Arrow] told us when we met that under [Arrow's] agreement with Tiefenbacher [Arrow] are free to buy from anyone paying [x]% royalty." See ID 625, page 2.

724 ID 1297, page 33.

725 In Tiefenbacher's words: "The customers were absolutely free to choose the API source. Tiefenbacher had no preference in that case." and "Some companies initially using Cipla material were injuncted and re-entered the market successfully with Matrix API. At a later stage, all customers preferred Matrix for patent reasons." See ID 1713, page 1. Arrow argued in its reply to the Statement of Objections that "the Tiefenbacher Agreement makes no reference to Tiefenbacher having multiple sources of citalopram API" and that "Arrow did not have an option to choose between different API sources; this was a matter entirely for Tiefenbacher." See ID 6082, pages 15 and 16 respectively. However, Arrow's marketing authorisation authorised both Cipla and Matrix as API suppliers (see recital (424) below) and the contract with Tiefenbacher did not exclude that Arrow would choose the API supplier. The Commission refers to Article 6.1 of the agreement between Lundbeck and Arrow. See ID 619.

726 Matrix stated in the United Kingdom Lagap litigation that it began supplying citalopram to the EEA in March 2002. Lundbeck has stated to the Commission that it first became aware of Matrix's citalopram being sold on a market in the EEA (Denmark) in June 2002. See recital (153) above. See also ID 5394, page 163.

727 ID 610, page 7.

728 See recital (113) above.

729 ID 5394, page 166.

demonstrated that the specific impurity level could only have been obtained through the Crystallization Process, in violation of the Crystallization Patent."[730] In its reply to the Statement of Objections, Lundbeck also stated that between June 2001 and January 2002, it performed several analyses of Matrix's citalopram. According to Lundbeck, «WKH LPSXULW\ SURILOH FRXOG RQO\ KDYH &U\VWDOOL]DWLRQ 3URFHVV»[731]

(379) On 10 September 2001, Arrow Generics Limited ordered DM 2.8 million worth of citalopram tablets from Tiefenbacher.[732] In respect of this order, Arrow stated in its reply to the Statement of Objections: "Arrow simply ordered products from Tiefenbacher and did not specify a particular API source."[733] These tablets were produced by the Icelandic company Omega Pharma for Tiefenbacher, using API from Cipla.[734] They were packaged and labelled by the German company Dragenopharm.[735] A first shipment of these tablets was delivered to Arrow in November 2001 and a second shipment in the second week of January 2002. The total number of tablets (in strengths of 10, 20 and 40 mgs was 9 222 000.[736] These tablets were apparently stored in Germany.[737]

(380) An e-mail of Lundbeck's [employee function]* dated 6 November 2001 shows that Lundbeck had apparently obtained copies of parts of Cipla's DMF. A Cipla document giving a brief outline of the process used by Cipla stated: "Crude citalopram base is crystallised to get pure citalopram base."[738] On or around the same date, Lundbeck also obtained a copy of Matrix's DMF, which stated that "Citalopram base of batch No. RD006/0101 was crystallized twice in Iso propyl alcohol and Methanol and prepared Citalopram Hydrobromide by using aq.HBr in Isopropylalcohol."[739] According to Lundbeck, this DMF had served as the basis for the marketing authorisation granted in the Netherlands on August 31, 2002.[740]

(381) On 15 November 2001, Tiefenbacher prepared an analysis of the patents and patent applications Lundbeck had mentioned in its general warning letter to API producers and to certain generic suppliers in January 2001.[741] For Lundbeck's crystallisation utility model in the Netherlands (NL 1016435), which had been granted on 6

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730 ID 5394, pages 166-167 and page 222. It should be noted that in the Lagap litigation, Lundbeck initially made a similar argument that chloro and bromo impurities in Matrix's product necessarily had to mean that Matrix had used Lundbeck's crystallisation process, After the inspection of Matrix's process, however, Lundbeck withdrew this argument. Lagap's expert stated in that case that "Some of [Lundbeck's allegations], in particular those concerning so called "fingerprints" for purification PHWKRGV DUH See recitals (150), (158) and (160) above.

731 ID 5394, pages 171-172.

732 ID 620, page 2.

733 ID 6082, page 16.

734 ID 623, page 3.

735 ID 2024, page 1.

736 ID 622, page 2.

737 See the preamble of the United Kingdom agreement: "Whereas ARROW has threatened to import into the UK the said Citalopram from Germany". See ID 8, page 235.

738 ID 5439, page 5. In its reply to the Statement of Objections, Lundbeck argued that this statement of Cipla confirmed "beyond any reasonable doubt that the process used by Cipla infringed the Crystallization Patent." For Cipla's analysis, see recital (510) below.

739 ID 5394, page 172. In its reply to the Statement of Objections, Lundbeck argued that this statement of Matrix "showed, again, that Matrix's process infringed the Crystallization Patent."

740 ID 5394, page 172.

741 See recitals (148) and (225) above.

November 2000, and the corresponding application in the United Kingdom (GB2357762), Tiefenbacher concluded: "Describes the production of high purity Citalopram through the crystallisation of the base. In principle not applicable, as in our processes the base is not crystallised, but the product is cleaned through re-crystallisation of the hydrobromide. But: in some writings, protection for the production of high purity citalopram (>99.8%) is filed for. Will be monitored."[742]

(382) On 14 December 2001, a meeting took place between Arrow and Tiefenbacher, in which the patent situation was discussed.[743] Lundbeck's PCT patent application WO 01/68627 for the crystallisation process[744] was identified as problematic for Cipla. According to Arrow's report:

"The material destined for the UK is from Cipla and is purer than the VIS material. The purity level is in excess of 99.8%. In purifying their material Cipla have said that they take an acidic solution of the citalopram base and neutralize using ammonia to precipitate the base which is then converted to the salt. This method, they claim, corresponds to that shown in a 1977 patent. Matrix on the other hand do not isolate the base in crystalline form but convert the base as an oil to the oxalate (twice) and then convert the oxalate to the hydrobromide.

A patent has been filed by Lundbeck, WO 01/68627, to purified base in crystalline form as an intermediate in the production of the hydrobromide salt. This patent has yet to grant in the UK so could not be used for injunction purposes. Matrix have taken steps to ensure that they do not isolate the base in a pure form but Cipla do isolate the base. Cipla's base is of unknown purity but could infringe this patent when granted.[745] Cipla's defence is that they employ a method of purification as disclosed in a 1977 patent.

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742 ID 673, page 174, translation from German. The original German text uses the word "Umkristallisation", here translated as "re-crystallisation". Tiefenbacher sent this analysis to Merck dura, one of its other clients, but it is unclear whether Arrow also received it. See recital (248) above. That Arrow shared the view that Lundbeck's patent only applied to crystallisation of the base, and not to crystallisation of the hydrobromide salt is clear from an internal e-mail of 24 June 2002 in which Arrow explored whether citalopram produced by the Chinese API producer Zhejiang Huahai Pharmaceuticals would be infringing or not. Arrow observed, in this respect, "Lundbeck have been suing everyone in the EU on a patent which claims purification of the base by crystallization. From the flow sheet Huahai do not give any details on whether the base is crystallized or kept in solution and converted to the hydrobromide salt and crystallized. They do refer to the hydrobromide salt as "crude" which suggests that they purify the salt rather than the base. If this is the case then the process is non-infringing." ID 641, page 2, quoted in recital (422) below.

743 ID 623, pages 3-4.

744 See recitals (149) and (151) above. It is recalled that this patent application included several claims for the crystalline base of citalopram as such.

745 The references in this meeting report (ID 623, pages 3-4) to Lundbeck's application for a patent "to purified base in crystalline form as an intermediate" and to "Cipla's base is of unknown purity but could infringe this patent when granted" imply that participants were, at this time, foremost concerned with possible infringement by Cipla of the product claims in Lundbeck's patent application WO 01/68627. As mentioned in recital (151) above, Lundbeck's product claims on the crystalline base of citalopram were later found by the EPO and the Dutch Industrial Property Office to lack novelty and therefore invalid. The United Kingdom crystallisation patent GB 2357762, however, was granted including these product claims (as well including claims regarding pharmaceutical formulations). This meant that the United Kingdom patent was on the one hand more likely to be infringed than without these claims, but on the other hand also more likely to be found at least partially invalid.

A second patent filed by Lundbeck, WO 01/47877, claims a method of film distillation for purification of the salt form. Neither Matrix nor Cipla employ this method.[746]

In view of the fact that Lundbeck will undoubtedly move for an injunction it seems best to prepare a defence position now in order to try and void such an injunction.

The product bound for the UK employs Cipla raw material. Unfortunately, Cipla are not forthcoming with the actual detail on the process they use. This requires to be shored up if we wish to claim non-infringement. We could strike a deal with Cipla whereby the process could be shown to the court "in secret" without us seeing the detail. We will need this at least to avoid an injunction. Matrix are much more open with the detail of their process but presumably we cannot switch at this stage".[747]

Arrow's cover email to this report stated that "[an Arrow employee] has been through the issues surrounding purification of the base and Cipla and [sic] Matrix seem to be OK."[748]

(383) On 21 December 2001, Arrow purchased from Tiefenbacher a request for marketing authorisation Tiefenbacher had lodged earlier in the United Kingdom.[749]

(384) On 27 December 2001 the United Kingdom Medicines Control Agency issued a positive opinion on Arrow's request for a marketing authorisation in the United Kingdom.[750] However, as Arrow was to find out, because this request was based on a Tiefenbacher registration file and Lundbeck had opposed Tiefenbacher's file in the Netherlands[751], the United Kingdom Medicines Control Agency was not prepared to issue the United Kingdom marketing authorisation until Lundbeck's opposition in the Netherlands had been resolved. Arrow's United Kingdom marketing authorisation was in fact issued only in July 2002, after Lundbeck had lost its appeal in the Netherlands, more than six months later than expected by Arrow.[752] Based on the documents in the case file, it was only on 27 February 2002 that Arrow inquired with the United Kingdom Medicines Control Agency why the marketing authorisation had not been issued yet.[753]

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746 Patent application WO 01/47877 corresponded to United Kingdom patent GB 2356199: Production of citalopram in pure form, by cyanide exchange; the film distillation patent. This United Kingdom patent, mentioned in Arrow's agreement with Lundbeck for the United Kingdom (see recital (393) below), was revoked by the United Kingdom Patent Office on 23 June 2004, the reason being that it covered the same invention as European Patent (UK) EP 1181272, with the same priority date. This action was not contested by Lundbeck. See ID 651, pages 2 to 5. In its reply to the Statement of Objections, Lundbeck stated with respect to the film distillation patent: "Lundbeck, however, subsequently renounced enforcing that patent because it lent itself to invalidity claims and, most importantly, because Lundbeck had realized that it was possible for generic companies to design around the Film Distillation 3 D W H. Qe WI 5394, page 162.

747 ID 623, pages 3-4.

748 ID 623, page 2.

749 ID 610, page 6, ID 1325, page 10.

750 ID 610, page 6, ID 636, page 2, ID 846, page 168.

751 See recital (168) above.

752 ID 642, page 2.

753 ID 610, page 6 and ID 636, page 2. [employee name]* declared in a statement prepared for the Commission, in reply to the Statement of Objections, that "I was not aware of all the technical issues relating to the marketing authorisation but Arrow's management team was well aware that it had not been granted and that there were concerns of delays to the marketing authorisation being granted. We were aware of this prior to the settlement discussions with Lundbeck. My recollection is that the delay

(385) An e-mail of 11 January 2002 from Cipla's United Kingdom agent[754] to Arrow reported that Cipla was « V X S S R U W L Q J 7 L H I H Q E D F K H U D J D L Q V W Tiefenbacher's first registration was in Holland and it is against them that they are filing a claim, which Cipla are supporting Tiefenbacher in. As there are several other Indian producers of Citalopram, all of whom are infringing, [Cipla] is not willing to make available [its] process to other third parties, as you told us when we met that under your agreement with Tiefenbacher you are free to buy from anyone paying a [y]% royalty.".[755]

(386) An e-mail of 11 January 2002 from an American wholesaler acting on behalf of Ranbaxy to Arrow stated:

$V GLVFXVVHG DW WKH HQG RI ODVW \HDU ZH KDY H of Analysis of the following APIs:

«

Citalopram

«

All are produced by Ranbaxy. May I also ask you if you could be available between Jan 21 and I R U D P H H W L Q J « "[756]

(387) An e-mail of 15 January 2002 of Cipla's United Kingdom agent to Arrow stated:

"I have had a further chat with [Cipla] and he in turn has talked to Tiefenbacher. Apparently, he would like you to talk to him as he is quite happy to defend you in court and will make the necessary information available to the appropriate authorities."[757]

(388) On 18 January 2002, Lundbeck's lawyers wrote to two Queen's Counsels in the United Kingdom to retain their services to "prepare for and appear in an application for an interim injunction" against Alpharma, Tiefenbacher, Omega and Arrow.[758]

(389) On 21 January 2002, Lundbeck wrote to Arrow referring to a meeting with Arrow on 14 January 2002, in which Arrow had informed Lundbeck that it would in the very near future offer for sale in the United Kingdom a citalopram hydrobromide product from Tiefenbacher. There is no indication that Arrow identified the product as coming from Cipla.[759] Lundbeck warned Arrow that Lundbeck believed Arrow's product would infringe two Lundbeck process patents in the United Kingdom: GB 2356199: Process for the preparation of pure citalopram, by cyanide exchange (the film distillation patent), granted on 3 October 2001, and GB 2357762: Crystalline

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was due to proceedings brought by Lundbeck against the grant of the marketing authorisation for citalopram in The Netherlands. The UK authority were relying on the marketing authorisation in The Netherlands and as a result of the challenge in The Netherlands, we were aware in January 2002 that the grant of marketing authorisations in the UK would also be delayed. Nevertheless, « $ U U R Z V W L O O hoped to obtain a marketing authorisation within a reasonable period." See ID 6070, pages 6-7.

754 ID 670, page 5.

755 ID 625, page 2.

756 ID 624, page 2.

757 ID 626, page 2.

758 ID 5477.

759 As Tiefenbacher's marketing authorisation in the Netherlands covered both Cipla and Matrix as suppliers, Arrow's citalopram could in principle have come from either of them.

base of citalopram, to be granted on 30 January 2002.[760] Lundbeck threatened to start infringement proceedings failing a satisfactory undertaking by Arrow not to infringe such patents.[761] Arrow wrote back on 22 January 2002 saying: "We were alerted to these patents as a result of your action against the Dutch Health Authorities. We have looked at these in some detail and do not believe that we infringe these patents."Arrow invited Lundbeck "before you commence proceedings, if that is your intention"to "meet to discuss your allegations in more detail."[762]

(390) On 23 January 2002, Arrow's subsidiary Resolution Chemicals wrote in an e–mail to the company Neulands, a potential second citalopram API supplier, with respect to citalopram: "We launch in UK next week and we are keen to qualify Neulands as a 2nd source."[763]

(391) In January 2002, Lundbeck expected Arrow imminently to become the first company to launch generic citalopram from Tiefenbacher in the United Kingdom.[764] Lundbeck was unaware that through its administrative and legal proceedings against Tiefenbacher's marketing authorisation in the Netherlands, it was successful in considerably delaying the granting of Arrow's marketing authorisation in the United Kingdom, which was based on the Tiefenbacher file.[765] Until as late as 8 February 2002, Lundbeck appears also to have been in doubt whether Arrow's citalopram came from Matrix or Cipla.[766]

7.4.2. The agreement

(392) On 24 January 2002, the same day as Lundbeck's United Kingdom agreement with Merck (GUK), H. Lundbeck A/S concluded an agreement with Arrow Generics Limited and Resolution Chemicals Ltd (Arrow's API producer in the United Kingdom).[767] The agreement covered the United Kingdom. Its term was "from the date of signature until a final unappealable, enforceable UK-court decision has been rendered or until 31 December 2002, whichever event occurs first."[768] Arrow entered into the agreement "on behalf of other members of its group of companies."[769]

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760 With respect to Lundbeck's patent application GB 2357762, the crystallisation patent, Lundbeck specifically mentioned in the letter to Arrow claims 1 and 12 to 16. It may be recalled that claim 1 of the corresponding patent at the EPO level was later deleted from the amended claims which were eventually upheld by the EPO in 2009. See recital (166) above. It may also be noted that claims 12 to 16 covered product claims and pharmaceutical composition claims. As mentioned in recital (151) above, Lundbeck's product claims on the crystalline base of citalopram as well as its claims regarding pharmaceutical compositions were later found by the EPO and the Dutch Industrial Property Office to lack novelty and therefore to be invalid.
With respect to Lundbeck's patent GB 2345199 (the film distillation patent), Lundbeck stated in the reply to the Statement of Objections that Lundbeck "realized that it was possible for generic companies to design around the Film Distillation Patent" and "renounced enforcing that patent because it lent itself to invalidity claims." See ID 5394, page 162.

761 ID 627, pages 2-3.

762 ID 628, page 2.

763 ID 1294, page 1.

764 ID 846, page 168. See also ID 823, page 20.

765 See recital (168) above. See also ID 904, page 182. Arrow received its United Kingdom marketing authorisation only on 26 July 2002.

766 ID 850, page 102. See also ID 8, page 198. See also recital (411) below.

767 ID 8, pages 234 to 240.

768 Article 4.1, ID 8, page 239.

769 ID 8, page 235.

(393) The preamble to the agreement stated:

"Whereas ARROW has obtained a licence from a third party to import into the UK Citalopram not manufactured by Lundbeck or with the consent of Lundbeck ("the said Citalopram", which definition shall for the avoidance of doubt comprise only Citalopram for marketing and sale in the UK and shall exclude Citalopram for marketing and sale in other countries)."

The preamble continued by stating that Lundbeck had performed a laboratory analysis of Arrow's citalopram and that Lundbeck believed that the importation by Arrow of the bulk citalopram in question violated Lundbeck's patent rights, in particular its patents GB 2357762 (preparation of crystalline base or salts of citalopram – the crystallisation patent), GB 2356199 (process for the preparation of pure citalopram, by cyanide exchange - the film distillation patent)[770] and EP(GB) 171943 (novel intermediate and method for its preparation - the diol patent).[771] It then stated:

"Whereas ARROW does not consider that it infringes the Proprietary Rights and/or consider that the Proprietary Rights are valid or enforceable but accepts that Lundbeck has a reasonable belief that the Proprietary Rights may be valid and infringed and ARROW does not at present have any demonstrable incontrovertible evidence otherwise.

Whereas Lundbeck has threatened interim injunction proceedings and intends to pursue the alleged infringement in the Patents Court of the English

(394) In Article 1.1 of the agreement "ARROW on its own behalf and on behalf of all associated and related entities undertakes to Lundbeck that in the UK to make, dispose of, offer to dispose of, use or, after the Second Delivery Date, import or keep for the said purposes (1) the said Citalopram or (2) any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights and, to enable Lundbeck to ascertain if there may be an infringement, during the Term to provide Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale pending a final judgment, Arrow later confirmed to the Commission that "The Lundbeck Agreements cover citalopram in any form, including both as an API and a medicine".[772] Arrow also agreed for the term of the agreement not to transfer, license or otherwise deal in any United Kingdom marketing authorisations relating to any such citalopram. In Article 1.2 Arrow agreed to give these undertakings to the court by way of a formal court order if requested to do so by Lundbeck.

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770 Arrow reported to the Commission that this patent GB 2356199 was revoked by the United Kingdom Patent Office on 23 June 2004 because it had been granted for the same invention as EP patent 1181272 (which was granted on 28 August 2002). See ID 610 page 25 and ID 651.

771 This last patent was granted in 1988. This patent covered the so-called diol process, which Lundbeck used itself to produce citalopram in this period. This patent expired in 2005. In its reply to the Commission's request for information of 19 March 2010, Arrow stated in respect of this patent: "Although Lundbeck would ultimately assert its granted EP (GB) 171943 patent against Arrow, Arrow was aware of this patent but it was not a primary concern as Arrow believed that it was possible to manufacture around the intermediate that this patent claimed." See ID 610, page 6.

772 ID 610, page 25.

With respect to the words "any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights", Arrow later explained to the Commission that "The test established by Article 1.1 of the Agreement is a subjective test of alleged infringement, not actual infringement. Therefore, citalopram products that have not been found by a court to be non-infringing but do not actually infringe Lundbeck's patents could have been within the scope of Article 1.1, but that is entirely usual in agreements of this nature."[773]

Article 1(1) implied that for the duration of the agreement Arrow not only committed itself not to import or sell any citalopram which Lundbeck alleged to be infringing, but also not to manufacture citalopram itself, through its subsidiary Resolution Chemicals, at least not if Lundbeck alleged such citalopram to be infringing.

(395) Article 1.2 of the agreement stated that "ARROW agrees during the Term to give the above undertakings to the Court by way of a formal Court Order if requested to do so by Lundbeck during the course of the Infringement Litigation."

(396) Article 2.1 stated that Lundbeck would commence legal infringement proceedings on the merits as soon as possible "with the aim to establish whether ARROW has, is or ZRXOG LQIULQJH /XQGEHFN V 3URSULHWDU\ 5LJKWV« Patents Court in KH 8. DV VRRQ DV SRVVLEOH«7KH SDUWL endeavours to have the case on the merits set down for a speedy trial, if so requested by either of the parties".

(397) Article 2.2 stated:

"In consideration of the undertakings in clause 1.1 and ARROW not seeking a cross-undertaking in damages in respect of the period comprising the Term, Lundbeck shall provide ARROW with a total of five million pounds sterling (GBP 5 million)." This money was to be paid in four instalments covering the entire term of the agreement, the first payment being scheduled to take place seven days after the first delivery of Arrow stock to Lundbeck (which was to take place before 6 February 2002).[774]

(398) Arrow later explained to the Commission that the amount of GBP 5 million represented "a broad estimate of what Arrow would have received under a cross undertaking in damages in the event that the Lundbeck Process Patents were not infringed and/or were found to be invalid".[775] Another way of saying this is that the amount of GBP 5 million represented the amount of profit Arrow estimated it could have earned in the period concerned if it had successfully entered the United Kingdom market with its own generic product. In other words, by not selling Arrow now received a similar amount of money as it could have earned by selling in the market, but without any of the inherent commercial and litigation risks.

(399) It is to be noted that the agreement did not contain any provision that if Lundbeck won the main proceedings on infringement, Arrow would have to pay back to Lundbeck part or the entirety of the money Lundbeck had paid to Arrow it up front.

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773 ID 610, page 28.

774 In fact, the actual payments were later linked by Lundbeck to Arrow receiving a marketing authorisation and made in five instalments, see recital (412) below.

775 ID 610, page 8. See also ID 610, pages 28-29.

Arrow was therefore given the certainty by Lundbeck that in accepting the agreement it could keep the money, irrespective of any result of litigation on infringement.

(400) Article 2.3 stated:

"In the event that the final unappealable, enforceable UK-court decision in the Infringement Litigation rules that ARROW does not or has not infringed Lundbeck's Proprietary Rights the compensation granted by Lundbeck in accordance with clause 2.2 shall constitute full and final compensation from Lundbeck."

This also indicates that the amount of compensation was set based on Arrow's expected profits in the United Kingdom in the period concerned if it had successfully sold generic citalopram.

(401) Article 3 provided that Arrow would give 5 million tablets of the said citalopram in escrow to Lundbeck, as security. This stock was to be returned to Arrow if the final unappealable United Kingdom court decision ruled in favour of Arrow or upon the expiry of the agreement whichever event occurred first.

(402) In its explanations to the Commission, Arrow tried to justify entering into the agreement by saying that the concern that Cipla might be infringing Lundbeck's patents, "placed Arrow, which was still a relatively newly-formed start-up company, in a commercially intolerable position: it had devoted considerable resources to its citalopram project and was now at serious risk of incurring very substantial costs in patent litigation and of being unduly exposed to the investment it had already made in trying to commercialise its citalopram product for the US market. In these circumstances, Arrow did the best as it could, by reaching an agreement with Lundbeck on the best possible commercial terms it could secure."[776]

7.4.3. Events during the implementation and extension of the agreement

(403) On 25 January 2002 Lundbeck lodged a claim form for infringement by Arrow of United Kingdom Patent GB 2356199 (the film distillation patent) in the United Kingdom High Court of Justice, Chancery Division, Patents Court, indicating that the "Particulars of Claim will follow in due course".[777]

(404) On 25 January 2002, a Friday, at 13.09 hours, [employee name]*'s sent an e-mail to Tiefenbacher stating:

"[Arrow employee] told me about the conversation she had with you last Tuesday [22 January 2002]. She said that you suggested that Cipla raw material possibly does infringe Lundbeck's patents, although you were not sure either way. You asked [Arrow employee] to check the patent. [Tiefenbacher employee], understand that we need to know how exactly Cipla produces the product. It does not help to look in patents in isolation. How are we going to defend ourselves? Please understand that there is much more at stake than just the UK. Please let me know what the position is with Cipla (who incidentally have refused to give us any information, claiming only that they do not infringe and will only deal with you) and what your plans are for defending the position."[778]

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776 ID 610, page 8.

777 ID 630, pages 1 to 4.

778 ID 631, page 5.

(405) On the same day, at 13.13 hours, Arrow received an e-mail from Cipla's United Kingdom agent reporting about a contact with Cipla as follows:

"Since our meeting, I have discussed the matter once more with [Cipla]. He tells me that Tiefenbacher is well aware of Lundbeck's warning to issue an injunction against them and they are prepared and equipped to defend all those that they have sold OLFHQFHV WR VXFK DV «\RXUVHOYHV >&LSOD@ ZDV unable to help you when you asked for it.

I do not know where the truth lies in all of this. Whether Tiefenbacher is being awkward or whether [Cipla] has not given him the information. This I don't know.

Anyway, I can confirm that [Cipla] is not willing to divulge the information to Arrow and that we have approached him as Cipla's UK agent for the supply of Cipla raw material."[779]

(406) On 28 January 2002, [employee name]* sent an e-mail to Tiefenbacher stating:

"Thank you for your call of today and your e-mail reply. I note that you have no information from Cipla on the final purification steps that Lundbeck claims in their patents. Cipla have told us that they will only work through you (not directly with us). So, we are stuck! [Tiefenbacher employee] has just confirmed with [Arrow employee] that he is very nervous about the pending Lundbeck patents. Clearly you KDYH QRW GRQH \RXU KRPHZRUN [Tiefenbacher] [780]

Tiefenbacher's reply of the same day stated:

"As you know Lundbeck is still publishing a lot of patents and nobody can give JXDUDQWHHV :H DUH FXUUHQWO\ FKHFNLQJ WKH VL even clear whether the application came through or not and so which claims came through or not. All I can say for today is that there is a certain likelihood that we have to react."[781]

(407) On 29 January 2002, [employee name]* wrote to Tiefenbacher:

"Cipla are refusing to talk to us, claiming that they will only give you [Tiefenbacher] the evidence and moreover, they are telling us, through their UK agent, that they have given you all the required information. We are going to be injuncted any day now. We have no amunition other than to say to the court that we accept that we may be infringing. We do not know and we are unable to independently check the patent."[782]

(408) On 30 January 2002, as Lundbeck had already announced[783], Lundbeck's United Kingdom crystallisation patent GB 2357762 was granted.[784] Lundbeck did not, however, initiate infringement proceedings against Arrow on the basis of this patent, nor on that of the third patent mentioned in the agreement, EP(GB) 171943 (novel

779 ID 629, page 2.
780 ID 631, page 4.
781 ID 631, page 3.
782 ID 631, page 2. In the e-mail exchange with Tiefenbacher, Arrow made no mention of the agreement it had just concluded with Lundbeck.
783 See recital (389) above.
784 ID 723, page 19.

intermediate and method for its preparation; the diol patent).[785] These patents were, however, mentioned in the consent orders with Arrow of 6 February 2002 and 30 January 2003.[786]

(409) On 6 February 2002, a Master of the High Court of Justice, Chancery Division, Patents Court, granted at the request of the parties an order that Arrow be restrained from importing or selling "(1) Citalopram not manufactured by Lundbeck or with the consent of Lundbeck or (2) any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights (including patent rights to inventions of Citalopram and to processes relating to the manufacture thereof, including but not limited to in particular GB patents no 2 357 762, 2 356 199 and EP(GB) 171943) and, to enable Lundbeck to ascertain if there may be an infringement, during the Term to provide Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale, until a final unappealable, enforceable UK-court decision in this matter has been rendered or until 31 December 2002, which ever shall first occur".[787] The Master also ruled that 7KLV &RXUW PDNHV QR IXUWKHU RUGHU RQ WKLV DSSOLFDWLRQ.[788] The text of this order had been drafted by the parties themselves (with minor amendments by the Master).[788]

(410) With respect to the main proceedings, which in Article 2.1 of their agreement the parties had indicated they would pursue to find out whether Arrow infringed, it appears that in reaction to Lundbeck's initiation of the infringement proceeding[789], Arrow had the intention by 21 February 2002 to claim the invalidity of the patent in suit (GB 2356199 – the so-called film distillation patent).[790] However, from that moment on, neither Lundbeck's infringement claim nor Arrow's invalidity counter-claim was pursued further.[791] Arrow explained to the Commission that "neither Lundbeck nor Arrow took any steps to progress the proceedings until the proceedings were, by DJUHHPHQW VWD\HG E\ ZD\ RI DQ RUGHU Lundbeck never issued Particulars of Claim. It would only have been if Lundbeck wished to reactivate the proceedings, for example by enforcement of the undertakings embodied in the consent order, that there would have been any necessity for Lundbeck to issue Particulars of Claim. Equally, in those circumstances, there was no basis for a substantive argument on the question of infringement of Lundbeck's patents GB235762, 2356199 and EP(GB)171943.

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785 See recitals (393) and (403) above. Lundbeck only launched infringement proceedings based on the second patent mentioned in the agreement, GB 2356199: process for the preparation of pure citalopram, by cyanide exchange (the film distillation patent). While Lundbeck has stated in its reply to the Statement of Objections that "The notice of claim filed in the UK High Court against Arrow did not mention the Crystallization Patent, because the patent had not yet been granted at the time of filing" (see ID 5394, page 206), this does not explain why Lundbeck did not enlarge the infringement action to also cover the crystallisation patent after it had been granted. This is particularly strange given Lundbeck's claim in the reply to the Statement of Objections that «WKH &U\VWDOOL]DWLRQ 3DWHQW ZDV JUDQWHG EHIRUH WKH YHUY HVVHQFH RI WKH See ID 5394, page 206. GLVSXWH EHWZHHQ /XQ

786 See recitals (409) and (429) below.

787 ID 683, page 109, ID 632, pages 4-5.

788 ID 683, pages 95 to 99.

789 See recital (403) above.

790 ID 1444, page 1.

791 Lundbeck stated in its reply to the Statement of Objections that Lundbeck "realized that it was possible for generic companies to design around the Film Distillation Patent" and "renounced enforcing that patent because it lent itself to invalidity claims". See ID 5394, page 162.

Accordingly, and in line with the court rules, Arrow did not pursue the issue of invalidity of the patents in these proceedings as it would only have counterclaimed for invalidity after receiving the Particular of Claim for Lundbeck."[792] Arrow also stated to the Commission: "..Arrow consented to the extension of the time for the Particulars of Claim to be served that Lundbeck requested."[793] To the Commission, Arrow explained its lack of drive to resolve the legal issues as caused by Cipla's refusal to reveal the details of their citalopram manufacturing process, the likelihood that Cipla was in fact infringing Lundbeck's crystallisation patent, and Arrow's claimed inability to challenge the validity of Lundbeck's crystallisation patent.[794] There was never any ruling in the legal proceedings between Lundbeck and Arrow on the validity of Lundbeck's patents or on their infringement by Cipla's manufacturing process.

(411) Lundbeck has reported to the Commission that on 7 and 8 February 2002, Lundbeck performed an analysis of Arrow's citalopram, as obtained pursuant to the United Kingdom agreement with Arrow. According to Lundbeck, "The results were consistent with those of the previous analyses [of Cipla material], and Lundbeck therefore concluded that Arrow's products were based on API from Cipla..."[795]

(412) On 12 February 2002 Lundbeck confirmed to Arrow that it had received over 5 million citalopram tablets from Arrow.[796] Lundbeck also announced it would transfer the GBP 5 million in three instalments over the period of the agreement, the first one taking place "upon receipt of approved UK Marketing Authorisation".[797] However, as Arrow's United Kingdom marketing authorisation was significantly delayed[798], Lundbeck in fact agreed to make most of the payments already before Arrow's marketing authorisation was issued in July 2002. Lundbeck's payment of the GBP 5 million was in fact made in five instalments of GBP 1 million each, which took place on 14 March 2002, 15 April 2002, 27 May 2002, 25 June 2002 and 31 December 2002.[799] Lundbeck also ensured that the 5 million tablets it had received from Arrow were not destroyed, as they might have to be given back to Arrow.[800]

(413) On 13 February 2002, Tiefenbacher wrote to Arrow's [employee function]*: "Lundbeck seems to be in the possession of the DMF's. We have no idea how they got it! In the Netherlands they cited few pages. Unfortunately it is written in the Cipla DMF ±open part±that the base is crystallized. You have seen the papers on your

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792 ID 1517, page 4.

793 ID 610, page 24.

794 ID 610, pages 8 and 24.

795 ID 5394, page 168.

796 ID 683, page 102, ID 634, page 2. With respect to that part of the stock that was not given to Lundbeck in escrow, Arrow explained to the Commission that "The remainder of those stocks of Citalopram were sent by Arrow to jurisdictions where Lundbeck did not have patent protection such that infringement of Lundbeck's patents was not a concern." See ID 610, page 26.

797 ID 634, page 3.

798 See recital (168) above.

799 See ID 1517, page 5. See also for instance ID 904, page 156, approving on 22 May 2002 a transfer of GBP 1 million to Arrow.

800 ID 683, page 64. By the time of the second addendum to the agreement, the stock was physically returned to Arrow, but Arrow was not allowed to dispose of it in any way. See ID 610, page 26 and recital (441) below.

patent meeting with [Tiefenbacher employee] on December 14th."[801] With respect to this e-mail, Arrow stated to the Commission: "At the time that Arrow became aware RI &LSOD V SURFHVV RI PDQXIDFWXUH LQ)HEUDU\ into the agreement with Lundbeck dated 24 January 2002, it realised that its product, developed from Cipla's API, infringed Lundbeck's patent GB 2357762, which had been granted on 30 January 2002."[802]

(414) A Lundbeck internal e-mail of 23 February 2002 indicates that Lundbeck expected Arrow to receive a marketing authorisation for generic citalopram in the United Kingdom in the next couple of days.[803]

(415) On 27 February 2002, Arrow inquired with the United Kingdom Medicines Control Agency as to the reasons why its marketing authorisation had not yet been issued, following the positive opinion Arrow's application had received on 27 December 2001. The Medicines Control Agency replied on 13 March 2002 to confirm receipt. It stated that it would answer as soon as possible.[804]

(416) On 4 April 2002, the American wholesaler acting for Ranbaxy[805] sent a draft confidentiality agreement to Arrow "to cover the technical and legal issues on Citalopram." The e-mail proposed "to discuss the Ranbaxy products in the presence of their representatives which are planning to tour Europe. They are most likely available duriQJ ZHHN LH VWDUWLQJ 0RQGD\ $SULO pricing...I will come back to you early next week."[806]

(417) On 17 April 2002, an Arrow e-mail to a contact person in Australia stated:

"We are looking for a source of citalopram free of both process patents and purification patents for the different markets through out the world. We know that you have already sent use copy of the citalopram route of synthesis from [potential new API supplier]. What we would now like is pages from the DMF outlining some detail of any process steps especially to do with the purification steps involved. There are numerous patents granted across Europe claiming different purification steps from film distillation to simple recrystallisatons! [Potential new API supplier] gets around all the later process patents however, we are not too sure about the purification patents."[807]

(418) On May 1, 2002, Tiefenbacher applied for a type I variation of its marketing authorisation in the Netherlands, the Reference Member State, to include its new washing process.[808] Lundbeck stated in its reply to the Statement of Objections that Tiefenbacher obtained this type I variation to its MA in the Netherlands on 16 July 2002.

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801 ID 635, page 2. This is, of course, without prejudice to the question of the validity of Lundbeck's crystallisation patent. It is recalled that Cipla believed it was using technology that had already been disclosed in 1977 and that Lundbeck's crystallisation patent therefore lacked novelty. See recital (382) above.

802 ID 610, page 28.

803 ID 904, page 182.

804 ID 636, pages 2-3.

805 See recital (386) above.

806 ID 1354, page 1.

807 ID 1293, page 1.

808 ID 5420.

(419) On 14 May 2002, the American wholesaler acting for Ranbaxy sent an e-mail to Arrow informing Arrow that a Ranbaxy representative from India "will be in Europe early June". The American wholesaler also confirmed that his company was "doing follow up work on API's for the market in Europe with the authorisation of Ranbaxy's API export department."[809] In another e-mail to Arrow of the same day, the American wholesaler acting for Ranbaxy stated:

« Z H K H U H E \ W U D Q V P L W R X U R I I H U W R N J R I Dublin.

Samples are available upon request.

[Ranbaxy representative] will be visiting Europe, beginning of June. He is available for a meeting with you either in London or Dublin on Thursday June 6th.»

% H V L G H V & L W D O R S U D P P R V W R I W K H S U R G X F W V Z H[810]

(420) According to information submitted by Arrow to the Commission, on 22 May 2002 Arrow made an application for a variation to its United Kingdom marketing authorisation to the United Kingdom authorities. This application was approved on 23 December 2002.[811] This variation concerned Matrix's process.

(421) On 31 May 2002, Tiefenbacher sent Arrow a detailed description of a new Matrix process for purifying the oily citalopram base, which avoided the appearance of base crystals. Tiefenbacher wrote: « Z H D U H F R Q Y L Q F H G W K D W W K H L Q I U L Q J H The e-mail stated that Matrix had made a PCT filing to request a patent for this purification process. The text of the patent application was attached. Attached also was a protocol of a trial performed on the new process by the University of Hamburg from 26 to 28 March 2002. The conclusion of this trial was:

"The trial demonstrates that with the purification method described known impurities of Citalopram hydrobromide obtained via the Bromphtalide route can be reduced to a value below 0.1%. Formation of crystalline base was not observed. It was nor isolated neither used [sic] for any purification step."[812]

(422) In an internal e-mail of 24 June 2002 Arrow explored whether citalopram produced by the Chinese API producer Zhejiang Huahai Pharmaceuticals would be infringing or not. Arrow observed, in this respect, ""Lundbeck have been suing everyone in the EU on a patent which claims purification of the base by crystallization. From the flow sheet Huahai do not give any details on whether the base is crystallized or kept in solution and converted to the hydrobromide salt and crystallized. They do refer to the hydrobromide salt as "crude" which suggests that they purify the salt rather than the base. If this is the case then the process is non-infringing."[813]

(423) According to information submitted by Arrow to the Commission, on 8 July 2002, Arrow again applied for a variation regarding Matrix's process. This application was approved by the United Kingdom authorities on 4 June 2003.[814]

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809 ID 1354, page 11.
810 ID 1354, page 12.
811 ID 1297, page 38.
812 ID 640, page 24.
813 ID 641, page 2.
814 ID 1297, page 38.

(424) On 26 July 2002, Arrow received United Kingdom marketing authorisations for the distribution of citalopram tablets of 10, 20 and 40 mg.[815] These marketing authorisations indicated both Cipla and Matrix as authorised API manufacturers.[816]

(425) On 12 August 2002, Tiefenbacher sent an e-mail to Arrow to inform it that "Due to the patent situation it become necessary that also Cipla, the second API manufacturer for Citalopram changes the route of synthesis. The Dutch authorities checked the corresponding documentation and informed us that the change in the route of synthesis is a t\SH , YDUL DWLRQ«" Tiefenbacher asked Arrow to make the corresponding application in the United Kingdom.[817] According to information submitted by Arrow to the Commission, this application was made by Arrow on 30 September 2002 and was approved by the United Kingdom authorities on 3 February 2003.[818]

(426) In October and November 2002, further contacts took place between Arrow's subsidiary Resolution Chemicals and the Indian API supplier Neulands regarding certain orders of citalopram API Resolution had placed with Neulands for certification purposes.[819]

(427) On 14 November 2002, an internal Arrow e-mail considered concerning the process of the API supplier Reso: «WKH SDWHQW DJHQW LV UHVHUYLQJ an infringement to go via a patented intermediate if it's only formed transiently in the process.»[820]

(428) An internal Arrow e-mail of 26 November 2002 mentioned that the Indian producer Sun Pharmaceuticals produced citalopram.[821]

(429) With the expiry of the original court order coming up by 31 December 2002[822], Lundbeck and Arrow agreed on 19 December 2002 on the text of a new draft order to be issued by the Master of the High Court of Justice, Chancery Division, Patents Court.[823] The Master issued the consent order with only marginal changes on 30 January 2003. He ruled that "all further proceedings in this claim be stayed save for the enforcement of the undertaking given by the Defendants in this Order." The undertaking given by Arrow "on its own behalf and on behalf of all associated and related entities" was that "until a final unappealable enforceable UK Court decision in this matter has been rendered or until at least 1st April 2003, which ever shall occur first", Arrow would refrain from making, importing or selling in the United Kingdom "(1) Citalopram not manufactured by Lundbeck or with the consent of Lundbeck or (2) any other Citalopram which Lundbeck alleges to infringe its Proprietary Rights (including patent rights to inventions of Citalopram and to processes relating to the manufacture thereof, including but not limited to in particular GB patents no 2 357 762, 2 356 199 and EP (GB) 171 943) and, to enable Lundbeck to ascertain if there may be an infringement, during the Term to provide

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815 ID 682, page 7.
816 ID 1632. See also ID 1297, page 48.
817 ID 1359, page 1.
818 ID 1297, page 38.
819 ID 1294, pages 5 to 9.
820 ID 1291, page 1.
821 ID 643, page 2.
822 See recital (409) above.
823 ID 1449, pages 1 to 4 and ID 1450, pages 1 to 4.

Lundbeck with sufficient samples for analysis purposes at least one month prior to aQ\ WKUHDWHQHG PDQXIDFWXUH LPSRUWDWLRQ VDOH Also, Arrow committed not to transfer, license or otherwise deal in any United Kingdom marketing authorisations relating to such citalopram.[824]

(430) From the two consent orders issued on 6 February 2002 and 30 January 2003, it appears that while these proceedings served to obtain enforceable court orders restraining Arrow from selling generic citalopram, there is no indication in the file that either of the two parties asked the High Court, Chancery Division, Patents Court to substantively examine the question whether any of the three Lundbeck patents mentioned in the agreement had been infringed or whether it was valid. As Lundbeck explained to the Commission, "Lundbeck v. Arrow Generics Limited and Resolution Chemicals (HC 02 CO 216) was an action brought by Lundbeck against Arrow Generics Limited and Resolution Chemicals Limited for infringement of one of Lundbeck's patents (UK patent no 2, 356, 199). The Claim Form was issued on January 25, 2002. On the basis of undertakings given by the defendants to the court in two consent orders dated February 20, 2002 and December 19, « UHVSHFWLYHO\ WKH DFWLRQ ZDV VWD\HG[825]

(431) Apparently only by the end of January 2003[826], after the original agreement had expired on 31 December 2002, did Arrow and Lundbeck formally agree to extend their agreement for the United Kingdom. The addendum, signed without a date by H. Lundbeck A/S and Arrow Generics Limited and Resolutions [sic] Chemicals Ltd, covered the United Kingdom for the period from 1 January 2003 to 31 March 2003.[827] It extended the provisions of the original agreement, using virtually the same preamble and definitions. A new element in the preamble was the mention of the new consent order Lundbeck had obtained against Arrow (agreed between the parties on 19 December 2002 and issued by the court on 30 January 2003).

(432) Article 1.1 of the extension agreement repeated the substantive obligations on Arrow already stated in Article 1.1 of the original agreement and in the consent order of 30 January 2003. In essence, in the United Kingdom Arrow was prohibited from making, importing or selling citalopram which Lundbeck alleged to be infringing or in dealing in any marketing authorisations pertaining to such citalopram.

(433) Article 2.1 provided:

"In consideration of the undertakings in clause 1.1 and ARROW not seeking a cross-undertaking in damages in respect of the period comprising the Term, Lundbeck shall provide ARROW with a total of four hundred and fifty thousand pounds sterling * % 3 . The money was to be paid in three instalments of GBP 150 000 for each month of the duration of the term.

824 ID 645, pages 1 to 5.

825 ID 823, page 40. United Kingdom patent no; 2356199 was Lundbeck's patent for a process for the preparation of pure citalopram, by cyanide exchange (the so-called film distillation patent). See recital (393) above.

826 ID 904, pages 53 to 60.

827 ID 8, pages 241 to 245.

Arrow later explained to the Commission that the amount of GBP 150 000 per month in the first and second addenda "represented a realistic (albeit broad) estimate of the likely damages that would be recovered under a cross-G H U W D N L Q J[828] L Q G D P D

(434) On 27 March 2003, Arrow received an e-mail from Ranbaxy, in which Ranbaxy stated:

"You would recall, during our meeting in London, we had discussed possible co-operation on some products like:

«

Citalopram

«

Citalopram

(435) You had expressed interest during the meeting, as you believe your current source is infringing. We believe, our product is clear of all such issues. Should you desire, we can send you a small sample for testing.[829]"

(436) The negotiation of a second addendum also took considerable time. A draft was still exchanged on 4 May 2003, more than a month after the first addendum had expired. In the accompanying e-mail, Lundbeck told Arrow:

"If lagab trial is withdrawn, you will have to invalidate the patent yourself. I believe that is fair."[830]

(437) On 28 May 2003, the Indian API supplier Neulands reported to Arrow's subsidiary Resolution Chemicals: "From the current process, we cannot meet your target, especially in view of patent situation.[831]"

(438) A second addendum was agreed on 1 June 2003.[832] Its term was "from the 1st April 2003 until 7 days from the date of the decision by the High Court of Justice, Chancery Division, Patents Court in the Lagap Litigation or the 31st January 2004, which ever occurs first". The second addendum therefore tied the extension of the agreement to the fate of the on-going Lagap litigation (dealing with citalopram from Matrix) rather than to the litigation between Arrow and Lundbeck (dealing with citalopram from Cipla), which had been stayed and was never continued.

(439) Article 1.1 of the second addendum was similar to Article 1.1 of the first addendum and Article 1.1 of the original agreement: Arrow's obligation not to make, import or sell in the United Kingdom citalopram which Lundbeck alleged to be infringing or to deal in any marketing authorisations pertaining to such citalopram was prolonged for the duration of the second extension.

(440) In Article 1.2, "In consideration of the undertakings in Clause 1.1 and ARROW not seeking a cross-undertaking in damages in respect of the period comprising the Term", Lundbeck agreed to pay Arrow GBP 1.5 million, again amounting to GBP

828 ID 610, page 29.
829 ID 1354, pages 17-18.
830 ID 845, page 23.
831 ID 1294, page 10.
832 ID 8, pages 246 to 252.

150 000 for each month of the ten months term. The money was to be paid in ten monthly instalments.

(441) Article 3 of the second addendum was new and provided:

"As the time limit for sale of ARROW's stock expires before October 2003, Lundbeck agrees to purchase the stock from ARROW for destruction, if the High Court of Justice, Chancery Division, Patents Court finds in the Lagap Litigation that the Proprietary Rights are invalid. In such case Lundbeck shall pay an amount of GBP 750.000 (seven hundred and fifty thousand) to ARROW within 30 days from delivery of Arrow's stock and following the court's decision. If the High Court of Justice, Chancery Division, Patents Court in the Lagap Litigation gives judgement that the Proprietary Rights are not invalid Lundbeck shall obtain delivery of the stock, but shall not pay for the stock. If the Lagap Litigation is settled, withdrawn or where no ruling is made in the Lagap Litigation on or before 31 January 2004, time being of the essence, Lundbeck agrees to purchase 2/3 of the stock on the same conditions as set out above in this Clause 3, 2nd sentence against payment of GBP 500,000 (five K X Q G U H G W K R X V D Q G « ' X U L Q J W K H 7 H U P R I W K L V $ delivered to Lundbeck, ARROW shall store the stock and may not dispose of such stock in any way."

According to exhibit 3.1 to the second addendum, the amount of GBP 750 000 represented the cost price of the over 5 million tablets, not the resale value.[833] This amount included Arrow's packaging cost.[834]

(442) An e-mail of Arrow's [employee function]* dated 5 August 2003 summarised the European citalopram situation over the last couple of years as follows: "Towards expiry of the basic compound patent in Europe there was essentially [only] one source of raw material, VIS. The route that they employed was essentially that shown in the basic patent and this formed the basis for the generic registrations around Europe. In an attempt to restrict generic entry Lundbeck bought VIS and refused to supply material to generic companies. Lundbeck also started to file numerous patent applications aimed at blocking the "old" route of synthesis from being used. Of these by far the most troublesome was WO 01/68627 which covered a method of purifying citalopram base by recrystallization before conversion to the marketed hydrobromide salt. Lundbeck argued that material from the "old" VIS process was impure and required to be purified before use. Unfortunately, the raw materials available all employed a base crystallization and Lundbeck successfully managed to keep everyone off the market initially. There are essentially three raw materials we have worked with from Cipla, Matrix and [third API supplier]. Initially, all three Z H U H F D X J K W E \ W K H S D W H Q W D E R Y H 6 L Q F H W K H Q Since this step has been introduced there have been a series of non-infringement decisions in various European courts (Denmark, Sweden Norway, Netherlands and Germany)."[835]

(443) On 26 August 2003, Resolution Chemicals sent an e-mail to Arrow, stating: "[employee name]* asked me to check if our process in India [that of the API suppler Neulands] was worth using. He says Matrix, Ranbaxy and Max are all free

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833 ID 8, page 252.
834 ID 846, page 170.
835 ID 649, page 2.

so only makes sense if there are no issues in Europe or the States." The answer from Arrow stated: "Even if [Lundbeck] did injunct, we'd still have the other source [Tiefenbacher] registered so there's no way they could remove us from the market."[836]

(444) On 15 October 2003, Lundbeck wrote to Arrow to inform it that the Lagap litigation had been settled on 13 October 2003 and that Lundbeck consequently terminated the agreement with Arrow as of 20 October 2003.[837] Although Lundbeck did not consider the settlement equivalent to a decision by the High Court of Justice[838], it believed that, as it later explained to the Commission, "because the Lagap settlement provided a licence to Lagap to sell citalopram in the UK, Lundbeck considered it [illegible]".[839] Arrow acknowledged the termination and thanked Lundbeck for its cooperation.[840] Lundbeck paid GBP 100 000 for the period from 1 October 2003 to 20 October 2003 and then stopped its regular monthly payments to Arrow.[841]

(445) On 4 November 2003 Lundbeck and Arrow agreed that Arrow would not deliver 2/3 of the stock to Lundbeck as foreseen in Article 3 of the second addendum, but that instead Lundbeck would pay Arrow GBP 350 000.[842] Lundbeck did not specify that these tablets should be destroyed and Arrow in fact sold them in the United Kingdom when it entered the citalopram market there. This entry, however, took place only in February 2004, following the expiration of the originally envisaged term of 31 January 2004 mentioned in the agreement with Lundbeck, despite the fact that Lundbeck had already terminated the agreement on 20 October 2003.[843] To the Commission, Arrow explained this late entry by saying that "In the absence of a High Court decision in the Lagap case, Arrow determined that the prudent course was to await the expiry of the Second Addendum before launching its citalopram products in the UK."[844] In this respect, Arrow did not indicate to the Commission that there was any link between Lundbeck's payment of GBP 350 000 and Arrow's decision to enter the United Kingdom market only in February 2004.

(446) Arrow indicated to the Commission that for the first and second extensions of Arrow's agreement with Lundbeck, Lundbeck made the following payments to Arrow:

GBP 150 000 on 7 February 2003;

GBP 150 000 on 25 February 2003;

GBP 150 000 on 26 March 2003;

GBP 300 000 on 16 June 2003;

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836 ID 1294, page 15.
837 ID 8, pages 497-498.
838 See recital (438) above.
839 ID 823, page 41.
840 ID 682, page 79.
841 ID 8, page 497, ID 682, page 77.
842 ID 904, page 48.
843 ID 610, pages 10, 25, ID 682, page 79. Arrow had obtained an extension of a year of the shelf life of the citalopram tablets in question from the United Kingdom Medicines Control Agency. See ID 610, page 27.
844 ID 610, page 10.

GBP 150 000 on 30 June 2003;

GBP 150 000 on 31 July 2003;

GBP 150 000 on 29 August 2003;

GBP 150 000 on 30 September 2003;

GBP 100 000 on 11 November 2003; and

GBP 350 000 on 13 November 2003.[845]

(447) In total, over the entire period of operation of the agreement from 24 January 2002 to 20 October 2003, Lundbeck transferred a value to Arrow of GBP 6.8 million (corresponding to approximately EUR 10.4 million)[846] under the agreement regarding the United Kingdom, consisting of:

– GBP 5 million for the first year (until 31 December 2002);

– 3 times GBP 150 000 in the first extension between January 2003 and March 2003 = GBP 450 000;

– 6 times GBP 150 000 in the second extension between April 2003 and September 2003 = GBP 900 000;

– GBP 100 000 in the second extension between 1 October 2003 and 20 October 2003;

– GBP 350 000 in the second extension, related to Arrow's stock.

7.4.4. Subsequent events

(448) When Arrow entered the United Kingdom market in February 2004 with its citalopram from Cipla, Lundbeck did not pursue Arrow for patent infringement.[847]

7.5. Lundbeck's agreement with Arrow regarding Denmark

7.5.1. The negotiation of the agreement

(449) On 20 September 1999, the Danish company Nycomed, with which Lundbeck had concluded a co-marketing agreement[848], started selling Lundbeck-manufactured citalopram in Denmark under the brand name Akarin, at prices comparable to Lundbeck's own-brand citalopram.[849]

(450) On 11 February 2002, Lundbeck's crystallisation patent was granted in Denmark as patent DK 173903.

(451) According to Arrow, early in March 2002, Lundbeck and Arrow met.[850] Following this meeting, on 11 March 2002, Lundbeck sent a draft agreement for Denmark and Sweden to Arrow/Resolution Chemicals in the United Kingdom.[851]

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845 ID 1517, pages 5-6.

846 Using an average annual exchange rate for 2002 of 1 EUR = 0.62883 GBP and for 2003 of 1 EUR = 0.69199 GBP, source European Central Bank.

847 ID 610, page 25, ID 823, page 40.

848 ID 813, pages 48 and 62.

849 ID 813, page 84. See also ID 200. Another Lundbeck document mentions January 2000 as Nycomed's launch date of citalopram. See ID 903, page 3.

850 ID 1325, page 2.

851 ID 1327, pages 1 to 5 and ID 1325, page 2.

(452) In March 2002, the company A/S Gea (linked to Hexal) launched generic citalopram in Denmark, based on Cipla API.[852] Lundbeck started infringement proceedings before a Danish court 17 April 2002 and obtained an interim injunction on 5 July 2002.[853]

(453) In May 2002, Biochemie launched generic citalopram in Denmark, also using Cipla API.[854] Lundbeck started infringement proceedings on 12 June 2002 and obtained an interim injunction on 8 November 2002.[855]

(454) On 8 May 2002, Tiefenbacher informed Arrow Scandinavia AB in Stockholm, Sweden (a holding company for Arrow Group's Scandinavian subsidiaries[856]), that it had obtained a marketing authorisation in Denmark for the company Jacobsen Pharma A/S on 2 May 2002.[857] On 17 May 2002 Arrow Group A/S and Tiefenbacher agreed an appendix to their earlier contract of 22 May 2001.[858] This appendix specified that Tiefenbacher agreed that Arrow could, instead of obtaining its own licence through the mutual recognition procedure, purchase a national licence granted to a third party in Denmark and Sweden based on Tiefenbacher's registration file (which covered citalopram sourced from Cipla or Matrix).[859] This meant that Arrow could, in particular, buy the marketing authorisation obtained in Denmark by Jacobsen Pharma A/S.[860] Arrow could then start selling generic citalopram in Denmark, whether from Cipla or Matrix.[861]

(455) On 23 May 2002, a new draft text of an agreement between Arrow and Lundbeck was sent from Lundbeck to Arrow Generics in the United Kingdom, foreseeing that Arrow would consent to an injunction for Denmark and Sweden in exchange for a compensation payment by Lundbeck of USD 500 000 for each Member State.[862] Arrow Scandinavia AB was also involved in the negotiation.[863] In an e-mail of 27 May 2002, Arrow proposed that Arrow Group A/S in Copenhagen should be the party to the agreement for the Arrow group of companies and that "all affiliates" of Arrow Group A/S should be covered by the agreement. A new draft sent by Lundbeck on 31 May 2002 shows that the idea of a consent injunction for Sweden had been dropped.[864]

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852 ID 904, page 261.

853 The case was settled in 2005. See ID 234, page 6.

854 ID 904, page 261.

855 The case was settled in October 2003. See ID 234, page 5.

856 ID 1325, page 9.

857 ID 907, pages 95 to 97.

858 See recital (375) above.

859 ID 1329, pages 1 to 4.

860 Arrow informed the Commission that in fact Arrow did not buy any national marketing authorisation under this provision, including from Jacobson Pharma A/S. See ID 1325, pages 2, 3 and 5. It appears from the agreement that Lundbeck believed at the time of the conclusion of the agreement that Arrow could use or might come to use the marketing authorisation in Denmark of Jacobson Pharma A/S, see ID 8, page 255 and ID 823, page 45. Following the conclusion of the agreement with Lundbeck, there would have been no longer any incentive for Arrow, at least for the duration of the agreement, to buy a marketing authorisation for Denmark, as the agreement prohibited Arrow from selling there anyway.

861 ID 8, page 199.

862 ID 845, pages 54 to 68.

863 ID 907, page 66, ID 907, pages 94 to 97.

864 ID 907, page 166. The precise reasons why the parties did not pursue an agreement for Sweden are unclear. Denmark may have been more important to Lundbeck than Sweden because in Denmark

7.5.2. The agreement

(456) On 3 June 2002 Arrow Group A/S and H. Lundbeck A/S concluded an agreement for Denmark.[865] The preamble to the agreement noted that "Arrow is in the process of obtaining a licence from a third party to import bulk Citalopram not manufactured by Lundbeck or with the consent of Lundbeck into the Territory" and that "Arrow intends to import bulk Citalopram into the Territory from Germany". The preamble then stated that Lundbeck had performed laboratory analyses of Arrow's citalopram and that the results of these analyses gave Lundbeck "substantial reason to believe" that Arrow's citalopram infringed Lundbeck's patent DK 173903 (the Danish crystallisation patent) and DK patent application PA 2000 01943 8 (the Danish film distillation patent application)[866]. The preamble continued by saying that "…Arrow has had no intention or knowledge of any infringement of Lundbeck's intellectual property rights and makes no admission of infringement, but acknowledges that Lundbeck is of the opinion that the findings by Lundbeck may lead to the conclusion that an infringement has taken place or would take place", that "Lundbeck represents that it would have pursued the said alleged infringement before the relevant courts", that Lundbeck had obtained a voluntary injunction in the United Kingdom against Arrow and that "…the parties are in agreement that further litigation between them should be avoided also taking into consideration the costs involved in such litigation and the risks for both parties concerning the outcome of same".

(457) Article 1.1 of the agreement provided:

"Arrow consents to cancel, cease and desist from any importation, manufacture, production, sale or other marketing of products containing Citalopram which Lundbeck alleges to infringe its intellectual property rights in the Territory for the term of this Agreement, however only until a final, unappealable and enforceable, judicial decision in the Infringement Litigation, as defined above, has been rendered by the Courts in the UK. The obligation of Arrow under this clause 1.1 shall hereinafter be referred to as the "Consent Injunction"."

This provision also meant that Resolution Chemicals Ltd, as a subsidiary of Arrow Group A/S, was prohibited from manufacturing citalopram destined for sale in Denmark if Lundbeck alleged such citalopram to infringe its intellectual property rights in Denmark. Arrow later confirmed to the Commission that "The Lundbeck Agreements cover citalopram in any form, including both as an API and a medicine."[867]

Lundbeck had since February 2000 built up a considerable market share for its authorised generic supplier Nycomed selling Lundbeck-produced material, see ID 844, page 29. Arrow speculates that Sweden may have been dropped because several other generic companies had entered the Swedish market in February 2002 (see ID 1325, page 3), even though Lundbeck was, at least initially, successful in both Sweden and Denmark in obtaining interim injunctions (see ID 222, pages 18 to 22 and 29 to 32).

865 ID 8, pages 253 to 262.

866 This patent was granted in Denmark on 29 June 2002 as patent DK 2001 00386. Source: Espacenet.

867 ID 610, page 25. In a later response on the Danish agreement, Arrow confirmed that "Subject the following qualifications, the substantive terms of the Danish Agreement are essentially the same as the UK agreement, and are explained fully in Arrow's First Response" (ID 1325, page 5). The qualifications that then followed did not indicate any change to the coverage of citalopram both as an API and as a medicine in the Danish agreement.

It should be noted that Article 1.1 of the Danish agreement did not provide for any testing of samples on the basis of which Lundbeck would "ascertain if there may be an infringement" as Article 1.1 of the United Kingdom agreement stated.

(458) Article 1.2 of the agreement provided that "During the term of this Agreement, Arrow shall maintain all licences and marketing authorisations and may not dispose of such licences or marketing authorisations neither as a sale, license or in any other way".

(459) Article 2.1 provided that "Lundbeck shall grant Arrow a compensation for the Consent Injunction under clause 1 of USD 0.5 million (USD 500,000.00)". Lundbeck Pharma A/S was identified as "holding the license on behalf of Arrow". The product was identified as "a product supplied by Alfred E. Tiefenbacher".

(460) Article 2.2 provided:

"In the event the final, unappealable and enforceable court decision in the Infringement Litigation rules that Arrow does not and has not infringed Lundbeck's intellectual property rights, the compensation paid by Lundbeck in accordance with clause 2.1 shall constitute full and final compensation from Lundbeck for any and all alleged and/or documented loss sustained or allegedly sustained by Arrow due to the Consent Injunction under this Agreement or otherwise resulting from this Agreement."

This indicates that the amount of compensation Lundbeck granted to Arrow for not selling generic citalopram to the market in Denmark was based on Arrow's expected profits in Denmark in the period concerned if Arrow had sold generic citalopram and had not been found to infringe Lundbeck's patents or if those patents had been found invalid.

(461) Article 3.1 provided:

"On payment of compensation as provided in clause 2 Lundbeck shall obtain delivery of Arrow's current stock of Citalopram tablets consisting of approximately 1 million tablets which shall comply with the marketing authorisation granted by the Danish DXWKRULWLHV DW FRVW SULFH EHLQJ 86' «

(462) Article 4.1 provided:

"The term of this Agreement shall be from the date of signature until a final and unappealable court decision in the Infringement Litigation has been rendered or until 1 April 2003, whichever of these events occurs first". The term "Infringement Litigation" was defined in the preamble as the "voluntary injunction against Arrow in the High Court of Justice, Chancery Division in London on 6 February 2002 ordering Arrow to be restrained until further order from infringing GB Patent 2 356 199B being equivalent to DK patent no. 173903"[868].

[868] Arrow explained to the Commission that in fact the United Kingdom patent and the Danish patent mentioned as equivalent here erroneously did not cover the same subject matter, GB patent 2 356 199B being the film distillation patent and DK patent no. 173903 being the Danish equivalent of GB 2 357 762, the crystallisation patent. Given that the United Kingdom proceedings concerned the film distillation patent, parties probably meant to refer to the equivalent Danish film distillation patent application, PA 2000 01943 8, mentioned earlier in the preamble. Arrow also informed the Commission that at the time the agreement was concluded, no patent litigation was taking place on citalopram between Lundbeck and Arrow in Denmark. See ID 1325, page 2.

(463) Article 4.2 provided that if any third party tried to import, manufacture or sell generic citalopram in Denmark, Lundbeck was obliged to pursue such action based on its patents. If Lundbeck were unsuccessful in such litigation, Arrow had the right to annul the agreement, repay to Lundbeck that portion of the compensation for the Consent Injunction which applied to the period after generic entry and buy back its stock of tablets at the same cost price as for which it had sold them to Lundbeck.

(464) A copy of Jacobsen Pharma's marketing authorisation was annexed to the agreement.

7.5.3. Events during the implementation of the agreement

(465) In June 2002, United Nordic Pharma launched Matrix citalopram in Denmark.[869] Lundbeck started infringement proceedings on 19 June 2002 and obtained an interim injunction on 21 March 2003.[870]

(466) Lundbeck paid the USD 500 000 to Arrow Group A/S on 17 June 2002.[871]

(467) In September 2002 Ratiopharm launched generic citalopram from Matrix[872] in Denmark. Lundbeck started infringement proceedings on 18 November 2002. The court denied an injunction on 25 April 2003.[873]

(468) In November 2002, Copyfarm launched generic citalopram from Matrix[874] in Denmark. Lundbeck started infringement proceedings in January 2003. An interim injunction was granted on 17 June 2003. On 26 January 2004, the Appeals Court ordered the injunction lifted.[875]

(469) Arrow explained to the Commission that "It had not sold any citalopram in Denmark prior to the conclusion of the Danish Agreement, and did not attempt to do so during the lifetime of the Danish Agreement"[876]

(470) Arrow also informed the Commission that "Arrow Group's tablets for Denmark were purchased from Tiefenbacher". A UK stock reconciliation suggests that shipments were made to Denmark in the quantities contemplated by Clause 3.1 of the Danish Agreement". Arrow "has a copy of an invoice sent to Lundbeck for payment of the US$147,000 under the terms of Clause 3.1 of the Danish Agreement"[877]. It therefore appears likely that the tablets transferred to Lundbeck were material which Arrow Generics Limited in the United Kingdom had purchased earlier from Tiefenbacher.[878] The stock was shipped from Ireland to Lundbeck in Copenhagen.[879] The invoice to Lundbeck was sent by Arrow Generics Limited and Lundbeck's payment for the stock was also made to Arrow Generics Limited.[880]

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869 ID 904, page 261.
870 The injunction was upheld on 24 June 2003. See ID 234, page 6.
871 ID 683, page 113.
872 ID 903, page 3.
873 ID 234, page 7.
874 ID 903, page 3.
875 ID 234, page 5.
876 ID 1325, page 5.
877 ID 1325, page 5, ID 1334, page 1, ID 1434, pages 1 to 3.
878 ID 1325, page 6.
879 ID 683, page 113.
880 ID 1325, page 5.

(471) Lundbeck confirmed to the Commission that "Lundbeck initially stored the products purchased from Arrow and, following the expiry date, ultimately destroyed them"[881]

(472) In total, over the entire period of operation of the agreement from 3 June 2002 to 1 April 2003, Lundbeck transferred a value to Arrow of USD 647 000 (corresponding to approximately EUR 684 000)[882] under the agreement regarding Denmark, consisting of:

– USD 500 000 for the duration of the agreement;

– USD 147 000 for Arrow's stock.

7.5.4. Subsequent events

(473) In the absence of a final and unappealable court decision in the "Infringement Litigation" between Lundbeck and Arrow before 1 April 2003, the agreement for Denmark expired on 1 April 2003. Lundbeck explained to the Commission: "Because generic versions of citalopram had entered the market in Denmark by the end of the agreement with Arrow, Lundbeck did not seek to extend the agreement with Arrow beyond this date"[883] and "In April 2003 there were several generic companies selling citalopram in Denmark. Lundbeck considered it was too costly to defend its citalopram intellectual property rights via further litigation or settlement agreement in Denmark."[884]

(474) Lundbeck also explained to the Commission that "The agreements with Arrow only covered the UK and Denmark because these were the only Member States where Arrow, to Lundbeck's knowledge, intended to market citalopram"[885]

(475) Arrow, from its side, reported to the Commission that "Arrow Group only entered the Danish market in June 2005."[886] These sales were not subject to infringement litigation by Lundbeck.[887]

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881 ID 823, page 45.

882 Using an average annual exchange rate for 2002 of 1 EUR = 0.94557 USD, source European Central Bank.

883 ID 823, page 22.

884 ID 823, page 47.

885 ID 823, page 47.

886 ID 1325, page 5.

887 ID 823, page 45.

7.6. Lundbeck's agreement with Alpharma regarding the EEA

7.6.1. The negotiation of the agreement

(476) On 25 August 2000, Alpharma entered into an agreement with Tiefenbacher and Omega Farma providing Alpharma with the rights to future marketing authorisations for generic citalopram Tiefenbacher would obtain (covering supplies from Cipla and Matrix).[888] Tiefenbacher and Omega Farma had together developed registration files for finished dosage forms containing the active ingredient citalopram hydrobromide, in the form of film-coated tablets of 10, 20 and 40 mg. These registration files had been submitted in March 2000 to the Dutch health authorities. Following approval by the Dutch health authorities, Tiefenbacher would use the mutual recognition procedure to obtain as soon as possible a marketing authorisation for Germany. Tiefenbacher would license these marketing authorisations, after they had been obtained, on a non-exclusive basis to Alpharma. In addition, Alpharma obtained the right to either apply for marketing authorisations itself in all the remaining European countries using the registration files prepared by Tiefenbacher and Omega or to make Tiefenbacher extend its mutual recognition procedure to those countries (subject to additional payment). Alpharma also obtained the right to subsequently distribute the products concerned by the agreement in all European countries where it would have marketing authorisations. For a period of three years after launch in the United Kingdom, Alpharma would buy the product as tablets in bulk from Omega Farma and for an additional two years, Alpharma would buy the API exclusively from Tiefenbacher. Sales of the product by Alpharma would also be subject to a royalty payment to Tiefenbacher. The agreement stated that according to Tiefenbacher's best knowledge, there were no patents interfering with the project in Germany or, after 11 June 2002, in the Netherlands. However, neither Tiefenbacher nor Omega would "warrant for damages of ALPHARMA due to patent infringements caused by the execution of the agreement".[889]

(477) On 11 January 2001 Lundbeck sent a letter to Alpharma in Denmark saying that it was aware that Alpharma was involved in activities in relation to "our compound" (that is to say citalopram) and warning it of possible infringement of Lundbeck's patents relating to the preparation of that compound. This letter listed the recently granted Dutch utility model 1016435 which covered not only a process to purify citalopram through crystallisation of the free base, but also, in the words of Lundbeck in the letter: "The crystalline base of citalopram is claimed pr. se." The letter offered the possibility of "discussions of these matters."[890]

(478) On 2 February 2001 Alpharma sent an e-mail to Lundbeck saying that it was interested in investigating possibilities for cooperation with Lundbeck, in particular allowing Alpharma to introduce a generic version, possibly produced by Lundbeck, already before patent expiry on a profit-sharing basis.[891]

(479) On 12 February 2001 Lundbeck talked with Alpharma and agreed a meeting at Alpharma's premises on 29 March 2001.[892] Lundbeck stated in its reply to the

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888 ID 746, pages 14 and 210 to 220.

889 See Article 9.1 of the agreement, ID 746, page 216.

890 ID 903, pages 66 to 69. Regarding the Dutch utility model 1016435 see footnote 226 above.

891 ID 723, page 126.

892 ID 723, page 125.

Statement of Objections that the [employee function]* of Alpharma ApS participated in this meeting.[893]

(480) On 25 June 2001, in implementation of their earlier marketing authorisation purchase agreement of 25 August 2000, Alpharma and Tiefenbacher entered into a detailed supply agreement pursuant to which Alpharma would purchase exclusively from Tiefenbacher all finished dose citalopram products for sale in the EEA.[894] These products were to be produced by Omega Farma based on API from the Indian producers Cipla or Matrix. The tablets would be supplied by Omega in bulk form and would be packaged into blister packs and labelled for Alpharma by the packaging company Dragenopharm. The supply agreement with Tiefenbacher simply provided the product specifications that Tiefenbacher had to comply with and left it to Tiefenbacher to select the API supplier.[895] According to Tiefenbacher, for the products or API sourced from Tiefenbacher, Alpharma was free to specify to Tiefenbacher whether the citalopram should come from Cipla or Matrix.[896] Certainly the agreement did not prevent this. This having been said, initially, at least until the moment when Alpharma and Lundbeck concluded their agreement regarding the EEA, the citalopram products supplied by Tiefenbacher came from Cipla.[897]

(481) In its reply to the Statement of Objections, Lundbeck informed the Commission that between July 2001 and January 2002, it performed several analyses of Cipla's citalopram.[898] According to Lundbeck: "The results of these tests were all consistent and indicated the presence of 5-Chloro and 5-Bromo impurities and the absence of 5-Acetyl impurity, which showed that Cipla used the Cyanation 2002-1 Process. The low level of 5-Chloro and 5-bromo impurities and the rate between these two demonstrated that the specific impurity level could only have been obtained through the Crystallization Process, in violation of the Crystallization Patent."[899] In its reply to the Statement of Objections, Lundbeck also stated that between June 2001 and January 2002, it performed several analyses of Matrix's citalopram. According to Lundbeck, « W K H L P S X U L W\ OHYHO FRXOG RQO\ KDYH EHHQ REWDLQHG WKURXJK WKH &U\VWDOOL]DWLRQ 3URFHVV «[900]

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893 ID 5394, page 222.

894 ID 746, page 14 and ID1220, pages 11-12.

895 As Alpharma later explained to the Commission: "Alpharma AS was not involved in the selection of the API supplier as this was dealt with by Tiefenbacher as the applicant for the marketing authorisation and Alpharma simply purchased the finished dose form of the product from Tiefenbacher." See ID 746, page 14. Originally, Tiefenbacher had wanted to use the Italian API supplier VIS, but after this company had been acquired in October 2000 by Lundbeck, Tiefenbacher switched to Cipla and Matrix as possible suppliers. Cipla was the API supplier of the citalopram products purchased by Alpharma before Alpharma entered into the agreement with Lundbeck. See ID 4817, page 23.

896 ID 1713, page 1.

897 Matrix stated in the United Kingdom Lagap litigation that it began supplying citalopram to the EEA in March 2002. Lundbeck has stated to the Commission that it first became aware of Matrix's citalopram being sold on a market in the EEA (Denmark) in June 2002. See recital (153) above. See also ID 5394, page 163.

898 ID 5394, page 166.

899 ID 5394, pages 166-167 and page 222. It should be noted that in the Lagap litigation, Lundbeck initially made a similar argument […]*, After the inspection of Matrix's process, however, Lundbeck withdrew this argument. Lagap's expert stated in that case that "Some of [Lundbeck's allegations], in particular WKRVH FRQFHUQLQJ VR FDOOHG ILQJHUSULQWV" See recitals (156), (158) and (160) above.

900 ID 5394, pages 171-172.

(482) On 17 September 2001, Alpharma sent Tiefenbacher an e-mail stating:

"We have not had the opportunity to review the route of synthesis for the Cipla API or the other alternative source which you have yet to name to us. We need to do this to assure ourselves that there is no risk of patent infringement."[901]

One day later, on 18 September 2001, Tiefenbacher replied:

"- the process of Cipla as well as the other supplier follows exactly the route described in the basic patent, UK 1526331, priority date January 14, 1976 and its family members like DE 2657013, F 7701079 etc. This was double-checked by patent attorneys and confirmed by the impurities that are fund in the a.m. sources.

- we are also aware of the fact that a lot of additional patents and applications cover several routes of synthesis and intermediates, e.g. EP 171943, WO 01/02383, WO 98/19511, WO 98/19512, WO 98/19513, WO 00/13648, WO 00/11926, WO 99/30548, etc. etc. None of them leads to infringement by the process used by our suppliers.

- furthermore, we are aware of the fact that several patents and applications cover the purification of Citalopram, e.g. GB 2 356 199, GB 2 357 762 and the corresponding national family members. We are concerned about some of the claims of the latter one, and will immediately take legal action against it in case they are granted."[902]

(483) On 24 September 2001 Alpharma ordered a first stock of citalopram tablets from Tiefenbacher, to be delivered by 16 November 2001.[903] Orders for more tablets followed on 11 December 2001 and 29 January 2002.[904] These orders did not mention the producer of the API.

(484) Lundbeck later explained to the Commission that "In September 2001, Lundbeck had seen evidence that Alpharma may attempt to enter in the Netherlands as early as January 2002, apparently based on a "licence" obtained from Tiefenbacher"[905]

(485) An internal Alpharma document of 11 October 2001 indicates that Alpharma had the following expectations with respect to marketing authorisations and launch dates for its generic citalopram in EEA Contracting Parties:

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901 ID 4817, page 245.

902 ID 4817, pages 243-244. See recital (151) above. Tiefenbacher was one of the companies that filed opposition before the EPO.

903 ID 8, page 278.

904 ID 8, pages 279-280.

905 ID 823, page 24.

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	AT	DK	FI	DE	NL	NO	SE	UK
Patent expiry	04-03	01-02	01-02	- 94	01-02	01-02	12-01	01-02
MA est	03-02	02-02	02-02	04-02	Appr	02-02	02-02	02-02
Launch Target	-	03-02	05-02	04-02	01-02	04-02	03-02	02-02

"[906]

For all these countries together, plus Portugal, Alpharma expected citalopram sales in 2002 of USD 3.8 million (approximately EUR 4 million).[907]

(486) An e-mail of Lundbeck's [employee function]* dated 6 November 2001 shows that Lundbeck had apparently obtained copies of parts of Cipla's DMF. A Cipla document giving a brief outline of the process used by Cipla stated: "Crude citalopram base is crystallised to get pure citalopram base."[908] On or around the same date, Lundbeck also obtained a copy of Matrix's DMF, which stated that "Citalopram base of batch No. RD006/0101 was crystallized twice in Iso propyl alcohol and Methanol and prepared Citalopram Hydrobromide by using aq.HBr in Isopropylalcohol."[909] According to Lundbeck, this DMF had served as the basis for the marketing authorisation granted in the Netherlands on August 31, 2001.[910]

(487) On 15 November 2001, Tiefenbacher prepared an analysis of the patents and patent applications Lundbeck had mentioned in its general warning letter to API producers and to certain generic suppliers in January 2001.[911] For Lundbeck's crystallisation utility model in the Netherlands (NL 1016435), which had been granted on 6 November 2000, and the corresponding application in the United Kingdom (GB2357762), Tiefenbacher concluded: "Describes the production of high purity Citalopram through the crystallisation of the base. In principle not applicable, as in our processes the base is not crystallised, but the product is cleaned through re-crystallisation of the hydrobromide. But: in some writings, protection for the production of high purity citalopram (>99.8%) is filed for. Will be monitored."[912]

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906 ID 1595, page 2. Another internal Alpharma document of the same date estimated the launch in Finland in March 2002 (rather than May 2002) and the launch in Norway in March 2002 (rather than April 2002). See ID 1596, page 7.

907 Using an annual exchange rate for 2002 of 1 EUR = 0.9456 USD, source European Central Bank. See ID 1595, pages 1 and 15.

908 ID 5439, page 5. In its reply to the Statement of Objections, Lundbeck argued that this statement of Cipla confirmed "beyond any reasonable doubt that the process used by Cipla infringed the Crystallization Patent." For Cipla's analysis, see recital (510) below.

909 ID 5394, page 172.

910 ID 5394, page 172.

911 See recitals (148) and (225) above.

912 ID 673, page 174, translation from German. The original German text uses the word "Umkristallisation". Tiefenbacher sent this analysis to Merck dura, one of its other clients, but it is unclear whether Alpharma also received it. See recital (248) above.

(488) An internal Lundbeck e-mail of 4 December 2001 shows that Lundbeck expected Alpharma to launch a generic version of citalopram in Denmark by mid-February 2002.[913]

(489) An internal e-mail from Alpharma's Dutch subsidiary reported on 21 December 2001 that Lundbeck had failed in its attempt in the Netherlands to obtain an interim injunction against the prospective launch of generic citalopram products from Tiefenbacher. The Dutch subsidiary expected to be able to launch generic citalopram in the Netherlands in the first or second week of February 2002.[914]

(490) Another internal Alpharma e-mail of 21 December 2001 reported on the approval process for marketing authorisations:

"We just got the approval for Citalopram in the Concerned Member States (CMS), and I have enclosed the email from Tiefenbacher with the approved SmPC below. Our regulatory people now work hard to get the papers into the local authorities today. We hopefully can launch in most countries no later than February, hopefully earlier in Sweden, where the patent has expired and in the big UK market, but that is down to supply and logistics.[915]

(491) On 9 January 2002 Lundbeck received the following information from an informed market player in the United Kingdom regarding Alpharma's planned launch there:

$OSKDUPD«KDYH YHUEDO FRQILUPDWLRQ RI D FLWD would have been granted by now but due to the current train strike not all the relevant individuals have been available in the MCA.

Alpharma's current delivery date is 14.01.02.

This is a complete surprise to the rest of the generic industry all who thought Generics UK (GUK) were the front runner to launch mid to end of January.

«

The open part of Alpharma DMF is confirmed as Tiefenbacher although the closed part is not currently known.

The current prices being offered to generic distributors are relatively high at:

	Alpharma	Wholesaler price	Current NHS price
citalopram	10mg £6.96	£8.44	£9.64
	20mg £10.90	£14.02	£16.03
	40mg £19.57	£23.71	£27.10

[market player] believes that the margin per pack for each supplier will be £1.50 per pack which means that the price to the retailer for 20mg will be £12.40. This

913 ID 848, page 53.
914 ID 4817, pages 232-233.
915 ID 4817, page 231.

compares with the current market price for parallel import which is £13.00 average price."[916]

(492) On 17 January 2002, an internal Lundbeck e-mail stated:

"Just to show that Alpharma are expecting to launch imminent [in the UK] I attach a copy of their latest price list with citalopram on!

The prices are fairly high which would indicate that they only have limited supply.

Further [Merck (GUK)] today mentioned that Alpharma today had informed some of their customers that "due to an injunction" they could not deliver citalopram as promised. We do not believe that they have received their licence yet."[917]

The attached official price list of Alpharma indicated "Offer Prices available from 1 February 2002±28 February 2002." The prices for a pack of 28 citalopram tablets were: 10 mg - £8.19, 20mg – £12.82 and 40 mg £23.08. These were prices at retail level.[918]

(493) On 18 January 2002, Lundbeck's lawyers wrote to two Queen's Counsels in the United Kingdom to retain their services to "prepare for and appear in an application for an interim injunction" against Alpharma, Tiefenbacher, Omega and Arrow.[919]

(494) On 21 January 2002, Alpharma's Dutch subsidiary reported to the [employee function]* of Alpharma ApS:

"We have received information of Lundbeck's lawyer that the process patents NL 1016435(granted 6 nov. 2000) and NL 1017413 (granted 13 sept. 2001) are valid for 6 years after grant date and that our product (of Tiefenbacher) uses material which could be affected by those two patents.

They state these two patents describe the recristallisation to 'clean' the citalopram base by precipitation of its crystalline form whereafter it is transformed into a salt f.e. the hydrobromide or hydrochloride salt and that it is likely we have used this route in synthesis of the active ingredient (they say especially as described under conclusion point 5, 7 and 9 of the NL 1016435 and point 1, 2, 3, 4, 9 of the NL 1017413."[920]

(495) Also on 21 January 2002, an internal Alpharma e-mail from [employee function]* of Alpharma ApS reported:

"Subject: Lundbeck

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916 ID 904, pages 151-152. This shows that Alpharma intended to launch generic citalopram in the United Kingdom market with an initial price at retail level that would be slightly below the retail price level of parallel imports of Lundbeck's own citalopram. However, because of Lundbeck's appeal against the Dutch marketing authorisation, Alpharma's United Kingdom marketing authorisation was in fact delayed until 26 July 2002. See recital (540) below.

917 ID 682, page 127.

918 ID 682, page 128. Compare the official Alpharma price of £12.82 for a pack of 28 tablets of 20mg with the price of £12.40 estimated on 9 January 2002, see recital (491) above. It appears that, if Alpharma were to become the first generic undertaking to enter the United Kingdom citalopram market, it wanted its initial price to be just below the parallel import price level of £13.00 at retail level. This would provide sufficient incentive to pharmacists to buy the product from Alpharma, while maximising profits for Alpharma.

919 ID 5477.

920 ID 4817, pages 219-220.

Have just had [initials], one of them is particularly keen on a deal± in any case, not unless there is significant advantage for us. [initials] thinks that things can be done legally, but he obviously needs details. We therefore agreed on the following (which resembles what we talked about).

Have another meeting/discussion and say that, in principle, we might be willing to discuss matters, but that we need more facts.

Flag up what we see as two or three possibilities:

a) only dollars for example, as we said 18-20;

b) combination of dollars and rights to a licence in Europe;

c) combination of dollars, licence rights in Europe and early entry to [third country].

If matters are taken further, [initials] will act very fast and have our legal position settled by means of a contract.

It will be very interesting to hear what they have to say."[921]

(496) On 22 January 2002 Lundbeck's external lawyers sent a detailed warning letter to Alpharma alleging that if Alpharma were "in the very near future" to offer a generic citalopram hydrobromide product in the United Kingdom for sale, this would infringe Lundbeck's patents GB 2357762 (the crystallisation patent, to be granted on 30 January 2002) and GB 2356199: Production of citalopram in pure form, by cyanide exchange (the film distillation patent).[922] The letter stated, in particular: "On this basis, we have advised our client that your citalopram hydrobromide product has been manufactured by the process of at least claim 1 of UK patent 2 357 « .[923] The letter threatened an interim injunction. In its reply to the Statement of Objections Lundbeck stated that the allegations of infringement in this letter were based on several analyses Lundbeck had performed of Cipla-sourced citalopram between July 2001 and January 2002.[924]

(497) Also on 22 January 2002, the Dutch subsidiary of Alpharma reported that Dutch wholesalers had received letters of awareness from Lundbeck, which would "disturb our sales introduction."[925] The Dutch subsidiary also reported:

"I then spoke to [another generic company in the Netherlands], they received last week a letter from [employee of the other generic company] first was told by [employee of Tiefenbacher] that there was no problem and they were aware of it. Yesterday (or so) however [employee of Tiefenbacher] informed them there is a problem with this two patents and the product is infringing."[926]

(498) On 23 January 2002, at 11.08 hours in the morning, Alpharma's Dutch subsidiary reported the following:

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921 ID 4817, pages 217-218 (translation from Danish).

922 ID 1004, page 304. With respect to United Kingdom patent 2356199, Tiefenbacher considered that neither Cipla nor Matrix used the process described in this patent, see recital (382) above.

923 It may be recalled that claim 1 of the corresponding patent at the EPO level was later deleted from the amended claims which were eventually upheld by the EPO in 2009. See recital (166) above.

924 See recital (481) above.

925 ID 4817, page 207.

926 ID 4817, page 215.

« W K L V L V I L U P Z K D W W K H F R Q strategy: we will today cancel the planned blisterpacking for NL at Dragenopharm (planned for Monday next). [Alpharma employee] can thus use the bulk for UK. Novartis phoned this morning&will object the NL patent. They offered to combine with Hexal. It is decided that Alpharma start R Z Q S U R F H G X U H « : H N H H S R I F R X U V H L Q F R Q W D F W follow up with Pharmachemie. I can offer this product to them, where Pharmachemie act as a distributor for us. They have 30% market share. We pack under private label&MA holder Alpharma b.v. printed on their packs. I keep you posted on this issue and will of course need [Alpharma employee]'s help later on for quick supply of bulk for us and hopefully Pharmachemie."[927]

The reply of the [employee function]* of Alpharma ApS of the same morning was:

"Thank for the confirmation of our telephone conversation. Planning (SC) now need to see how the product freed up in NL can be applied elsewhere (UK, Scandinavia). Regarding the legal challenges by Lundbeck I expect that we will see the same in all countries (not just in NL) and I assume that [employee function]* of Alpharma ApS] will initiate the necessary measures to deal with them and keep the other countries updated on the developments."[928]

In reaction to this, Alpharma UK replied at 13.00 hours of the same day:

"Just to re-iterate that UK are very hungry for stock after a successful pre-sell."[929]

(499) At 11.26 hours of 23 January 2002, another string of internal Alpharma e-mails reported:

"Alpharma HollanG « F D O O H G P H M X V W Q R Z W R W H O O P H W K D for patent reasons. A new patent has been granted in Holland and is valid until 2006. However, they say it looks if the patent could be fought but this could take maybe 3 months. Therefore, they have to wait with the launch.

They said you can dispose of their quantities for the UK. The bulk was airshipped to Dragenopharm last Sunday. Therefore, it should have arrived at Dragenopharm meanwhile. The bulk is not yet packed. Therefore, if you need product to be packed I R U W K H 8 . W K L V Z R X O G E H \ R X U T X L F N H V W R S W L R Q

Of course, Alpharma Holland would most likely need product later if the patent falls. Therefore you could take their quantities and you give them the same quantities from your April shL S P H Q W «

Concerning the patent itself, [employee of Alpharma's Dutch subsidiary] told me that it was applied for also in other EU countries but for the time being only granted in Holland. She has already informed [employee function]* of Alpharma ApS] as well. Hopefully, none of us will be affected also."[930]

(500) Another e-mail of Alpharma's Dutch subsidiary, sent at 13.10 hours of 23 January 2002 stated:

0 H D Q W L P H , K D Y H S K R Q H G Z L W K 0 X O W L S K D U P D « Z H try to invalidate the patents as will Hexal and Multipharma, but with close contacts

927 ID 4817, pages 199-200.
928 ID 4817, page 199.
929 ID 4817, page 199.
930 ID 4817, page 175.

between the companies about the strategy (so we gain strength and harmonise our defence against Lundbeck)."[931]

(501) At 15.41 hours of 23 January 2002, an e-mail from the Dutch Alpharma subsidiary reported about a contact with Tiefenbacher:

"[Tiefenbacher] have contacted me about the patents. We were surprised by these two Dutch national ones, not having those checked as it were utility patents which are not proved on submission/granting by experts of the patent office. The[y] knew about the world patent application of these two, but he informed me experts had already a lot of comments and criticisms on those two so it was not likely they would be granted."[932]

(502) At 16.26 hours of 23 January 2002, an e-mail from [employee function]* of Alpharma ApS stated:

"Lundbeck is getting more aggressive, as you probably all know, and I have spoken to [employee function at Alpharma]* to prepare our self for the future. Alpharma B.V. is handling the case well in Holland through lawyer, but we need to address the situation in all other markets. Tiefenbacher [etc] is doing what they can, but we need to make arrangement for our own safety in the other countries. We might not need it, but I think its very prudent. We have been to address [etc] choice of counsellors, a.o.b."[933]

In a response of 24 January 2002, the United Kingdom subsidiary of Alpharma asked:

"The U.K. Marketing Authority is expected to be granted early next week, please advise that once received, UK can proceed to sell/despatch product??"[934]

The answer of Alpharma ApS of 24 January 2002, at 12.35 hours, was:

"We cannot give a clear cut answer to your question today. We will come back as soon as we have any result of our investigations."[935]

(503) Another internal Alpharma e-mail of 23 January 2002 reported as follows regarding the application for a marketing authorisation in the United Kingdom, following a conversation with the Medicines Control Agency:

"Licence application proceeding well, we remain positive that we will still be the first generic company to launch. We now for [etc] awarded, [etc] position of launching company is safe."[936]

(504) On 24 January 2002, the [employee function]* of Alpharma ApS wrote the following to Tiefenbacher:

"I am sure, that you know all the Patents and Patent applications on Citalopram by heart, and will contribute to the defence of your own product. We, at Alpharma on the other hand, cannot sit back and wait for the inevitable request for Injunctions

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931 ID 4817, page 196.
932 ID 4817, page 194.
933 ID 4817, page 179.
934 ID 4817, page 178.
935 ID 4817, page 177.
936 ID 4817, page 193.

from Lundbeck. We need to prepare our own defence strategy. In order to do so, we will need the full and detailed route of synthesis for the Citalopram API.

I am afraid I will have to insist on it, as I can hardly see any other option. The exception would be if Tiefenbacher would do all the legal battling on behalf of Alpharma, and that would be outside any contractual obligation. I fully understand why you have been reluctant to hand out the detailed information up until now, but our further defence work will be impossible, unless we have the information."[937]

(505) In response a couple of hours later, Tiefenbacher sent Alpharma "our overview on the patent situation concerning Cipla's citalopram". This document, which is not in the Commission's case file, is likely to have been an updated version of the patent overview document which Tiefenbacher had sent to Merck dura in November 2001.[938] At the Commission's request, Tiefenbacher sent the Commission a document dated 8 February 2002 and entitled "Patent Overview Citalopram". This document, which according to Tiefenbacher is likely to be very similar to the one Alpharma received two weeks earlier from Tiefenbacher[939], briefly analysed each of the Lundbeck's patents known to Cipla or Tiefenbacher. On the crystallisation patent, the document stated:

"Preparation of very pure Citalopram hydrobromide via crystallisation of the free base. However, claim 11 protects Citalopram hydrobromide with >99.8% purity without stating how it was obtained. This could be crucial because we might have the choice to infringe the patent or market AP/tablets with insufficient (= not "state of the art") purity. The applications are under investigation of our patent attorney.

Comment by Cipla:

The crystallisation of Citalopram free base is claimed (Claims 1,2).
In Cipla's process, the free base is obtained, not from the crude salt of mixture, but directly from the reaction work-up. Further, there is no step of 'initial purification' before the base is precipitated (claims 6, 7).
We do not practice claim 8&10.
Claim 9 is contingent on claims 1 to 8, which we do not practice.
Claim 13 is contingent on claim 12, which is contingent on claims 1 to 10, which we do not practice.
Regarding claim 11, we feel that any repeated crystallisations even on material produced according to the basic patent would yield a product having a purity more than 99.8%. According to us it is very obvious for someone skilled in the art to develop and isolate pure Citalopram base by crystallisation."[940]

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937 ID 4817, page 169.

938 See recitals (248) and (487) above.

939 In its cover e-mail to the Commission, Tiefenbacher stated: "I am sorry to inform you that we were not able to find the e-mail as such, but the pdf-file mentioned, dealing with the patent situation of Cipla´s Citalopram. Although I would have preferred to have the e-mail to be 100% sure that the pdf-files (on file/sent) are identical, it can be assumed with reasonable safety that this is the attachment sent on 24.01.2002. No other version of this file could be found." See ID 6486.

940 ID 6487, page 2. See also ID 6490. See also recital (510) below.

It should be noted that on October 18, 2001, Lundbeck had in fact filed an amended version of its patent application at the EPO, deleting claim 11 as referred to in this e-mail.[941]

(506) Later that same day, an internal Alpharma e-mail of the [employee function]* of Alpharma ApS reported:

"Alpharma UK have received a "letter of awareness" mentioning 2 patents. One of the patents are not likely to cause problems. The other one is actually an application WR EH JUDQWHG -DQXDU\«EDVHG RQ Wrkdel VDPH S [that is to say Lundbeck's crystallisation patent] «, KDYH DOVR VSRNH Tiefenbacher, and they are still not willing to hand out the route of synthesis. They were quite open, besides that, and are willing to answer any specific questions related to the manufacturing process via Cipla in India (Cipla is the manufacture[r] of the API). It might very well be that we can seek the Lundbeck patent application invalidated without specific knowledge of the Cipla API process. Tiefenbacher strongly believe that they can invalidate the utility models and other applications related to that family. I too believe that. Further it is not possible to file for injunctions based on Utility models (has to do with the fact that they are non-examined)."[942]

(507) Another internal Alpharma e-mail of the same day, 24 January 2002, reported that Alpharma's subsidiaries in Norway and Denmark wanted more launch stock of citalopram. According to the report: "If we can't find more goods for DK, they might have backorders already 1-2 months after launch. The reason for this is chain contracts which were received in December 2001, after launch orders were placed. DK expects to take 30% market share (volume). NO needs more goods because they this month have received positive signals from the UJHVW SKDUPDF\ FKDLQ [name] contract is covered by launch stock."[943]

(508) An internal Alpharma e-mail of the [employee function]* of Alpharma ApS of 25 January 2002 stated:

, KDYH VSRNHQ WR $OSKDUPD +RRODQG Wkel LV PRUQ Citalopram the first 2 months in NL, for strategic reasons. It might prove very difficult to sell in NL, because Wholesalers and Pharmacies are also threatened. This PHDQV WKDW ZH GRQ¶W KDYH DQ\ LQIUL QJHPHQW LQ Tiefenbacher, will be fighting the utility models in NL, and they will be clearing the SDWK VR WR VSHDN«, WKLQN RXU PDMRU HIIRUWV VK countries, these are also, by far, the largest markets."

Later on, the same e-mail said:

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941 See ID 2773, page 4. Nevertheless, after having split off the product claims in a divisional, Lundbeck did obtain a patent on the crystalline form itself (EP 1 227 088). This patent was opposed before the EPO and subsequently revoked by the EPO (see recital (151) above), whereas Lundbeck's patent on the crystallisation process (EP 1169314) was significantly amended and the scope of its claims limited before the EPO. See recital (166) above. As for the British patent GB 2357762, this patent appears to have been granted with the product and pharmaceutical composition claims included.

942 ID 4817, page 140. Lundbeck had utility models on the crystallisation process at least in Germany, Austria and the Netherlands. See recital (249) above and footnotes 226 and 390 above.

943 ID 4817, page 172.

"My personal opinion, regarding the patent in question [that is to say Lundbeck's crystallisation patent], is that we shall go ahead and market our product. The patent is not likely to pass scrutiny on novelty and inventive step. I expect that they will end up, either with no patent or a very limited and narrow patent, which should not cause us problems. We do however need the supportive opinion of [external lawyers]. If they coincide, then I would recommend a "go ahead". We might loose and have to pay a limited damage fee, but not entering the market, could also lead to a significant loss."[944]

(509) On 30 January 2002, an internal Lundbeck e-mail stated that Alpharma had obtained a marketing authorisation for Denmark.[945] Alpharma had indeed obtained this marketing authorisation on 23 January 2002.[946]

(510) Also on 30 January 2002, Tiefenbacher sent Alpharma the following analysis by Cipla comparing its process with Lundbeck's crystallisation patent in the United Kingdom:

"We have studied the patent GB 2357762A. The patent claims the process for the manufacture of salt of Citalopram from crystalline citalopram base, which is isolated from crude salt of Citalopram or crude mixture of citalopram.

The experimental details show heptane as solvent used for the crystallisation of citalopram. In Cipla's method we do not isolate base from the isolated salt of citalopram but isolate crude citalopram base from aqueous acidic solutions of citalopram base by adjusting the pH with ammonia which is prior art and filtration of the precipitated product from water. This is crude citalopram base. This is the process described in the patent US 4136193 application date Jan. 1977. In this patent the base is an oil whereas we achieved sold by this process.

The crude solid base is then crystallised without using heptane as solvent. The pure citalopram base is then converted to the hydrobromide salt.

The patent describes a process to make citalopram base from crude mixtures of salts or crude mixture of base by first converting it into the salt eg sulphate, extracting the citalopram base by adjusting the pH with NaOH and extracting the base into toluene. The toluene solution is concentrated to give an oil which is dissolved in hot heptane and latter gradually cooled to give crystalline citalopram base.

All the other claims in the patent especially claim 11 to 14 are based on the first two claims. Since they are contingent to claim 1 and 2 which we do not practice the purity of above 99.8% is specific to the methods described in this patent and should not betreated as generalised clai[m] for the product."[947]

Tiefenbacher added to his:

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944 ID 4817, pages 142-143.

945 ID 904, page 236.

946 ID 1244, page 21.

947 As mentioned in recital (151) above, Lundbeck's product claims on the crystalline base of citalopram as well as its claims regarding pharmaceutical compositions were later found by the EPO and the Dutch Industrial Property Office to lack novelty and therefore to be invalid. The United Kingdom crystallisation patent GB 2357762, however, was granted including these claims. This meant that the United Kingdom patent was on the one hand more likely to be infringed than without these claims, but on the other hand also more likely to be found at least partially invalid.

"Please find also attached the claims of GB 2357762 B which has been granted today, as well as the examination and comments of the EPO for the corresponding EP application of Lundbeck. Based on this, we are a bit surprised that the national applications are granted so quickly. We are also quite confident that it will be possible to get rid of them due to lack of novelty."[948]

(511) On 31 January 2002, one day after its crystallisation patent had been granted in the United Kingdom, Lundbeck filed a patent infringement lawsuit in the United Kingdom High Court of Justice Chancery Division seeking an injunction against Alpharma's envisaged[949] sale in the United Kingdom of products containing citalopram for allegedly infringing Lundbeck's patents GB 2356199 (the so-called film distillation patent) and GB 2357762 (the crystallisation patent). The claim was also directed against Omega Farma and Tiefenbacher.[950] In the application, Lundbeck's head of chemistry stated in an expert witness statement on behalf of Lundbeck: "Although we have as yet been unable to acquire any citalopram hydrobromide from the first defendant ("Alpharma"), either in the UK or (from its associated companies) elsewhere in Europe, we have been able to analyse material placed on the market elsewhere in Europe by other companies (such as Hexal) who are also believed to be sourced by the second defendant ("Tiefenbacher"). We believe the raw material for all of these products is to be produced in India by Cipla Limited. Such material has the fingerprints associated with the 2002-1 [Zyprexa] process, but at the reduced levels which are consistent to the best of my own knowledge only with purification using the processes disclosed in UK Patents 2 356 199 B and 2 357 762 B."[951]

(512) An internal Lundbeck e-mail of 4 February 2002 reported that Alpharma expected to launch its own generic citalopram product in Norway between April and July 2002.[952]

(513) An internal Lundbeck update on generic citalopram of 7 February 2002 reported: "Alpharma deal is being negotiated – license for N, downpayment, consent to injunction in all EU + N."[953] An internal Lundbeck e-mail of 12 February 2002 indicates that Lundbeck was considering granting Alpharma a licence to sell Lundbeck citalopram in Norway, as part of a wider deal covering other, larger European markets.[954]

(514) On 8 February 2002, Alpharma Inc.'s [employee function]* wrote in an internal Alpharma e-mail:

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948 ID 4817, pages 107-108. See footnote 947 above.

949 ID 8, page 264. According to Actavis: "as far as we are aware sales of [...] by the Alpharma Human Generics Business prior to the conclusion of the Settlement Agreement on 22 February 2002."See ID 746, page 13. According to Lundbeck, "With Alpharma's launch imminent, Lundbeck sued Alpharma to prevent it from selling [...] in the UK." See ID 723, page 24. Omeprazole, Alpharma obtained a marketing authorisation in the United Kingdom only on 26 July 2002. See recital (168) above.

950 ID 1004, pages 382 to 427.

951 ID 1004, page 415.

952 ID 723, page 58.

953 ID 903, page 42.

954 ID 723, page 60.

"In two weeks we should have a much better understanding of how strong our invalidity case is against the patent. Once we understand this, we can decide on a plan of action (some options we will consider are whether to launch in the face [illegible] the patent before the injunction hearing, approach Lundbeck for a license, wait until we have new supply)."[955]

(515) An internal Lundbeck e-mail of 14 February 2002 raised the question: "Should we pursue the case against Alpharma in the UK even if we reach agreement with them?

The internal advice given by the head of the patent department was: "I don't think we should pursue the injunction case to the end if we reach an agreement and if there is a risk that we might lose. In a few days we will have an overview of Alpharma's arguments. After that, we can assess what our chances are. If Alpharma don't mind losing and our chances of winning are good, it would be good for any subsequent cases if we were to win."[956]

(516) An internal Alpharma e-mail from the [employee function]* of Alpharma ApS of 14 February 2002 stated:

"Currently we are riding two horses:

Planning the launch of citalopram for UK, DK, NL, D, S, N, Fin
Negotiating with Lundbeck

However, next week we probably have to make a decision. To make the best possible decision I will like to get a short description of the legal situation in each of the seven markets and the risk exposure we have: I.e. risk of injunction, strength of Lundbeck's patent, can Lundbeck demand damage compensation if they win a VXEVHTXHQW FRXUW FDVH OLNHOLKRRG WKDW ZH FD[957]

(517) On 19 February 2002, an internal Alpharma e-mail sent to the [employee function]* of Alpharma ApS on the subject of "the legal and patent-related situation regarding Citalopram in the seven launch countries" stated:

"With regard to injunctions, it is reasonably clear that Lundbeck will be able to seek similar measures in all the countries in order to prevent us from selling the product. They seem also to have shown an intention to use this to keep us out for as long as possible. We could, if need be, counter their action in the same way as in the UK but, as we know, that is a time-consuming and expensive process. If we started to sell the product, and their patent was valid, we would be liable to pay compensation. However, it would take a long time for liability to be demonstrated if, in our defence, we were to maintain that the patent was invalid. Moreover, it would in any event take a year for the case to be heard, and an appeal could be lodged. A final decision would not, therefore, be in place for a number of years. Worst case scenario: if we were to lose the case and we had been selling the product all that time, the compensation payable would of course be fairly substantial."[958]

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955 ID 4817, page 55.
956 ID 723, pages 15-16.
957 ID 4817, page 35.
958 ID 4817, page 26 (translation from Danish).

(518) Later on the same day, 19 February 2002, an internal Alpharma e-mail from the [employee function]* of Alpharma ApS gave the following assessment of the situation:

"Currently we plan to launch Citalopram in UK, NL, DE, DK, NO, SE, FI within the next 2 ±6 weeks. However, the legal situation is complicated by the infringement of a key Lundbeck patent.

It is basically one family of patents, which Lundbeck currently are using in their defence of Cipramil. The name of the family is "Crystalline base of Citalopram", and it is present in one or more forms, in all HPI countries. The patent is already DSSURYHG JUDQWHG LQ VHYHUDO FRXQWULHV LQ UH

The product produced by Cipla (API) + Omega (tablets) ± Tiefenbacher is, to the best of all knowledge, infringing on the Lundbeck patent. This is the product currently on stock in most of our affiliates. (Stocking would be considered infringement).

Lundbeck has applied for Preliminary Injunction in NL and UK, and is likely to do so in all countries where they get the patent approved (a prerequisite for injunction).

We are currently establishing defence in UK and NL. An injunction hearing is set for 26 March in London high court, and we have to submit our defence by 4 March. Our defence will be to convince the court that the Lundbeck patent is foreseeable and therefore none inventive. It is likely that we can avoid an injunction, and we have a reasonable case to win a case of invalidation of the Lundbeck patent.

It can be lengthy and probably costly, but we should be able to get a substantial part back in damage fee, if we win! On the other hand Lundbeck can claim substantial damage compensation if they win!!

The second API supplier Matrix is, also to the best of all knowledge, using a none infringing process and this API could be used without the risk of infringement. It would mean a lot of scrapping and launch delay of roughly 3-4 month.[959]

If we halt all launch activities now, to clarify the legal situation and launch later in the spring/summer with the non infringing API from Matrix, we will have lost the competitive (time) advantage we have by launching the next 2 ±6 weeks and we have scrappings of USD 2 million. This will significantly influence the business case which has an NPV of USD 10 million.

Our recommendation is to pursue a deal with Lundbeck if a reasonable settlement can be achieved serving our legal and commercial interests."[960]

(519) On 20 February 2002 an internal Alpharma e-mail proposed to add the following paragraph to the preamble of the draft agreement with Lundbeck:

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[959] In its reply to the Statement of Objections, Lundbeck stated that "It was only in April 2002 that Lundbeck learned for the first time WKDW 0DWUL[PLJKW FODLP D PRGLILFDWLRQ and "United Nordic Pharma's launch in the Danish market on June 14, 2002, was the first time when Lundbeck learned that Matrix-based citalopram had been launched on the market." Lundbeck obtained more information about Matrix's additional washing step only at the end of September 20 « . See ID 5394, page 163.

[960] ID 4817, pages 22-23.

"WHEREAS, Lundbeck has agreed not to injunct [sic] or otherwise prosecute Alpharma for manufacturing, importing, selling, etc. Citalopram containing product after the termination of this contract."

The reason given for this proposal was that « , PLVV VRPHWKLQJ VWD /XQGEHFN GRQ¶W FDUU\ RQ ZLWK WKH 03. If we for RG D LQVWDQFH FKDQJH WR 0DWUL[$3, DQG ZH DUH IUHH want to be dragged round the circus once more."[961]

This paragraph was not retained in the agreement as actually concluded with Lundbeck.

(520) By the time Alpharma and Lundbeck entered into an agreement for the EEA on 22 February 2002, Alpharma had through Tiefenbacher obtained marketing authorisations for generic citalopram in the Netherlands (6 September 2001), Finland (21 January 2002), Denmark (23 January 2002) and Sweden (22 February 2002). After concluding the agreement with Lundbeck, and during its operation, Alpharma obtained again through Tiefenbacher further marketing authorisations in Norway (8 March 2002), Germany (18 April 2002), Austria (24 June 2002) and the United Kingdom (26 July 2002).[962]

7.6.2. The agreement

(521) On 22 February 2002 H. Lundbeck A/S and Alpharma ApS concluded an agreement covering the Union and Norway for a period expiring on 30 June 2003.[963] The preamble mentioned that Lundbeck believed that the production method used to produce Alpharma's citalopram infringed Lundbeck's patents rights, including in particular those listed in appendix A. This appendix listed for different European countries the national equivalents of Lundbeck's crystallisation patent (patent GB 2357762 in the United Kingdom) and of Lundbeck's patent for a process for the preparation of pure citalopram, by cyanide exchange; the film distillation patent (patent GB 2356199 in the United Kingdom).[964]

(522) The preamble mentioned that "Alpharma has manufactured, produced and/or purchased pharmaceutical products containing Citalopram with the intention of marketing such products in the Territory." The "Territory" was defined as "all EU countries, Norway and [third country]." The preamble then stated that Lundbeck had performed laboratory analyses of Alpharma's citalopram and that the results of these laboratory analyses gave Lundbeck "substantial reason to believe" that the production methods used to produce Alpharma's products infringed Lundbeck's intellectual property rights. The preamble continued by saying that Lundbeck had started infringement proceedings against Alpharma in the United Kingdom and that Alpharma "has acknowledged that the findings by Lundbeck are correct and has undertaken to refrain from marketing of such products." The preamble then said that

961 ID 4817, page 12.

962 ID 1244, page 21.

963 ID 8, pages 263 to 291.

964 Lundbeck explained in its reply to the Statement of Objections that film distillation removed different impurities than crystallisation of the free bases, so that theoretically it was possible for a manufacturing process to infringe both process patents. See ID 5394, footnote 14. Lundbeck also stated in its reply to the Statement of Objections that Lundbeck "realized that it was possible for generic companies to design around the Film Distillation Patent" and "renounced enforcing that patent because it lent itself to invalidity claims." See ID 5394, page 162.

"Lundbeck has agreed to compensate Alpharma in order for Lundbeck to avoid a costly and time-consuming patent litigation, the outcome of which cannot be predicted with absolute certainty" and "in order to settle the dispute Lundbeck has furthermore agreed to purchase all of Alpharma's stock of products containing Citalopram and to compensate Alpharma for such products."

(523) In Article 1.1 of the agreement Alpharma ApS agreed to cease importing and selling "pharmaceutical products containing Citalopram" in the territory covered by the agreement for the duration of the agreement, including through any of its affiliates or through any third party (including any licensees). "Affiliate" was defined as "any company which, directly or indirectly, controls or is controlled or is under common control" with Alpharma ApS. Lundbeck, in return, agreed to dismiss the pending infringement lawsuit against Alpharma in the United Kingdom. Article 1.1 also provided that "This Article 1.1 shall not apply to any product containing escitalopram."

(524) Article 1.2 stipulated that "In the event of any breach of the obligation set forth in Article 1.1 or at the request of Lundbeck, Alpharma and Alpharma's Affiliates will voluntarily submit to an interim injunction by any competent court in any applicable country in the Territory. Lundbeck shall be entitled to obtain such injunction without providing any kind of security. Alpharma and Alpharma's Affiliates waives any confirmatory action pursuant to any law or regulation in any applicable country in the Territory relating to such injunction proceedings and shall upon request from Lundbeck sign any document necessary to obtain such injunction." The same Article provided that in the event of any wilful or negligent material breach of the obligation set forth in Article 1.1, Alpharma had to pay Lundbeck damages equal to the payments made by Lundbeck under this Agreement.

(525) Article 1.3 provided that "As compensation for Alpharma's obligations set forth in this Agreement and in order for Lundbeck to avoid the cost and time of litigation, Lundbeck shall pay to Alpharma USD 12 million (USD 12,000,000.00), of which USD 11 million (USD 11,000,000.00) shall be for Alpharma's products containing Citalopram" This amount would be paid in three instalments of USD 4 million each, on 31 March 2002, 31 December 2002 and 30 June 2003 respectively, subject to Lundbeck receiving a copy of Alpharma's marketing authorisation for the United Kingdom.

(526) Lundbeck later explained to the Commission that "Under the agreement with Alpharma, and in lieu of any damages that might be available to Alpharma in the event that its citalopram products were not infringing, Lundbeck provided Alpharma with $12 million - $11 million of which was payment for Alpharma's stock of products containing citalopram"[965]

(527) In article 2.2 Alpharma agreed to deliver, not later than 31 March 2002, its entire current stock of products containing citalopram (specified as "approximately 25,400,000 tablets") to Lundbeck. Of this total number of tablets, 9,400,000 were

[965] ID 823, page 24.

already in Alpharma's possession, whereas the rest was on order. The tablets already received by Alpharma were stocked in the United Kingdom and Sweden.[966]

(528) Appendix A to the agreement listed a number of Lundbeck patent applications and patents in the different countries covered by the agreement. Appendix B listed the product specifications of the Alpharma tablets and Appendix C listed Alpharma's purchase orders. The tablets in question had been produced by Omega Farma in Iceland for Tiefenbacher. The documents did not indicate whether the API came from Matrix or Cipla. Appendix C also contained a "Citalopram tablets status report" of Alpharma which indicates that Alpharma paid EUR 3.7 million for the 25.4 million tablets which Lundbeck purchased for USD 11 million (EUR 11.6 million).[967] This shows that Lundbeck paid Alpharma roughly the expected resale value of the tablets in the market, not the purchase cost.[968]

7.6.3. Events during the implementation of the agreement

(529) In the evening of 22 February 2002, the day the agreement with Lundbeck was signed, Alpharma informed its external counsel that "we will withdraw from the case against Lundbeck".[969]

(530) A Lundbeck internal e-mail of 23 February 2002 indicates that Lundbeck expected Alpharma and Arrow to receive a marketing authorisation for generic citalopram in the United Kingdom in the next couple of days. This e-mail also stated: "Of course our fear is that a third and a fourth company will also receive a registration at the same time. If this is the case we will take legal action and sue for patent infringement on the spot ± our problem will be how to find out if anybody has received registration. (The one company that we fear most is Lagab [sic]"[970] Another internal Lundbeck e-mail of the same date reported that according to Lundbeck's information Alpharma had received a marketing authorisation in Sweden on 22 February 2002.[971]

(531) On 13 March 2002, the United Kingdom Patents Court, at the request of Tiefenbacher and Omega, struck out a claim of joint tortfeasance Lundbeck had against these two companies as part of the infringement proceedings initiated on 31 January 2002. According to the United Kingdom judge, who noted that Lundbeck had settled with the first defendant, Alpharma: « W K H S D W H Q W V J U D Q W H G

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966 ID 8, page 277. In its reply to the Statement of Objections, Lundbeck stated: « K D G / X Q G E H F N Z L V K H to market the tablets, it could not have done so since the Agreement did not provide for Alpharma to transfer its MA to Lundbeck's. See ID 5394, page 232.

967 Using an average annual exchange rate for 2002 of 1 EUR = 0.94557 USD, source European Central Bank. See ID 8, page 277.

968 See also ID 681, page 42. In this internal e-mail of 18 April 2002 Lundbeck calculated the value, based on cost prices, of 16 million tablets which had been ordered by Alpharma, but not yet delivered to Lundbeck, at approximately USD 2.3 million. If one compares this figure to the figure of USD 11 million Lundbeck agreed to pay for 25.4 million Alpharma tablets, then it confirms that Lundbeck paid to Alpharma the resale value in the market of those tablets and not the cost price. After all, if 16 million tablets have a cost price of USD 2.3 million, then 25.4 million tablets would have a cost price of approximately USD 3.7 million, not USD 11 million. Indeed, using the price in the agreement, the resale value of 16 million tablets was USD 6.9 million (16/25.4 times USD 11 million), which is exactly three times the cost price of USD 2.3 million. See also ID 904, page 172.

969 ID 4817, page 289.

970 ID 904, page 182.

971 ID 681, page 147. See also recital (520) above.

only have national effect. We cannot stop importers into this country from going to JHW WKHLU VWRFNV RU VXSSOLHV IURP VRXUFHV RX is nothing on the pleadings which goes any way beyond showing, at the most, that the Second and Third Defendants are knowingly assisting the First Defendant in importing into the United Kingdom. In my view, this is not an arguable case of joint tortfeasance....[972]

(532) Also on 13 March 2002, an e-mail exchange between Lundbeck and external legal counsel identified Lagap as "the potential new defendant" in the United Kingdom.[973]

(533) An e-mail of 22 March 2002 from Alpharma to Lundbeck reported the delivery of over 6 million Alpharma citalopram tablets to Lundbeck on 21 March 2002.[974]

(534) An internal Lundbeck e-mail of 25 March 2002 mentions that Lundbeck made a payment of USD 2 million to Alpharma and that USD 2 more million were still to be paid.[975]

(535) By 4 April 2002, Alpharma had delivered a total of 8.5 million tablets to Lundbeck.[976]

(536) By the middle of April 2002, Lundbeck and Alpharma agreed to enter into a consent order under which the judge would rule "that all further proceedings in this claim be stayed" taking into account that Alpharma had agreed to refrain from importing, making or selling "pharmaceutical products containing citalopram made utilising any of the processes claimed under GB patents 2 357 762 B and GB 2 356 199 B or any equivalent patent granted or applied for in relation to any of the Relevant 7HUULWRULHV".[977] As Lundbeck later explained to the Commission, "In UK civil litigation, a consent order merely records an agreement reached between the SDUWLHV « WKH FRQVHQW RUGHU « ZDV GHVLJQHG WR J Alpharma Agreement. The consent order enabled Lundbeck, as claimant, to enforce the undertakings given by Alpharma without the need to commence a fresh action. Under English law, had Alpharma breached this consent order, it would have been liable for contempt of court. Moreover, Lundbeck could have immediately obtained a preliminary injunction against Alpharma. Therefore, Lundbeck would have enforced the consent order, rather than the Agreement, in case of breach by Alpharma of its undertakings."[978] Parties agreed that Lundbeck would only be entitled to enforce the consent order if Lundbeck had complied with its (payment) obligations in the agreement.[979]

(537) On May 1, 2002, Tiefenbacher applied for a type I variation of its marketing authorisation in the Netherlands, the Reference Member State, to include Matrix's

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972 ID 5449, page 4.

973 ID 5480.

974 ID 681, page 32 and ID 684.

975 ID 904, page 155. See also ID 681, pages 34-35.

976 ID 688.

977 ID 396, pages 175 to 181. This wording in the draft consent order had been drawn up by the parties themselves. In this kind of consent order, a so-called Tomlin order, parties can keep the precise terms of their agreement, including in this case the payment from Lundbeck to Alpharma, confidential. Also, the terms of the agreement can include matters outside of the jurisdiction of the court or the scope of the case in hand.

978 ID 5394, pages 231-232.

979 ID 396, pages 175 to 181.

new washing process.[980] Lundbeck stated in its reply to the Statement of Objections that Tiefenbacher obtained this type I variation to its MA in the Netherlands on 16 July 2002.

(538) On 2 May 2002, the High Court of Justice, Chancery Division, Patents Court granted upon the application of the parties a consent order to stay all further proceedings in Lundbeck's infringement claim, subject to Alpharma's contractual commitment to Lundbeck (without undertaking the same to the court) to desist until 30 June 2003 from importing or selling in all Union countries and Norway "pharmaceutical products containing citalopram made utilizing any of the processes claimed under GB patents 2 357 762 B and GB 2 356 199 B or any equivalent patent granted or applied for in relation to any Relevant Territories."[981] Moreover, according to a contemporaneous Lundbeck document: "As to the infringement case against Tiefenbacher and Omega, the judge in view of the settlement with the primary defendant, i.e. Alpharma, dismissed the case."[982]

(539) By 26 June 2002, Alpharma had delivered a total of 22.4 million tablets to Lundbeck.[983]

(540) On 26 July 2002, Alpharma received a United Kingdom marketing authorisation for the distribution of citalopram tablets of 10, 20 and 40mg.[984]

(541) On 9 August 2002, Lundbeck ordered the tablets it had received from Alpharma to be destroyed.[985]

(542) In September 2002, the type I variation to cover Cipla's patent free purification method (the Cipla II process) was submitted in the Netherlands and approved two and a half months later.[986]

(543) An e-mail exchange between Lundbeck and Alpharma of 7 November 2002 shows that Lundbeck asked Alpharma whether part of the tablets which had been on order at the time of conclusion of the agreement with Lundbeck and which were supplied to Alpharma by Tiefenbacher and then supplied from Alpharma to Lundbeck, were "Matrix new", thereby referring to the Matrix II process.[987]

(544) On 18 November 2002, Lundbeck wrote to Alpharma saying that it had still not received 3 million tablets (out of the agreed total of 25.4 million tablets, which should have been supplied to Lundbeck not later than 31 March 2002) and would, if no further deliveries were received, hence reduce the purchase price of USD 11 million with USD 1.3 million. This correction would be made with the second

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980 ID 5420.

981 ID 1004, pages 447-448. See also ID 723, page 89.

982 ID 846, page 47. See recital (531) above.

983 ID 904, pages 149-150.

984 ID 682, page 4.

985 ID 681, page 25. This instruction was repeated on 26 November 2002. See ID 683, page 64. See also ID 682, page 1.

986 ID 1713, page 1.

987 In fact, Lundbeck stated in the e-mail: "I'm going on the basis that it is the Matrix new". Alpharma replied that it would deliver 1.4 million tablets. See ID 681, page 53. See also ID 6782, page 9.

instalment payment, the due date of which was 31 December 2002.[988] Alpharma did actually make at least one further delivery (which was also destroyed).[989]

(545) On 13 December 2002 Lundbeck wrote to Alpharma saying that, based on the total number of tablets received until then (23.3 million tablets instead of the agreed 25.4 million tablets), it would withhold USD 900 000 from the agreed USD 11 million for Alpharma's stock of citalopram.[990] This deduction was made to the second instalment payment which was due on 31 December 2002.[991]

(546) The third and last instalment of USD 4 million was paid by Lundbeck towards the end of June 2003.[992] The agreement expired as foreseen on 30 June 2003. It was not extended.

(547) In total, over the entire period of operation of the agreement from 22 February 2002 to 30 June 2003, Lundbeck transferred a value to Alpharma of USD 11.1 million (corresponding to approximately EUR 11.7 million)[993] under the agreement regarding the EEA, consisting of:

– USD 10.1 million for Alpharma's stock;

– USD 1 million for Lundbeck's saved litigation costs.

7.6.4. Subsequent events

(548) After the expiry of the agreement with Lundbeck, Alpharma started selling citalopram in the EEA, beginning with Germany in August 2003.[994] Sales in the Netherlands started in October 2003[995]. The United Kingdom followed in April 2004[996], Denmark in July 2004, Finland in August 2004[997] and Sweden and Norway in July 2005.[998] Those sales appear to have been made with Matrix product.[999] None of these sales were subject to infringement litigation by Lundbeck.[1000]

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988 ID 904, page 239.

989 ID 682, page 1.

990 ID 1224, page 1.

991 ID 904, pages 237 and 241, ID 723, page 82.

992 ID 723, page 82.

993 Using an average annual exchange rate for 2002 of 1 EUR = 0.94557 USD, source European Central Bank.

994 ID 746, page 13.

995 ID 1244, page 4.

996 ID 2616.

997 ID 1244, page 4.

998 ID 1244, page 4. This information is based on data provided by Actavis. According to the sales information provided by Xellia Pharmaceuticals, Alpharma's sales of generic citalopram in Norway started in October 2004. See ID 1226, page 1.

999 ID 746, pages 241 to 267. This would have been Matrix product produced with the new and process including the washing step. In its reply to the Statement of Objections, Lundbeck stated: "Alpharma started selling in the UK only in April 2004, and launched even later in other EEA countries, presumably because of fear of preliminary injunctions." However, Lundbeck also stated in the same reply: "Alpharma encountered, at the time, difficulties to supply itself with API because Tiefenbacher refused to maintain commercial relations with Alpharma following the latter's admission that Tiefenbacher's Cipla-based products infringed Lundbeck's patents". See ID 5394, page 233.

1000 ID 823, page 36.

7.7. Lundbeck's agreement with Ranbaxy regarding the EEA

7.7.1. The negotiation of the agreement

(549) On 11 January 2001, Lundbeck wrote a warning letter to Ranbaxy in India saying it was aware that Ranbaxy was developing a process for the manufacture of citalopram and pointing out that Lundbeck had a large portfolio of patents relating to the preparation of citalopram.[1001]

(550) In February 2001, Ranbaxy and Lundbeck opened discussions on the idea that Lundbeck might buy citalopram supplies from Ranbaxy.[1002]

(551) By May 2001, following a Ranbaxy visit to Lundbeck, the discussions had advanced to the stage where Ranbaxy asked Lundbeck: "On Citalopram, can we agree that the contract would be signed subject to Ranbaxy demonstrating non-infringing technology. Can we fix timelines for this?"[1003]

(552) In July 2001, Lundbeck informed Ranbaxy that after all it did not want to go ahead with the supply project.[1004] Ranbaxy complained to Lundbeck that « W K H H Q W L U H strategy of Ranbaxy on Citalopram revolved around this relationship. We had consciously not pursued other opportunities coming our way as we opted to work with M/s Lundbeck."Ranbaxy asked Lundbeck to purchase at least 400 kg citalopram before the end of 2001. [1005] The price for 400 kg citalopram would be around USD 1 to 1.5 million.[1006] Lundbeck refused to buy any citalopram from Ranbaxy and concluded internally: "That was exactly what we were playing for when we started the dialogue".[1007]

(553) An internal Alpharma e-mail of 12 December 2001 stated:

"Ranbaxy claim to have developed non-infringing API with full supporting documentation. Unable to find out if they have finished product. Will keep you updated."[1008]

(554) An e-mail of 11 January 2002 from an American wholesaler representing Ranbaxy to Arrow in the United Kingdom shows that Ranbaxy had started to explore selling own-manufactured citalopram API in Europe. The e-mail stated:

1001 ID 850, pages 144 to 147. See also recitals (180) to (183) above.

1002 ID 904, page 129.

1003 ID 848, page 51. Lundbeck stated in its reply to the Statement of Objections that at this time Lundbeck suffered from capacity constraints for the production of citalopram and was therefore interested in recruiting new contract suppliers. See ID 5394, page 236. Neither Lundbeck nor Ranbaxy explained satisfactorily to the Commission why it would be important in this context for Ranbaxy to show that it was able to produce citalopram without infringing Lundbeck's process patents. If Ranbaxy was to work as a contract supplier to Lundbeck, could Lundbeck not have licensed its own patented production technology?

1004 In its reply to the Statement of Objections, Lundbeck stated that at this time Lundbeck had solved its capacity constraint problem by other means and no longer needed Ranbaxy as a contract supplier. See ID 5394, page 237.

1005 ID 848, page 50.

1006 ID 904, page 129.

1007 ID 904, page 129, translation from Danish. In reply to the Statement of Objections, Lundbeck argued that this e-mail would at least also show that its discussions regarding supplies from Ranbaxy had also the purpose of ensuring "… Lundbeck a buffer of stock", whereas "… the situation had changed and we were no longer interested" (see ID 904, page 129, Lundbeck's translation from Danish). See ID 5394, pages 237-238.

1008 ID 4817, page 235.

$V GLVFXVVHG DW WKH HQG RI ODVW \HDU ZH KDYH of Analysis of the following APIs:

«

Citalopram

«

All are produced by Ranbaxy. May I also ask you if you could be available between - DQ DQG IRU D PHHWLQJ« "[1009]

(555) An internal e-mail of Ranbaxy's patent department of 21 March 2002 entitled "Citalopram patent applications of concern" stated:

"Some recent PCT/EP application on citalopram are of concern to us as they try to cover compounds/processes which are part of prior art and we fall under the scope of such claims."

With respect to Lundbeck's crystallisation patent, the e-mail stated:

"Crystalline base of citalopram was obtained/set free/isolated in EP 347066 (Example 3, application published in March 1995) and converted to the hydrobromide salt. The process is therefore disclosed earlier and not novel in any way. Our process does not involve any purification/recrystallization of the citalopram base, however it is set free at one stage and the product is a thick oil which tends to solidify on cooling (at the bottom of the reactor). In order to overcome any potential infringement issue on account of claim 1, the citalopram base oil is directly dissolved in a solvent (without allowing any solidification) and then converted to the hydrobromide salt. No handling or analysis of the citalopram base is done."[1010]

Moreover, the e-mail stated:

"The patent application also claims a crystalline base of citalopram, or a hydrochloride or a hydrobromide salt of citalopram characterized in that it has a purity of more than 99.8% w/w preferably more than 99.9% w/w (claim 11). The claim being independent covers citalopram hydrobromide of purity 99.8% w/w irrespective of the process of preparation. ... Citalopram hydrobromide obtained by our process is also greater than 99.8% w/w but we follow a different process (two patent applications have been filed on the same). Thus Citalopram hydrobromide of purity 99.8% w/w is not limited to the claimed process. We would obviously like to market the product of purity more than 99.8%."

The reply of Ranbaxy's management in the same exchange of e-mails stated:

"We shall oppose the British patent after consulting the file wrapper. Action in other European countries will be decided accordingly."[1011]

[1009] ID 624, page 2.

[1010] ID 5178, pages 1-2. Patent EP 347066 was an earlier Lundbeck patent on new enantiomers and their isolation, which had been applied for on 20 December 1989. Source: Espacenet. It is recalled that claim 1 of the crystallisation patent was deleted in the amended version eventually accepted by the EPO in 2009. See recital (166) above.

[1011] ID 5178, pages 1-2.

It should be noted that on October 18, 2001, Lundbeck had in fact filed an amended version of its patent application at the EPO, deleting claim 11 as referred to by Ranbaxy in this e-mail.[1012] However, this product claim remained present in the United Kingdom patent for the crystallisation patent (patent GB 2357762) as granted in the United Kingdom on 30 January 2002. There is no indication that Ranbaxy, after having concluded the agreement with Lundbeck, actually opposed this United Kingdom patent.

(556) The same e-mail of Ranbaxy's patent department also analysed another process patent application for citalopram of Lundbeck's, WO 01/68631. It stated that "none of WKH SURFHVV FODLPV « but observed that the application also claimed an intermediate which Ranbaxy had in its process. According to the e-mail, this intermediate "has been reported in literature" in 1977 and thus "We believe that this compound should be excluded from this claim."[1013]

The reply of Ranbaxy's management stated:

"The concerned product claims of the patent application are not of concern in view of the prior at and would not be valid in case of grant."[1014]

(557) On 4 April 2002, the American wholesaler acting for Ranbaxy[1015] sent a draft confidentiality agreement to Arrow "to cover the technical and legal issues on Citalopram." The e-mail proposed "to discuss the Ranbaxy products in the presence of their representatives which are planning to tour Europe. They are most likely availabl H G X U L Q J Z H H N L H V W D U W L Q J 0 R Q G D \ $ S U pricing...I will come back to you early next week."[1016]

(558) On 17 April 2002 a meeting took place between Lundbeck and Ranbaxy at the latter's offices in London. Ranbaxy's [employee function]* led the discussion from Ranbaxy's side. Ranbaxy's position, as reported in Lundbeck's e-mail, was:

– "We have a non-infringing process
– Not crystallising the free base
– [Lundbeck] knows our process
– We will file now for UK & Germany, where we have our own subs expect registration in 8 months

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1012 See ID 2773, page 4. Nevertheless, after having split off the product claims in a divisional, Lundbeck did obtain a patent on the crystalline form itself (EP 1 227 088). This patent was opposed before the EPO and subsequently revoked by the EPO (see recital (151) above), whereas Lundbeck's patent on the crystallisation process (EP 1169314) was significantly amended and the scope of its claims limited before the EPO. See recital (166) above. As for the British patent GB 2357762, this patent appears to have been granted with the product and pharmaceutical composition claims included. There is no indication in the case file that Ranbaxy opposed this patent, as it intended to do before it concluded the agreement with Lundbeck. See recital (151) above.

1013 This PCT patent application for a method for the preparation of citalopram by alkylation was published by the European Patent Office on 18 December 2002. The application was withdrawn by Lundbeck on 13 September 2005. The patent was granted only in New Zealand. Sources: WIPO Patentscope and EPO Espacenet.

1014 ID 5178, pages 1-2.

1015 See recital (554) above.

1016 ID 1354, page 1.

– We are discussing with a partner for Northern Europe, who will be able to bring our product to the market in 3-4 months' time if signature is close

– Q: Is that Tiefenbacher? A: No, we are also talking to Tiefenbacher, but it is not them [Most likely it is Tiefenbacher/Delta however it could also be] Merck Generics if Natco really is infringing]

– Annual capacity for [third countries] & EU ±4.5 ton

– Do you want a deal? Please let us know before end of April!"[1017]

Below this, the Lundbeck representative wrote:

"Do we want a deal? I guess a deal will be $10M-$20M or even more. My opinion is that it will be difficult ± D Q W L W U X V W Z L V H F R V W V D Q G Y D O X H I[1018]

(559) On 14 May 2002, the American wholesaler acting for Ranbaxy sent an e-mail to Arrow informing Arrow that a Ranbaxy representative from India "will be in Europe early June". The American wholesaler also confirmed that his company was "doing follow up work on API's for the market in Europe with the authorisation of Ranbaxy's API export department."[1019] In another e-mail to Arrow of the same day, the American wholesaler acting for Ranbaxy stated:

« Z H K H U H E \ W U D Q V P L W R X U R I I H U W R N J R I Dublin.

Samples are available upon request.

[Ranbaxy representative] will be visiting Europe, beginning of June. He is available for a meeting with you either in London or Dublin on Thursday June 6th «

% H V L G H V & L W D O R S U D P P R V W R I W K H S U R G X F W V Z H[1020]

(560) On 16 May 2002, Lundbeck became aware that Ranbaxy had filed two patent applications in India for processes for manufacturing citalopram. In the e-mail reporting this, Lundbeck's [employee function]* wrote: "Both these processes can be in conflict with our process patents."[1021]

(561) An internal Lundbeck Business Development document entitled "Generic citalopram update 21 05 2002" stated:

"Ranbaxy

– Meeting 8 May in Paris

– 12 months ceasefire + possible patent infringement against

  – UK distribution: 10% volume at a 40% margin --2M

  – Cash sum $5.3M

  – Total cost ±appr. $7-8M

[1017] ID 681, page 88. In reply to the Letter of Facts, Ranbaxy argued : "…it usually took around two years for it to obtain marketing authorizations […]. For citalopram, Ranbaxy obtained them [in.] 17 months…" See ID 6802, page 6.

[1018] ID 681, page 88.

[1019] ID 1354, page 11.

[1020] ID 1354, page 12.

[1021] ID 8, page 339, translation from Danish. See also ID 5394, page 240.

– Alternative: Piggy-bag Tifi[Tiefenbacher] and hit the market in August 2002."[1022]

(562) Lundbeck sent a draft of a "Settlement Agreement" to Ranbaxy (UK) Limited on 24 May 2002. This draft mentioned Ranbaxy (UK) Limited as a party to the agreement together with Ranbaxy Laboratories Limited in India. [1023]

(563) On 27 May 2002, Ranbaxy UK sent an e-mail to Lundbeck describing a production process for the manufacture of citalopram.[1024] Lundbeck claimed in its reply to the Statement of Objections that this e-mail described Ranbaxy's production process for citalopram and that "the process described in these schemes was clearly covered by Lundbeck's patented Iodo Process, with an additional purification step based on the patented Amide Process".[1025]

(564) An internal Lundbeck document of 31 May 2002 analysed "the Ranbaxy process as it appears from the reaction schemes that we have received" and concluded that there were arguments for considering that it infringed Lundbeck's patent application EP 1159274: Method for the preparation of citalopram (the iodo process patent)[1026] and Lundbeck's patent EP 1015416: Method for the preparation of citalopram (the amide process patent).[1027] Regarding the former, Lundbeck's [employee function]* considered in this document: "EP 1159274 has a claim 11 covering the intermediate 5-iodo-citalopram per se. Since such a claim may be considered analogous with a process claim, importation of a product which is a direct result of conversion of 5-iodo-citalopram to citalopram may be considered infringement of EP 1159274."[1028] Regarding the latter, he took the view that « L W L V S R V V L E O H W K D W W K H carboxamido-citalopram to citalopram in step two of the Ranbaxy process will be regarded as an infringement of EP 1015416."[1029]

(565) A Lundbeck e-mail to Ranbaxy (UK) Limited of 7 June 2002 explained:

"According to our contract to be signed in June the mechanism for allocating quantities to Ranbaxy will be as follows:

While the contract is in force Ranbaxy can in a month purchase [up] 10% of Lu-UK last month's volume of

– Cipramil 10mg 28 tabs
– Cipramil 20 mg 28 tabs
– Cipramil 40 mg 28 tabs

3 U L F H V D U H D V P H Q W L R Q H G L Q W K H F R Q W U D F W >« @[1030]

1022 ID 847, page 32.
1023 ID 904, pages 159 to 169. The actually concluded agreement was with Ranbaxy Laboratories Limited in India only.
1024 ID 5397.
1025 ID 5394, pages 15 and 49. See also recital (564) below.
1026 This patent was granted by the EPO on 26 March 2003, see Espacenet and ID 5176, page 15.
1027 ID 8, pages 336 to 338. Lundbeck had filed these two process patents (referred to by Lundbeck as its iodo process patent and amide process patent respectively, see ID 5394, page 12) in 1998 and 1999 respectively, see recital (144) above.
1028 ID 8, pages 336-337.
1029 ID 8, pages 336-337. This patent is referred to by Lundbeck as the amide process patent.
1030 ID 681, page 98.

(566) By the time Ranbaxy and Lundbeck entered into an agreement for the EEA on 16 June 2002, Ranbaxy had already produced around 500 kg of citalopram API and had already sold citalopram API to Sweden and Italy.[1031] On 14 June 2002, Ranbaxy had filed a Drug Master File for its citalopram API with the United Kingdom authorities. At the same time, the dossier necessary for Ranbaxy's application for a marketing authorisation to sell citalopram medicines itself was sent from India to Ranbaxy's United Kingdom office.[1032] Ranbaxy sent a technical data package or the open part of its Drug Master File to potential API customers in Italy, Portugal, Greece and France, both before conclusion of the agreement with Lundbeck and during its operation.[1033] By 16 June 2002, Ranbaxy had not yet filed for any marketing authorisations in EEA Contracting Parties to distribute citalopram medicines itself.[1034]

7.7.2. The agreement

(567) On 16 June 2002, H. Lundbeck A/S and Ranbaxy Laboratories Limited in India concluded an agreement covering the then EEA (as well as a number of third countries, collectively referred to as "the Territory") for a period of 360 days.[1035] The preamble noted that « 5DQEDA[\ KDV ILOHG WZR SURFHVV SDWH (264/DEL/2001 and 779-DEL/2001) relating to the manufacture of Citalopram and has, furthermore, manufactured pharmaceutical products containing Citalopram with the intention of marketing such products in the Territory through affiliates, licensees or customers of Ranbaxy". The preamble then stated that Lundbeck had performed laboratory analyses of Ranbaxy's products and that based on the results of these laboratory analyses Lundbeck believed that "the production methods used to produce Ranbaxy's products infringe Lundbeck's intellectual property rights, in particular EP patent No 1015416[1036] and EP Patent Application No 1159274[1037]". Ranbaxy noted in the preamble that it "disputed the claim of Lundbeck that the Patent filed by Ranbaxy and the production method used by Ranbaxy infringe Lundbeck's intellectual property rights". Finally, the preamble noted that Lundbeck and Ranbaxy had "arrived at a Settlement in order to avoid costly and time-consuming patent litigation, the outcome of which cannot be predicted with absolute certainty."

It should be noted that when the agreement was concluded, no litigation between Lundbeck and Ranbaxy on citalopram was taking place anywhere in the EEA.[1038]

1031 ID 601, page 8, ID 597, page 1. The amount sold in Sweden was negligible, but in Italy Ranbaxy sold 16 kg of citalopram API to the Italian company Pharmacare before the agreement was concluded at a price of USD 3.1 million, see ID 597, page 1. Ranbaxy stated in its reply to the Statement of Objections "that this company acted as a broker in the past and may well have been doing so in this instance in which case the API would have been destined for a market outside the EEA." See ID 5176, page 37. It appears that Ranbaxy later issued credit notes to the Italian company against the invoices concerned. According to Ranbaxy, this meant that the product never found an ultimate buyer. See ID 5176, page 37.

1032 ID 1748, page 2, ID 5176, page 27 and ID 5182.

1033 The Italian company Pharmacare received a technical data package in December 2001. The French company GNR Pharma received a technical data package in January 2002. See ID 1748, page 3.

1034 Ranbaxy filed its United Kingdom application for a marketing authorisation in early August 2002.

1035 ID 8, pages 292 to 299.

1036 Referred to by Lundbeck as the amide process patent.

1037 Referred to by Lundbeck as the iodo process patent.

1038 ID 823, page 62, ID 601, page 7.

(568) Article 1.1 of the agreement stated:

"Subject to the terms and conditions of this Agreement and subject to payment of the Settlement Amount by Lundbeck, Ranbaxy shall not in the Territory claim any rights on the Patent Application or any production method used by Ranbaxy and shall cancel, cease and desist from any manufacture or sale of pharmaceutical products based hereon, in the Territory through itself, its Affiliates and/or any third party during the term of the Agreement." Affiliate meant any company directly or indirectly controlled by Ranbaxy Laboratories Limited or Ranbaxy (UK) Limited.

Ranbaxy signed the agreement on 11 June 2002, whereas Lundbeck signed it on 16 June 2002. Further to a Lundbeck letter of 14 June 2002, Ranbaxy sent Lundbeck on 17 June 2002 a signed side letter to the agreement which stated:

"The Agreement is signed by Lundbeck and returned to Ranbaxy subject to the explicit proviso that the term "pharmaceutical products" also covers bulk and any other form containing the active ingredient and that products delivered to Ranbaxy under Article 1.3 are only for sale in the UK."[1039]

(569) Article 1.2 provided that "In the event of any breach of the obligation set forth in Article 1.1 or at the request of Lundbeck, Ranbaxy Laboratories Limited, Ranbaxy (UK) Limited and Ranbaxy's Affiliates will voluntarily submit to an interim injunction by any competent court in the Territory." Ranbaxy would "waive any confirmatory action pursuant to any law or regulation in the Territory relating to such injunction and shall upon request from Lundbeck sign any document necessary to obtain such injunctions."[1040]

(570) In Article 1.3, "in consideration of the Settlement arrived at" Lundbeck agreed to pay Ranbaxy an amount of USD 5 million, "being the Settlement Amount", payable in five instalments spread over the duration of the term of the agreement, the last instalment being due on the last day of operation of the agreement.

(571) Also in Article 1.3, Lundbeck agreed to sell citalopram tablets (10 mg, 20 mg and 40 mg) to Ranbaxy in the United Kingdom during the term of the agreement, in quantities to be negotiated. Appendix B specified the sales price from Lundbeck to Ranbaxy as the current Lundbeck ex-factory price less 40%. Lundbeck estimated the cost of this arrangement to Lundbeck at GBP 1.5 million.[1041] As for the quantities, it was agreed that Ranbaxy would be entitled to sell in the United Kingdom every month up to 10% of Lundbeck's last month's sales volume of citalopram in the United Kingdom.[1042] Ranbaxy would "use its dispensing doctor field force at its own expenses to promote the product in the UK." Finally, Article 1.3 provided that Ranbaxy and Lundbeck would be free to choose their customers and wholesalers in the United Kingdom market.

(572) Article 1.4 of the agreement provided: "During the term of this Agreement, Lundbeck and Ranbaxy undertake not to initiate legal proceedings against each other based on any of the patents set out above."

1039 ID 246, pages 1 to 3.

1040 There is no indication in the file that any voluntary interim injunction was put into force by the parties in the EEA in the period covered by the agreement. Ranbaxy assured Lundbeck that following the agreement it did not export any citalopram to the EEA, see recital (577) below.

1041 See recital (561) above and recital (576) below.

1042 See recital (565) above and recital (576) below.

7.7.3. Events during the implementation and extension of the agreement

(573) On 19 June 2002, Lundbeck made the first payment of USD 1 million to Ranbaxy (UK) Limited.[1043]

(574) In July 2002, Ranbaxy filed a PCT application WO 02/007872 for the process for which it had already filed DEL '779 application in India. For Ranbaxy's DEL '264 application in India, a PCT application had already been filed as WO 02/072565 in March 2002.[1044]

(575) In early August 2002, Ranbaxy filed an application for a marketing authorisation to sell medicines in the United Kingdom.[1045]

(576) A Lundbeck Business Development document with the title "Generic citalopram update 04 09 2002" stated:

"Ranbaxy
update 04