

COMMISSION DECISION

of 15 June 2005

relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement

(Case COMP/A. 37.507/F3 – AstraZeneca)

(ONLY THE ENGLISH AND SWEDISH TEXTS ARE AUTHENTIC)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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, and in particular Article 7(1) and Article 23(2) thereof¹.

Having regard to the complaint lodged by Generics (UK) Limited and Scandinavian Pharmaceuticals Generics AB on 12 May 1999, alleging infringements of Article 82 of the Treaty and Article 54 of the EEA Agreement and requesting the Commission to put an end to those infringements,

Having regard to the Commission decision of 25 July 2003 to initiate proceedings in this case,

Having given the undertakings concerned the opportunity to make known their views on the objections raised by the Commission pursuant to Article 19(1) of Council Regulation No 17² and Commission Regulation (EC) No 2842/98 of 22 December 1998 on the hearing of parties in certain proceedings under Article 85 and 86 of the Treaty³,

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

Having regard to the final report of the hearing officer in this case⁴,

¹ OJ L 1, 4.1, 2003, p.1. Regulation as amended by Regulation (EC) No 411/2004 (OJ L 68 of 6.3.2004, p. 1).

² First Regulation implementing Articles 85 and 86 of the Treaty (OJ 13, 21.2.1962, p. 204).

³ OJ L 354, 30.12.1998, p. 18. Article 34(2) of Regulation (EC) No 1/2003 states that procedural steps taken under Regulation No 17 are to continue to have effect for the purposes of applying Regulation (EC) No 1/2003.

⁴ OJ [...]-

Whereas:

I. FACTS

A. INTRODUCTION

- (1) On 12 May 1999 the company Generics (UK) Limited (hereinafter “Generics”) and the Swedish company Scandinavian Pharmaceuticals Generics AB (hereinafter “Scand Pharm”) lodged a joint complaint pursuant to Article 3 of Regulation No 17 against Astra AB. Generics and/or Scand Pharm, which belong to the same group⁵, will hereinafter be referred to collectively and individually as “the complainant”.
- (2) The complainant contends that Astra AB has abused its dominant position for omeprazole-based medicines (*inter alia* marketed as Losec) in a number of national markets within the EEA. Its main argument is that Astra AB has prevented it from bringing therapeutically equivalent generic versions of omeprazole to a number of EEA markets and has thus infringed Article 82 of the Treaty and Article 54 of the EEA Agreement.
- (3) Broadly speaking, this decision deals with two alleged abuses in connection with Astra’s strategy in relation to its applications for so-called supplementary protection certificates (hereinafter “SPC”) extending the protection for the active substance omeprazole in its anti-ulcer medicine Losec; and Astra’s strategy in relation to a switch (mainly in 1998) from capsule to tablet formulations of Losec.
- (4) The alleged abuses involve behaviour in several Contracting Parties within the EEA (notably Belgium, Denmark, Germany, the Netherlands, Norway, Sweden and the United Kingdom). As regards Norway, the Commission’s jurisdiction in this case derives from Article 56 (2), second sentence, of the EEA Agreement.
- (5) It should be mentioned at the outset that the said two alleged abuses respectively concern behaviour in relation to two distinct regulatory systems: a) the patent system whereby extra protection is granted under Community patent law in the form of SPCs for pharmaceutical products and b) the procedures and conditions under Community and national pharmaceutical law relating to the authorisation to market pharmaceutical products. However, both abuses have the same objective of preventing or delaying market entry of generic omeprazole based products.
- (6) Briefly, as regards the patent system, in Europe both patents and SPCs are granted by the national patent offices (national patents). Patents, but not SPCs, are also granted by the Munich-based European Patent Office under the European Patent Convention of 1973 (European patents) to which *inter alia* all EEA Contracting Parties are parties. In order to obtain a European or national patent, the applicant has to fulfil certain substantive conditions such as *industrial applicability*, *novelty* and *inventive step*. Once granted, a European patent results in a “bundle” of national patents in those

⁵ Scand Pharm and Generics form part of Merck Generics, the generic arm of Merck KGaA, a German pharmaceutical and chemicals company based in Darmstadt. Merck KGaA should not be confused with Merck & Co, the US research based company.

countries which were designated by the applicant. Enforcement issues relating to infringements and the validity of SPCs and patents – be they national patents or European patents – are dealt with by national courts in accordance with national patent law. The legal or natural person to whom a patent has been granted is a “patent holder”.

- (7) The procedure for granting patents should be distinguished from the Community and national legislation relating to the authorisation of pharmaceutical products. The latter body of law is applied by the issuing authorities (i.e. national medicinal authorities or the European Commission based on opinions by the European Medicines Evaluation Agency). In order to obtain a market authorisation for a pharmaceutical product, the applicant essentially has to prove *the safety, efficacy and quality of the product* to the said authorities. The legal or natural person to whom a market authorisation has been granted is a “holder of a market authorisation”.

B. THE PARTIES

1. ASTRAZENECA AND ITS PRECEDESSOR ASTRA

- (8) The alleged abuses in this case mainly concern conduct involving the Swedish company Astra AB⁶ based in Södertälje, the parent company of a research based pharmaceutical group, as well as certain of its subsidiaries, mainly two wholly owned subsidiaries in Mölndal in Sweden: AB Hässle⁷ and Astra Hässle AB⁸. Other companies involved in the alleged behaviour include subsidiaries within the Astra group in Södertälje⁹ and in the Nordic countries¹⁰. With effect from 6 April 1999, Astra AB merged with the United Kingdom company Zeneca Group Plc to form the United Kingdom company AstraZeneca Plc. As a result of the merger, Astra AB’s function as the group holding company has been assumed by the London-based holding company AstraZeneca Plc. Astra AB in Södertälje has remained in existence as a research and development, marketing and production company under the new name AstraZeneca AB, a wholly owned subsidiary of AstraZeneca Plc¹¹. For ease of reference, companies within the Astra AB and AstraZeneca Plc groups will hereinafter be referred to as “AZ”.

⁶ Until 20 June 1994 the registered name was in fact “Aktiebolaget Astra” [1932]. Note: page numbers on the Commission’s file are in brackets.

⁷ AB Hässle is the proprietor of the key Losec related patents in this case [1853-1857, 1924-1928]. AB Hässle has been dormant since 1992 and has no staff [1925, 5379].

⁸ For info on Astra Hässle AB (R & D company) see [1865 et seq, 4956, 7789]. Hässle Läkemedel AB in Mölndal is also a wholly owned by Astra AB. This subsidiary is a marketing company and the holder of the market authorisation for Losec in Sweden [1861, 1871 et seq, 4957, 7427].

⁹ Another Södertälje based company relevant for this case – also wholly owned by Astra AB – is Astra Läkemedel AB (a marketing company) [4957].

¹⁰ The Nordic subsidiaries – as they were named at the time of the behaviour relevant to this Decision - are principally Astra Norge AS, Astra Danmark A/S and Astra Finland Oy (Suomen Astra Oy until 1 April 1998) which hold the market authorisations for Losec in the respective countries. Those three subsidiaries were wholly owned by Astra AB [7963, 8033, 8104, 8178, 8260, Vol 1, Annex 3.2 AZ Reply].

¹¹ Astra AB changed name to AstraZeneca AB with effect from 3 January 2000 [1891, 9266-9328]. AstraZeneca Plc initially held a 99.7% stake of the shares in Astra AB which then increased to 100%.

- (9) AZ is one of the world's leading pharmaceutical and healthcare companies involved in inventing, developing and commercialising innovative products. Its pharmaceutical business is focused on a number of therapeutic areas including the gastrointestinal area, where AZ's major products include notably Losec (the brandname used for most European markets, including most markets relevant in this case). Exceptional growth has characterised Losec's market development since its launch in 1988¹². At the end of 1993 it became the world's third largest pharmaceutical (sales of USD 1.7 billion). In 1998, 1999 and 2000, it became the best selling prescription medicine ever with sales of, respectively, USD 4.8 billion, USD 5.9 billion and USD 6.3 billion. In 1999 and 2000, Losec accounted for almost 40% of AZ's total sales.

C. THE PROCEDURE

- (10) By Decision of 9 February 2000 pursuant to Article 14 (3) of Regulation No 17, the Commission required AZ, including its subsidiaries, to submit to an investigation at its premises in London and Södertälje concerning possible abuses of a dominant position. In 2002 and 2003, AZ also replied to three requests for information pursuant to Article 11 of Regulation No 17.
- (11) On 29 July 2003, the Commission addressed a Statement of Objections to AstraZeneca AB and AstraZeneca Plc. The two addressees of the Statement of Objections submitted a joint reply on 3 December 2003 (hereinafter "AZ Reply"). A meeting was held between AZ and the Commission on 29 January 2004 to discuss certain economic evidence submitted as part of the AZ Reply. In connection with that meeting, AZ submitted various documents including memoranda dated 27 January 2004 and 11 February 2004 *inter alia* addressing issues raised by the Commission at the meeting. On 13 February 2004, AZ provided the Commission with materials relating to the second abuse in this case.
- (12) An Oral Hearing took place on 16-17 February 2004. On 26 February 2004 the Commission sent a request for information pursuant to Article 11 of Regulation No 17 to AZ requesting certain information relating mainly to the issue of dominance. The request partly concerned documents which the Commission had originally requested pursuant to Article 11 on 8 May 2003. On 12 March 2004, AZ replied to the request. Before that, on 8 March 2004, AZ submitted a memorandum to the Commission containing comments concerning the Oral Hearing. By letter of 23 November 2004 the Commission offered AZ the opportunity to comment on a number of factual elements and considerations in support of the objections already notified, but not explicitly referred to in the Statement of Objections, to which the Commission could refer in an eventual decision ("letter of facts). AZ provided its observations by letter of 21 January 2005.

D. THE PRODUCT LOSEC

1. LOSEC: A PROPRIETARY MEDICINAL PRODUCT

¹²

[2704].

- (13) Losec is a so-called proprietary medicinal product (as defined by Article 1 (1) of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products)¹³. Even though the terms “medicine”, “drug” and “pharmaceutical product” are not defined in Community pharmaceutical legislation, in this decision they will be used interchangeably with the term “medicinal product”.

2. LOSEC’S ACTIVE SUBSTANCE AND ITS FORMULATIONS

- (14) The key component of a medicinal product is its active substance (sometimes called “active ingredient”). Novel active substances are often patented at an early stage of the research and development process. Substance patents normally provide the strongest legal protection for pharmaceutical products¹⁴ and are therefore the most valuable part of a medicinal product. The active substance in Losec is omeprazole.
- (15) The active substance of a medicinal product normally takes one of two forms. First, medicinal products may contain the active substance in its neutral form (often referred to as the “free base”). For Losec, the active substance is omeprazole in its neutral form. Alternatively, the active substance may be a derivative of the basic substance, in particular a salt derived from that substance. The choice between the free base and derivatives does not normally entail significant differences in terms of therapeutic effect. For Losec, there exist magnesium and sodium salt versions of omeprazole (see recitals (17)-(18)).
- (16) Medicinal products are marketed in various formulations (or “dosage forms”), such as capsules or tablets. The formulations are also often patented. Formulation patents do not in general offer the same degree of protection as substance patents, as other companies may circumvent the formulation patent by incorporating the active substance (if not patented) into a different formulation.
- (17) At its launch in Europe at the end of the 1980s, Losec was sold mainly in a capsule formulation. At the end of 1998, AZ withdrew the capsules in several European countries and replaced them by tablets with the brandname Losec MUPS (“Multi-Unit Pellet System”) with a magnesium salt of omeprazole as its active substance. Both the capsules and tablets come in three strengths (in terms of the active substance’s weight): 10, 20 and 40 mg.
- (18) Losec is also marketed as an intravenous injectable formulation (containing the sodium salt of omeprazole as its active substance) as well as in the form of a solution for infusion. These formulations are mainly used in hospital treatment. This decision however only concerns the oral formulations capsules and tablets in their various strengths.

¹³ OJ 22, 9.2.1965, p. 369. Directive 65/65/EEC, with amendments, was incorporated into the EEA Agreement at point XIII.1 of Annex II thereto with effect from 1 January 1994. Directive 65/65/EEC, as amended, has been consolidated into 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, p. 67). This Decision will however refer to Directive 65/65/EEC, as amended, since it was applicable at the time of the behaviour in question.

¹⁴ [2398].

3. THE PATENTS PROTECTING OMEPRAZOLE AND LOSEC

- (19) AZ's patent protection for Losec protects omeprazole and other structurally related compounds¹⁵.
- (20) AZ filed its application for omeprazole with the European Patent Office on 3 April 1979. In its application, AZ designated nine European Patent Convention States (Belgium, Luxembourg, the Netherlands, Switzerland, Germany, France, the United Kingdom, Italy and Sweden). The European patent granted for these States expired 20 years as from the date of filing, i.e. on 3 April 1999.
- (21) For certain other European jurisdictions (including Denmark, Norway, Finland, Austria and Ireland) AZ obtained national patents by filing applications with national patent offices around the same time as it filed its application with the European Patent Office. These patents expired on 10 April 1999 in Norway, on 11 April 1999 in Denmark, on 12 April 1999 in Finland and Austria, and on 8 August 1999 in Ireland.
- (22) In addition, AZ acquired formulation patents, which expire in April 2007. There are two basic formulation patents, which protect AZ's original capsule formulation¹⁶. One patent covers formulations containing omeprazole (and structurally related compounds) as the active substance. The other patent covers formulations containing other so-called proton pump inhibitors than omeprazole and structurally related compounds (see recitals (36) and (87)).
- (23) As regards the patent protection around Losec reference is made to AZ's own internal assessments: "[t]o the best of Astra's knowledge, no other major pharmaceutical product has been subjected to so many innovations relating to it. The patent position throughout the world is unique¹⁷ ... [t]he patent situation concerning ... Losec is remarkable and far better than those that have ever covered other major pharmaceutical products ... no leading substance in the history of [the] pharmaceutical industry has had such a strong, overall protection as omeprazole"¹⁸. In addition to the basic substance patents covering the omeprazole substance and the formulation patents covering the oral formulations (capsules and tablets) there is a whole array of other patents for Losec. One internal AZ document lists nearly 20 different types of patents protecting AZ's omeprazole-based products¹⁹. In a press release dated 29 September 1997, AZ's CEO states that "[w]e firmly believe that the multiple patents for Losec represent an important competitive advantage to Astra, which we will be vigilant in preserving"²⁰.

4. GASTROINTESTINAL ACID-RELATED DISEASES AND CONDITIONS

- (24) The relevant therapeutic area in this case is acid-related gastro-intestinal diseases and conditions, notably the three main diseases described in this section 4.

¹⁵ [2240, 3669].

¹⁶ [3055, 3338, 3355, 3669-3671].

¹⁷ [4057].

¹⁸ [3773].

¹⁹ [2240-2255]; see also [5085].

²⁰ [5951].

- (25) The first main type of gastro-intestinal diseases caused by acid production in the stomach is peptic ulcer diseases (PUD). PUD involves sores or ulcers in the stomach (“gastric ulcer”) as well as ulcers in the small intestine (“duodenal ulcer”). The acid production may be caused by several factors. The primary cause is the bacterium *Helicobacter pylori* (“H pylori”)²¹. The standard treatment for PUD is to eradicate this bacterium. In addition, the use of certain medicines, in particular non-steroidal anti-inflammatory medicines (“NSAIDs”) may also cause acid production and lead to PUD. Finally, *Zollinger-Ellison syndrome*, a very rare condition usually associated with tumours, may involve excessive secretion of acid into the stomach and also lead to ulcers²². According to AZ’s own estimate around 10-15% of the world population incur PUD²³.
- (26) A second main type of disease is so-called gastro-intestinal oesophageal reflux (referred to as “GERD”, “GORD” or “reflux disease”). GERD involves involuntary movements of the stomach’s acid and other contents into the lower part of the throat (“oesophagus”). GERD often causes various pains, primarily so-called heartburn²⁴. Unlike H pylori-induced PUD, GERD has a high recurrence rate as no therapy currently corrects the underlying causes²⁵. Most patients therefore require long-term maintenance therapy²⁶. The more severe forms of GERD are generally characterised by inflammation (“[reflux] oesophagitis” or “RO”) involving mucosal damage in the throat. RO is often graded according to its severity (grades or levels I-IV). In an internal document of April 1994, AZ refers to two studies showing the distribution of patients between the four grades of RO²⁷.
- (27) GERD is a very widespread condition, although estimates vary as to its exact extent²⁸. As appears from AZ’s own publications²⁹, the more severe forms of GERD (in particular RO in its various levels/grades) are themselves common. Moreover, GERD is often linked to various complications³⁰, the most serious of which, so-called Barrett’s oesophagus, is by itself a widespread condition³¹.
- (28) The third major therapeutic use for Losec is *dyspepsia* (literally “bad digestion”), a condition involving a broad range of symptoms such as pain and discomfort in the upper abdomen. The condition is very common³². Dyspepsia has several possible causes, a significant number of which are believed to be acid-related³³. In cases where the cause cannot be determined the condition is called functional (also “non-ulcer”) dyspepsia which is estimated to account for at least half of all dyspepsia patients³⁴.

²¹ [2394, 2396]; see also [2582].

²² [6796 d-e].

²³ [2580]; see also [7792].

²⁴ [6737a].

²⁵ [10188]; see also [5079].

²⁶ [5078].

²⁷ [2720].

²⁸ See inter alia [5078, 7792, 8438, 10178-10179].

²⁹ See the documents referred to in the previous footnote. See also other documents such as [6737a] and [6730].

³⁰ [5078].

³¹ [6791-6792].

³² See [6801], [6738b] and [10207].

³³ [6801]; see also [6796b].

³⁴ [6801] and [10207].

- (29) It is sometimes difficult for doctors to determine if a patient has dyspepsia and, if so, which form of the disease³⁵. Indeed, AZ admits that dyspepsia is a disorder with symptoms resembling those of a peptic ulcer³⁶. A study undertaken by AZ's own medical experts concludes that a large share of prescriptions by Swedish doctors for possible acid-related dyspepsia should in fact have been based on a different diagnosis, namely GERD³⁷. Because some milder forms of dyspepsia could be treated by more cost-effective means, various reports published in Sweden and in the United Kingdom have recommended restrictions on the use of so-called proton pump inhibitors (PPIs) (such as Losec) to deal with dyspepsia³⁸. As regards the United Kingdom at least, these recommendations appear to have had little effect; spending on PPIs as a percentage of all spending on dyspepsia medicines have steadily increased from 59% in 1997, to 75% in 2000 and to 82% in 2001³⁹. It may also be noted that prescriptions for dyspepsia were written by doctors on an off-label basis, i.e. before AZ received its first official approval for the indication "acid-related dyspepsia" in May 1997⁴⁰ (see recital (102)).
- (30) At the end of 2002, the relevant national authorities in the EU Member States and Norway had approved seventeen indications in respect of the 10 mg, 20 mg and 40 mg versions of Losec capsules and Losec MUPS relating to the three main therapeutic uses described in this section⁴¹. Most indications relate to PUD (gastric and duodenal ulcers, H pylori eradication, NSAID and Zollinger-Ellison syndrome). In respect of GERD/RO, the authorities had approved three indications. For dyspepsia the only indication was "acid related dyspepsia". With very few exceptions the indications approved by the authorities for Losec capsules correspond to those approved for Losec MUPS. In fact, AZ admits that the choice between Losec capsules and Losec MUPS is clinically irrelevant⁴².

E. MEDICINAL PRODUCTS FOR THE TREATMENT OF ACID-RELATED GASTRO-INTESTINAL DISEASES AND CONDITIONS

1. MODES OF ACTION

- (31) Broadly speaking, medicines are classified by therapeutic group, i.e. by the disorder or symptom they are intended to treat. Within each therapeutic group, medicines are categorised by class. Some classes are based on the manner in which the medicine produces its therapeutic effect in the body, i.e. their mode of action. Medicines used to treat acid-related gastro-intestinal diseases or conditions either serve essentially to strengthen the mucosal defences, i.e. the membrane lining the stomach's and duodenum's walls (so-called *mucosal strengtheners*)⁴³ or to eliminate, reduce or neutralise the acid or pepsin secretion.

³⁵ [10207].

³⁶ [7793].

³⁷ [8835].

³⁸ See [6801] and [6738a-6738d].

³⁹ [8949].

⁴⁰ [7408].

⁴¹ [7406-7419].

⁴² [10157].

⁴³ [2394].

- (32) As regards the second category of medicines, a distinction must also be made between, on the one hand, prokinetics, antacids and alginates, and, on the other hand, the histamine receptor antagonists and the PPIs.
- (33) Many prokinetics, which facilitate emptying of gastric contents (including acid), include the active substance cisapride⁴⁴. Cisapride is in particular used in connection with the milder forms of GERD. Antacids are medicines which primarily neutralise the gastric acid. They have short-term effects, need to be taken frequently and mainly offer some short-lived and symptomatic relief (but no healing) in the case of PUD⁴⁵. Antacids are also often used in connection with milder forms of GERD. Alginates operate by forming a protective gel layer to prevent reflux. They also have short term effects in connection with milder forms of GERD.
- (34) On the other hand, histamine receptor antagonists (“H2 blockers”) and PPIs are classes of medicines which proactively inhibit the acid secretion into the stomach. Acid is pumped into the stomach by a specific enzyme (“the proton pump”) inside the so-called parietal cells along the stomach’s wall. However, the H2 blockers only block the so-called histamine receptors in the parietal cells and these histamine receptors are only one of the stimulants of the proton pump⁴⁶. In contrast, PPIs reach further into the acid-producing parietal cells and pin-point the proton pump itself⁴⁷. In other words, whereas H2 blockers only operate indirectly on the proton pump, PPIs do so directly. The uniqueness and groundbreaking character of PPIs (and AZ’s omeprazole in particular), as compared to H2 blockers is widely acknowledged⁴⁸.
- (35) The key H2 blockers are *ranitidine* (the active substance in Zantac, marketed by GlaxoSmithKline (GSK)), *cimetidine* (the active substance in Tagamet, marketed by GSK), *famotidine* (the active substance in Merck’s Pepcid) and *nizatidine* (the active substance in Eli Lilly’s Axid and Nizax)⁴⁹.
- (36) At its launch at the end of the 1980s, AZ’s *omeprazole* became the pioneer PPI. During the 1990s, omeprazole was followed by a number of other PPIs containing molecules similar to omeprazole⁵⁰: *lansoprazole* (launched by the Japanese company Takeda in 1992); *pantoprazole* (launched by the German company Byk Gulden⁵¹ in 1994) and *rabeprazole* (launched by the Japanese company Eisai in 1997). During 2000, AZ launched *esomeprazole*, the active substance in the medicinal product Nexium, the successor to Losec capsules and Losec MUPS⁵².

⁴⁴ [2396].

⁴⁵ [223]; [2394].

⁴⁶ Other stimulants include gastrin, acetylcholine, vagal excitation, caffeine and food. H2 blockers also reduce acid output caused by the said factors. See [224]; [6796c].

⁴⁷ [209-212] and [223].

⁴⁸ See [209-212], [2580], [2394], [2609], [2830], [6801-6802], and [6729, 6730].

⁴⁹ [6796c].

⁵⁰ As regards the different chemical structure and route of synthesis of PPIs and H2 blockers see the following pages of the complaint: [1104, 242-253]. The successor PPIs are often referred to as “class competitors” in internal AZ documents.

⁵¹ Byk Gulden currently forms part of the German company Altana AG. References to “Byk Gulden” below include Altana. [9735].

⁵² Community approval for Nexium was granted in July 2000 after which the product was launched in the United Kingdom, Germany, Sweden, Ireland, Norway, Denmark, Iceland, Finland, the Netherlands and Luxembourg in the course of 2000 [8436].

2. THERAPEUTIC USES

- (37) Due to their singular mode of action, the therapeutic effectiveness of PPIs is considered to be superior to that of other categories of medicinal products used for the treatment of gastrointestinal diseases related to conditions caused by acid production – including the H2 blockers. As explained, it is this specific mode of action which primarily accounts for omeprazole’s and the other PPIs’ superior characteristics in relation to H2 blockers in terms of healing rate, symptom relief⁵³, eradication rates (in the case of H pylori infection) and the prevention of relapse (in the case of GERD). Indeed, AZ states in its 1994 annual report⁵⁴: “*Losec (omeprazole) offers significant clinical advantages compared with H2-receptor antagonists. Comparative clinical studies of these pharmaceuticals have shown that patients treated with Losec become symptom-free earlier and more patients get their ulcers healed. This applies to peptic ulcer as well as to reflux oesophagitis. In the case of RO and [duodenal ulcer], long-term therapy with Losec is effective in preventing recurrence*”. In its 1996 annual report AZ notes that “*Astra’s success with Losec is due in large part to the product’s good clinical effect and specific mode of action: It inhibits the final stage in the formation of hydrochloric acid in the stomach. This means that Losec is more effective than previous drugs in the treatment of peptic ulcer, and it has essentially no side effects*”⁵⁵. The 1996 annual report also observes that in time it became clear that “*a unique pharmaceutical*” was born⁵⁶.
- (38) In sections (a)-(c) below the PPIs’ therapeutic superiority over other medicines used within the broad field of gastrointestinal acid-related diseases and conditions will be illustrated for each of the three main therapeutic uses. Several references will be made to one of AZ’s own publications which demonstrates the therapeutic superiority of omeprazole compared to other classes of medicines such as H2 blockers. The publication (from 1998) is based on an extensive bibliography citing over 130 scientific sources. Of these, some 40 date from the period prior to 1990. Some 40 further sources date from the period 1990-1994. This clearly suggests that the superiority of PPIs over other classes of medicines used within the same broad therapeutic area (such as H2 blockers) was recognised at the latest by the early 1990s. Apart from the therapeutic superiority of PPIs over other classes of medicines, it should also be observed that PPIs (including omeprazole) – by virtue of their therapeutic superiority – have proven to be more cost-effective than H2 blockers (considering *inter alia* that PPIs treat patients more quickly)⁵⁷.

(a) Peptic Ulcer Disease (PUD)

⁵³ Omeprazole is said to be the most effective medicine for symptom relief that science knows. “Drug Discovery – A Pharmacist’s Story” by Ivan Östholm, Swedish Pharmaceutical Press, 1995, (“Ivan Östholm article”). Östholm was the former head of R & D at Hässle and is regarded as the inventor of omeprazole, p. 198 (as quoted in the complaint) [1102]. See also various other AZ documents [10183], [2580], [2609-2610], [2737-2738], [4404]. See also [5089] and [6737a].

⁵⁴ [7810]. See also [7828].

⁵⁵ [7830]. See also [10148, 10152, 10162, 10167].

⁵⁶ [7832].

⁵⁷ See [6782-6783], [6784-6788], [6750a-6750b], [213] and [1103]. See also [222, 225-226] which contain a list of studies highlighting the cost-effectiveness of omeprazole over ranitidine in both the short-term and long-term management of reflux oesophagitis.

- (39) The healing rates of PPIs are, with minor differences, said to be "extremely high"⁵⁸. For example, the PPI omeprazole results in healing of ulcers even in patients who are resistant to H2 blockers⁵⁹.
- (40) More specifically, PPIs combined with antibiotics are generally seen as the most effective ("first line") treatment for the eradication of the H pylori bacterium which is the root cause of most cases of PUD⁶⁰. The eradication rates for PPIs have been significantly higher than the rates obtained by using H2 blockers and the relevant international expert commissions and consensus conferences recommend combination treatment with PPIs and antibiotics⁶¹. There is a significant patient population in which eradication treatment with H2 blockers is not considered to be adequate⁶².
- (41) Omeprazole is also considered to heal more quickly than H2 blockers in the case of NSAID-induced ulcers⁶³. In contrast to H2-blockers, Losec has, according to AZ, shown very good healing results in the treatment of NSAID-induced ulcers⁶⁴. H2 blockers are in general no longer used to treat these ulcers, especially if they occur in the stomach⁶⁵. An AZ publication refers to studies showing superior results for one PPI (AZ's Losec MUPS tablets) compared to ranitidine and misoprostol (a mucosal strengthener: see recital (31)) not only in terms of healing but also in preventive treatment⁶⁶.
- (42) Finally, in 1992, it was noted that omeprazole can be used to deal with cases of the hypersecretory Zollinger-Ellison syndrome in cases resistant to H2 blockers⁶⁷.

(b) GERD

- (43) GERD covers a wide spectrum from milder to more severe forms (see recital (26)). As treatment against the mildest forms of GERD even lifestyle changes may suffice⁶⁸. For other mild GERD conditions antacids and alginates may sometimes constitute adequate treatment. At an intermediate level, H2 blockers and prokinetics may sometimes be used. In general, however, omeprazole is considered to have advantages in relation to H2 blockers both in the short term (symptomatic or acute conditions) and the long term treatment of GERD⁶⁹.
- (44) For more severe grades of GERD, PPIs are generally seen as providing the only adequate treatment⁷⁰. This is in particular the case for the sizeable proportion of GERD patients who suffer from RO or more severe complications such as bleeding,

⁵⁸ See various AZ documents at [6796a], [2580] and [2609]. See also [5089] and [6746].

⁵⁹ See [223].

⁶⁰ See [10143], [10201, 10203, 10206], [6747], [6748a], [6749a] and [7793].

⁶¹ [10203], [2580, 2582], [6750a-6750c].

⁶² [6731].

⁶³ [2582].

⁶⁴ [7793].

⁶⁵ [6731], [6802, 6809].

⁶⁶ [10200].

⁶⁷ [6796e].

⁶⁸ [5078].

⁶⁹ [10183-10185, 10188-10191] and [2608].

⁷⁰ See [6761-6762], [6769], [6771], [6773] and [6799]. See also 6809].

strictures, ulceration and Barrett's oesophagus (see recitals (26)-(27))⁷¹. For instance, one publication observes that “[t]reatment other than standard dose [PPIs] is unlikely to prevent relapse of [RO] or strictures [i.e. one type of complication] ...”⁷². In another publication, PPIs are at the very least considered to be “necessary for severe cases of GERD”⁷³. In the case of erosive RO (a particularly severe form of GERD where long-term treatment is needed), Losec has proved to be effective in preventing relapse with patients who have reacted badly to H2 treatment⁷⁴. Moreover, superior healing rates and faster healing for PPIs compared with H2 blockers (as well as prokinetics, antacids and mucosal strengtheners) have been registered in respect of RO⁷⁵. One AZ publication also refers to the superiority of its product compared to products from other classes (H2 blockers and cisapride) in the long term treatment of RO which is a chronic disease with high rates of recurrence⁷⁶.

- (45) Specifically, according to one opinion in a medical journal concerning cases of severe RO, possibly with complications, a “step down” approach is recommended where the start of the treatment involves a two-month treatment course with PPIs⁷⁷. According to the same article PPIs may also be necessary in some cases of mild GERD (defined as no or mild RO). Here the article recommends a “step up” approach with alginates or antacids as the first step and (if this does not work) H2 blockers as a second step. In case H2 blockers do not adequately relieve the GERD symptoms, recourse should be had to PPIs. Indeed, one AZ publication states that it is known that acid-related GERD symptoms do not indicate the severity of the RO and that mild symptoms may mask severe RO⁷⁸.
- (46) In an advertisement for Losec capsules in Norway in 1995, AZ itself describes omeprazole as virtually the only effective medicinal product in cases of severe RO. AZ refers to an article from 1994 which notes that “[c]onsiderable clinical experience has accumulated on the use of omeprazole in patients with severe reflux oesophagitis, who have usually failed to respond or only partly responded to high-dose and prolonged acid-inhibitory therapy with [H2 blockers]. These studies have shown that omeprazole, 20 mg once daily, is effective in all but a minority of such patients”⁷⁹. In the same advertisement, AZ highlights the superiority of omeprazole over ranitidine in all cases of RO. It cites another article which refers to “[s]everal studies [which have] proved omeprazole to be more efficacious than ranitidine [a H2 blocker] on both healing and symptom relief in patients with moderate and severe reflux oesophagitis (RO)”. The study notes that “in patients with only mild RO (... grade I and II) omeprazole and ranitidine are seldom compared”. The findings of the examination concluded that “also in mild RO omeprazole 20 mg was clearly more efficacious on both symptom-relief and mucosal healing than ranitidine 300 mg”⁸⁰.

(c) Dyspepsia

71 Treatment of Barrett's must involve high doses of PPIs [6737d].
 72 [6764].
 73 [6771].
 74 [5079], [2580] and [2609].
 75 [10186] and [5079].
 76 [10188-10191].
 77 [6737d].
 78 [10179].
 79 [6775-6776].
 80 [6781].

- (47) Although there is in principle a wide range of treatments available to treat dyspepsia, the situation is comparable to GERD. Even though PPIs are sometimes perceived as too potent for milder forms of dyspepsia, at least the most severe forms of acid-related dyspepsia are considered to be only effectively treated with PPIs (see recital (502))⁸¹. One AZ publication (see recital (38)) refers to unsatisfactory results of use of prokinetics, antacids and H2 blockers in dyspepsia treatment (often no better results than placebo treatment) as well as to superior symptom relief and cost-effectiveness in the case of AZ's MUPS tablets (compared to other classes of medicines)⁸².

F. TRENDS WITHIN THE GASTROINTESTINAL ACID-RELATED DISEASE AREA AND THE EMERGENCE OF THE PROTON PUMP INHIBITORS

1. GENERAL MARKET DEVELOPMENTS

- (48) In 1991, AZ notes that sales of medicines in the acid related gastro-intestinal disease "market" have grown by 15%⁸³. Generally speaking, this therapeutic area expands rapidly during the 1990s. By the mid-1990s, at the latest, it is manifestly clear that in absolute terms AZ's omeprazole is the key beneficiary of this growth. Losec's worldwide sales constantly increase from USD 2.8 billion in 1995 to USD 6.3 billion in 2000. Worldwide sales of other PPIs like lansoprazole and pantoprazole also increase from the mid-1990s onwards. In 1998, lansoprazole sales were USD 1.8 billion, pantoprazole sales USD 300 million whilst the latecomer PPI rabeprazole sold for USD 45 million. By comparison, worldwide sales during 1998 of the H2 blocker Zantac reached USD 1.25 billion⁸⁴.
- (49) In a number of internal strategy documents adopted in the course of the period 1991-2000, AZ sets out its understanding of the major ongoing and future trends of the acid-related gastro-intestinal disease "market". Two trends emerge. First, in terms of therapeutic use, Losec sales for GERD go up in both absolute and relative terms and those of PUD go down even in absolute terms. Second, PPI sales increase at the expense of H2 blocker sales which decrease.
- (50) In its Vienna strategy document of 1994, AZ sees GERD and dyspepsia (as opposed to PUD) as growth areas and therefore considers them as strategic targets⁸⁵. AZ underlines the need to emphasise the role of acid in GERD and dyspepsia in order to increase sales of Losec in these two segments⁸⁶. At around this point in time (1993), virtually all Losec use relates equally to PUD and GERD⁸⁷.
- (51) AZ also notes that its sales of Losec have grown at the expense of H2 blockers since 1991 ("*Losec has doubled its penetration across all its use areas largely at the expense of H2 antagonists ...*"⁸⁸). For AZ, "[d]isplacement of the [H2s] remains our

81 [6731].
 82 [10207-10208].
 83 [2580].
 84 [5116].
 85 [2704].
 86 [2705, 2745].
 87 [2716].
 88 [2716].

*primary competitive objective*⁸⁹. It therefore intends to accelerate the move into “*the post H2 era*”⁹⁰.

- (52) In its Losec Post Patent Strategy (“LPPS”) document of April 1997, AZ expects a continued decline in sales of medicines for PUD since PPIs – combined with antibiotics – can eradicate the H pylori bacterium which is the major cause of PUD⁹¹. AZ describes the GERD segment once more as “pivotal” and expects that sales in this segment will grow. An increase in the NSAID-ulcer market is also envisaged. At this point (April 1997) Losec is approved for all major acid related diseases except dyspepsia⁹². GERD-related sales of Losec account for 50%; PUD sales for 20% and dyspepsia sales for 25%⁹³.
- (53) In the LPPS document, AZ reiterates its key competitive strategy to grow its sales further at the expense of H2 blockers (“[H2s] *remain competitive focus for Losec® in each segment.*”)⁹⁴. However, AZ expresses the fear that, following the expiry of the patent protection for Zantac (the main H2 blocker containing ranitidine as the active substance), generic ranitidine sales at heavily discounted prices could impact on patient management and prescribing patterns. Generic ranitidine first entered the market in Denmark (1994) followed by Germany (July 1995) where it was sold (as of October 1995) at 26% of the price of Zantac prevailing immediately before patent expiry⁹⁵. Generic H2 blockers containing other active substances than ranitidine had entered the market long before generic ranitidine.
- (54) As will be shown, AZ’s fear that Losec sales would suffer from sales of generic H2 blockers proved unfounded (see recitals (401), (423) - (424) and (452)).
- (55) In the years after 1997, the two main trends set out above (i.e. the shift from PUD to GERD and dyspepsia on the one hand and the transition from H2 blockers to Losec and other PPIs on the other hand) are confirmed.
- (56) As to the first of these trends, Losec sales for 1999 show a strong increase of GERD sales and a sharp decline of PUD sales in comparison to 1997: GERD (58% as compared to 50% in 1997); dyspepsia (23%); PUD (11% as compared to 20% in 1997) and NSAID (2%)⁹⁶. Over this short period of time the PUD segment nearly halved, mainly as a result of the increasing recourse to eradication treatment of H pylori related PUD.
- (57) As to the second trend, AZ notes on 23 April 1998: “... *characteristic of developments on the anti-ulcer market is the fact that PPIs gain increasing market shares and now predominantly compete with each other, not least with the price as a competitive factor. [...] It should however be remembered that [H2s] still account for a considerable share of the number of prescriptions and that this should be seen as a remaining possibility of expansion. The competition from lansoprazole [a PPI] is*

⁸⁹ [2707]. See also [2712] (“The [H2s] remain primary competitive focus”) and [2718]: “As previously emphasised across all our markets segments displacing [H2s] remains our primary competitive focus”.

⁹⁰ [2713].

⁹¹ [4392, 4398].

⁹² [4393].

⁹³ Ibidem.

⁹⁴ [4394].

⁹⁵ [1390].

⁹⁶ [5116].

*increasing ...*⁹⁷. In an attachment to a document dated 5 February 1999, AZ identifies the competitive threat as coming from the class competitors (i.e. PPIs) and, in particular, from generic omeprazole: *“In most markets class competitors are marketed at lower prices than Losec. Competition and authorities continue to exert pressure on Losec prices. As, and when, generic copies enter the market the pressure on price (and volume) will increase significantly”*⁹⁸. In a strategy document for Sweden dated 25 February 2000 AZ notes that *“[t]he Swedish anti ulcer market is characterised by a predominant use of [PPIs]”*⁹⁹.

2. TRENDS IN PPI AND H2 BLOCKER SALES (1991-2000)

- (58) Table 16 in the Annex displays a clear trend in the relative development of PPIs and H2 blocker sales (in value) during 1991-2000¹⁰⁰. In each of the seven EEA Contracting Parties listed, PPI sales constantly grew, virtually without exception, even during the years where H2 blocker sales grew or peaked in absolute terms.
- (59) Tables 9 to 15 which show PPIs and H2 blockers sales (in value) in absolute terms confirm this trend. To start with, PPI sales have steadily – and sometimes markedly – increased in the countries concerned over the period 1991-2000. In Norway, for which data is only available as of 1992, PPI sales increased by more than four times. In five Member States (Belgium, Denmark, Germany, the Netherlands and Sweden), PPI sales increased by more than five to seven times. In the United Kingdom, the increase in sales of PPIs was even more than 13-fold.
- (60) By contrast, over the period from 1992 (the peak year in terms of H2 blocker sales in the seven Member States with minor exceptions) until 2000 (1999 in Denmark), sales of H2 blockers decreased by down to a quarter of their initial level.
- (61) In each of the seven relevant EEA Contracting Parties sales of H2 blockers significantly decrease (by 8% to 26%) in 1993 compared to 1992, except in the Netherlands where they remain stable until 1995. In Denmark, the sales of H2 blockers continue to decrease constantly until 1999. In most of the relevant countries, H2 blockers sales stabilise after 1993, despite the overall increase of the combined sales of PPIs and H2 blockers. In some cases, the sales of H2 blockers increase again. Such is the case in Belgium, the Netherlands and Norway in 1995, in Germany in 1994 and in Sweden and the United Kingdom in 1995 and 1996. However, except for the Netherlands, these sales levels remain largely below – or at best equal to – the level of 1992. Moreover, these increases remain significantly inferior to the overall growth of PPIs and H2 blockers sales. For example, sales of H2 blockers reach similar levels in Sweden in 1992 and 1996; however, H2 blocker sales represent half of total sales of PPIs and H2 blockers in 1992, and only one quarter in 1996. Sales of H2 blockers decrease irreversibly after 1994 in Germany, after 1995 in Belgium, the Netherlands and Norway and after 1996 in Sweden and the United Kingdom.

⁹⁷ [2750-2751].

⁹⁸ [2412].

⁹⁹ [3899].

¹⁰⁰ The data in the Annex derive from IMS and cover sales to pharmacies of all oral formulations (capsules and tablets) of PPIs and H2 blockers. For Denmark available data for H2 blockers ends in 1999.

- (62) Sales of PPIs equal or exceed those of H2 blockers from 1992 in Sweden, 1994 in Belgium, 1995 in the Netherlands, Denmark, Norway and in the United Kingdom and 1996 in Germany.
- (63) The complainant has submitted IMS-based volume-related information on sales of PPIs and H2 blockers. This information is based on the number of treatments using respectively a representative selection of branded PPIs and a representative selection of H2 blockers during the same reference period 1991-2000 (see tables 17-23 in the Annex).
- (64) The pattern concerning the number of treatments is – as expected – similar to the one relating to PPI and H2 sales in value terms (shown at tables 9-16 in the Annex). The number of PPI treatments has increased dramatically in most Member States over the period, the smallest increase (in Germany) in PPI treatments being nearly five-fold.
- (65) Conversely, in most Member States the number of H2 blocker treatments has fallen between 1991 and 2000, sometimes dramatically (e.g. in Belgium and the Netherlands). In some Member States, the number of treatments remained more or less stable (e.g. in Denmark and Germany).

3. TRENDS IN PPI AND H2 BLOCKER PRICES (1991-2000)

(a) Price trends for PPIs and H2 blockers

- (66) Over the period 1991-2000, prices for PPIs were considerably higher than H2 blocker prices, as appears from tables 1-7 listed in the Annex to this Decision. The price information in those tables has been supplied by the complainant following input from the economic consultant Charles River Associates. The basis for this price information is raw data on sales in terms of value and units of the products concerned obtained from IMS Health, an independent market research organisation whose data are routinely used by pharmaceutical companies for their own market analyses and by the Commission in competition cases¹⁰¹.
- (67) The methodology of the said price information is based on a selection of comparable PPIs and H2 blockers which are representative within their respective class. Accordingly, in relation to H2 blockers (ranitidine, cimetidine, famotidine, nizatidine and roxatidine) the largest selling branded product and the largest selling generic and parallel import product in each respective country are selected as representative of the overall sales of that type of product. In relation to PPIs, there are no sales of generic products (with the exception of Germany in 1999 and 2000, where such products have consequently been included). The PPI prices have been adjusted to take account of the largest selling parallel imported PPI in those countries and years where there were such imports.
- (68) Unit prices (i.e. price per capsule or tablet) for the selected PPI and H2 blocker products in the price information submitted by the complainant have been obtained by dividing their sales value by the number of counting units (i.e. capsules or tablets) sold. The unit price has been multiplied by 28, thus yielding the cost of a four-week

¹⁰¹ See the IMS source data contained in the CD-Rom referred at [10316].

treatment course for peptic ulcer disease (PUD)¹⁰². The data thus cover sales of oral formulations (capsules and tablets). The value and volume data obtained from IMS in this case relate to pharmacy sales; sales to hospitals are not included. The pharmacy and hospital sectors are different in terms of the operation of the distribution chain, the type of patients seen and the nature of the therapy¹⁰³. Incidentally, the IMS sales data capture a very limited amount of “over-the-counter” (OTC) sales¹⁰⁴. OTCs are sold without prescription and are in general not reimbursable. During the relevant period, H2 blockers attained OTC status in a number of the relevant countries¹⁰⁵. Normally, OTC switches involve – at least initially – lower dosage strength formulations.

- (69) The general picture which emerges from the price information in tables 1-7 in the Annex, covering Belgium, Denmark, Germany, the Netherlands, Norway, Sweden and the United Kingdom, is that, on average, prices of a representative sample of PPIs have considerably exceeded those of a representative and comparable sample of H2 blockers during the period 1991-2000, with the exception, to some extent, of Germany for the period 1991-1995, during which years the price gap in any case widened. In the very large majority of cases, the PPI prices were at least 50% higher than the H2 blockers. In many cases the PPI prices exceed the H2 blocker prices by two- or even threefold¹⁰⁶.
- (70) The fact that national authorities in Europe increasingly enacted cost-saving measures during the 1990s helps to explain the general downward trend in prices for both PPIs and H2 blockers as demonstrated by tables 1-7 (in the Annex; see also recitals (113) *et seq.*). Indeed, in 1994 AZ draws attention to the increased use of such cost controls¹⁰⁷ (see also recitals (112)-(142)). A further AZ document of December 1994 looking ahead until 1997 states that “*the influence of doctors is decreasing whilst the choice of pharmaceuticals increases for pharmacists, wholesalers, patients and not least sick funds and authorities ... As a result, the price as a competitive factor has received a more prominent role – partly at the expense of purely medical criteria*”¹⁰⁸.
- (71) In the Netherlands, PPI prices rose between 1991 and 1992 and then fell sharply in the years 1993-1994. PPI prices rose again in 1995. From 1996 the rate at which PPI and H2 blocker prices fell was roughly equal. In Norway PPI and H2 blocker prices have fallen at approximately the same rate with PPI prices being twice as high compared to H2 blockers in 1992-1994 and 1998-2000 and around 50% or more expensive during 1995-1997. In Sweden the PPI and H2 blocker curves are virtually identical: a general fall in prices subject to a minor rise between 1991 and 1992 and 1993 and 1996. In the

¹⁰² The price information is based on the recommendations on treatment courses with PPIs and H2 blockers (e.g. the dosage strengths and modes of administration to be used) in the British National Formulary, which is based on advice from clinical experts [6243 *et seq.*].

¹⁰³ The weighted average of hospital sales of PPIs as a percentage of all PPI sales during 1991-2000 in the relevant countries was 6.3% (Vol 5, Annex 4.17 AZ Reply).

¹⁰⁴ See Vol 5, Annex 4.17 AZ Reply.

¹⁰⁵ See IMS Report, p. 3, AZ Reply Vol 5, Annex 4.17.

¹⁰⁶ Confirmation that Losec and other PPIs are roughly twice as expensive as H2 blockers in Sweden is also illustrated by a table comparing the costs of a four-week treatment of reflux disease [225]. Omeprazole is also the most expensive treatment for eradication of H pylori [6750a-6750b].

¹⁰⁷ [2709-2710]. The document mentions prescribing budgets, reference pricing, generic substitution of branded products, restrictive formularies, growing pressure to delist some categories of pharmaceuticals, parallel trade, increased copayments by patients and general curtailment of prescribers’ freedom of choice, paralleled by a shift to OTC products.

¹⁰⁸ [2584].

United Kingdom the curves showing the rate of the PPI and H2 blocker price falls (without any temporary price increases) are also almost identical.

(b) Price trends for PPIs

- (72) The price information submitted by the complainant also compares prices of a representative set of PPIs: see table 8 in the Annex. Compared to the price gap between PPIs and H2 blockers, the price gap between PPIs has been relatively minor during 1993-2000 (especially if only the prices charged by AZ and the other two main PPI producers Takeda and Byk Gulden are considered). More detailed information on the prices of the respective PPIs is set out in tables 31-37 in the Annex.
- (73) The situation in Germany in 1999 and 2000 merits particular attention considering that Germany is the only country where generic firms have launched generic versions of PPIs during 1993-2000. Following the expiry of the substance patent for AZ's omeprazole in April 1999, a considerable number of generic omeprazole versions receive marketing authorisations from the relevant German authority. By September 1999, eleven generic 20 mg capsule products have been introduced at prices between 26% and 36% lower than the price of AZ's Antra (Losec's brandname in Germany) MUPS 20 mg tablets¹⁰⁹. Until then (from 1993 to 1998) the gap between the most expensive and cheapest (non-generic) PPIs had been at most 14%. In 1999 the most expensive non-generic PPI is 59% more expensive than the generic omeprazole product marketed by the generic firm Hexal.
- (74) In addition, under price pressure from generic firms, prices for non-generic PPIs fall from around USD 45 in 1999 to USD 38 in 2000. Over the same period, the price of Hexal's generic product decreases from 29 to 22 USD. In spite of lowering their prices, the key non-generic PPIs in Germany (omeprazole, pantoprazole and lansoprazole) all sell considerably fewer counting units following the generic market entry¹¹⁰. In 1998 AZ sells 78 million units of omeprazole. Its sales volume then falls in 1999 to 59 million and in 2000 to 45 million. Lansoprazole sales fall from 16 million in 1998 to 10 million in 2000 whereas pantoprazole falls from 24 million to 11 million over the same years. At the same time, Hexal's sales increase from 31 million counting units (i.e. the number of capsules or tablets) in 1999 to 72 million units in 2000.

(c) Correlation study of demand-side substitution between PPIs and H2 blockers

- (75) Together with the IMS data and sales value and units (as well as price data derived therefrom), the complainant also submitted a correlation study ("Correlation study") examining demand side-substitution between PPIs and H2 blockers, i.e. whether consumers had switched from one type of product to another in response to a change in the relative price of the product¹¹¹. More specifically, the study examines the correlation between the relative price of PPIs (i.e. weighted average price of PPIs/weighted average price of H2 blockers) and the relative size of the market for PPIs (sales of PPIs/sales of H2 blockers) in eight markets, six of which are relevant

¹⁰⁹ [3304]. On the total number of generic omeprazole-based products authorised from 1999 to 2002 in Germany, see [7404-7405].

¹¹⁰ [6309].

¹¹¹ See in particular [6227a-6234].

markets in this case (Belgium, Denmark, Germany, the Netherlands, Sweden and the United Kingdom).

- (76) The Correlation study assumes that only the existence of a consistently negative pattern (i.e. a negative correlation coefficient of between 0 and -1) between relative prices and relative sales across all countries would indicate that there is *prima facie* evidence of substitution between PPIs and H2 blockers¹¹². However, of the six relevant countries, the study only finds a negative correlation coefficient in Sweden. According to the study the correlation for Sweden is so small (-0.26) that it is impossible to conclude that changes in prices and volumes were related. For three other of the relevant countries, the correlation coefficient is close to the positive maximum (i.e. +1): Germany (+0.92); Denmark (+0.88) and the United Kingdom (+0.82)¹¹³. For Belgium and the Netherlands the correlation coefficient is also positive (+0.15 and +0.54). For all these countries, the study concludes that, on the sole basis of the correlation coefficients, there is *prima facie* no substitution between PPIs and H2 blockers.

4. AZ'S OMEPRAZOLE AND THE OTHER PPIs

- (77) The present section describes more closely the relationship between the main research based PPI producers and their products, in particular (apart from AZ), Takeda (the manufacturer of lansoprazole based products) and Byk Gulden (the manufacturer of pantoprazole based products).

(a) AZ, Takeda and Byk Gulden in terms of resources and performance

- (78) Based on information in annual reports, it is clear that AZ's resources and performance in a number of respects (such as sales, assets, net earnings, return on equity and research and development expenditure) markedly outclass Takeda's and Byk Gulden's resources and performance over the period most relevant to this decision (1993-2000)¹¹⁴. While AZ's operations and total sales during the relevant period predominantly concern the pharmaceutical sector¹¹⁵, a large share (around one-third) of both Takeda's and Byk Gulden's total sales are unrelated to pharmaceuticals (mainly chemicals in Byk Gulden's case and in Takeda's case chemicals, bulk vitamin and food as well as agro products)¹¹⁶.
- (79) Total sales (including non-pharmaceutical products): AZ's sales have increased more than fivefold during the relevant period from SEK 22.6 billion (USD 2.9 billion) in 1993 to USD 15.8 billion in 2000. In 1993 Losec accounted for about one third of AZ's total sales whereas in 2000 it accounted for almost 40% of total sales. During

¹¹² [6232].

¹¹³ [6233].

¹¹⁴ The figures in this section derive from the annual reports of AZ, Takeda and Byk Gulden, which form part of the Commission's file. The figures appear in the currency mentioned in the annual reports. Where needed, they have also been converted into USD [10030-10034].

¹¹⁵ During the relevant period 1993-2000 AZ sold medical devices accounting for around 1-2% of its total sales [7916, 8057, 8117, 8190, 8286]. As a result of the 1999 merger, 20% of AZ's sales were attributable to non-pharmaceutical products (mainly an agrochemical activity inherited from Zeneca, and sold in 1999-2000) [8286].

¹¹⁶ For Byk Gulden, see [9713]; for Takeda, see [10006, 9954].

1995-2000 Takeda's total sales increased from over Yen 770 billion (USD 8.2 billion) to Yen 923 billion (USD 8.6 billion). During the same period Byk Gulden's total sales increased from just over EUR 1 billion (USD 0.8 billion) to around EUR 1.9 billion (USD 2.1 billion).

- (80) Total assets: AZ's total assets more than doubled from SEK 35.3 billion (USD 4.6 billion) in 1994 to SEK 76.1 billion (USD 9.6 billion) in 1998. In 1999, AZ's total assets again doubled to USD 19.8 billion after which year they fell to USD 18.4 billion in 2000. Takeda's total assets amounted to Yen 1052 billion (USD 10.3 billion) in 1994 and rose to Yen 1467 billion (USD 13.6 billion) in 2000. In 1994, Byk Gulden's total assets were EUR 1.0 billion (USD 0.8 billion) and by 2000 they had increased to EUR 1.8 billion (USD 1.9 billion).
- (81) Earnings after tax: AZ's net earnings after tax increased from SEK 6.8 billion (USD 0.9 billion) in 1994 to SEK 11.8 billion (USD 1.5 billion) in 1998, after which its net earnings after tax fell to USD 1.1 billion in 1999 and then more than doubled to USD 2.5 billion in 2000. Takeda's net income after tax increased from Yen 47.6 billion (USD 0.5 billion) in 1994 to USD 1.1 billion in 2000. During the period 1994-2000 Byk Gulden's earnings after tax rose from EUR 56 million (USD 43.3 million) to EUR 175 million (USD 190 million) in 2000.
- (82) Return on equity: During the period 1994-1998 AZ's return on equity after tax fell from 39.6% to 25.6%. During the period 1996-1998 Takeda's return on equity rose from 8.8% to 10.3%. Byk Gulden's return on equity after taxes was as follows between 1994 and 1998: 14.8% (1994), 12.5% (1995), 11.6% (1996), 12.2% (1997) and 13.4% (1998).
- (83) Financial strength: In its annual report for 1996, AZ reports that its financial position is very strong with liquid assets at year end amounting to SEK 18.1 billion (USD 2.7 billion) corresponding to more than one third of total assets. The report notes that AZ's rapid growth from 1987 onwards (more or less coinciding with the market launch of Losec in 1988) has been achieved without any increase in interest bearing liabilities and that AZ's equity ratio has strengthened gradually over a ten-year period from 46% to 73%. By comparison, Byk Gulden's equity ratio rose from 39% in 1994 to 55% in 2000.
- (84) Research and development expenditure: AZ's R & D spending has risen steadily¹¹⁷: SEK 4.1 billion (USD 0.5 billion) (1994), SEK 5.8 billion (USD 0.8 billion) (1995), SEK 7.0 billion (USD 1.0 billion) (1996), SEK 8.7 billion (USD 1.1 billion) (1997), SEK 10.6 billion (USD 2.8 billion) (1998)¹¹⁸ and USD 2.9 billion (1999). During 2000 AZ's research and development expenditure fell somewhat to USD 2.6 billion. By comparison, Takeda's research and development expenditure (including non-pharmaceutical products) was Yen 62.9 billion (USD 0.6 billion) in 1994 and rose generally until 2000, with peak expenditure in 1998 of Yen 81.2 billion (USD 0.6 billion)¹¹⁹. From somewhat over EUR 100 million (USD 77.3 million) in 1995, Byk Gulden's research and development spending (including on non-pharmaceuticals) rose

¹¹⁷ [8054], [8127], [8202], [8413] and [8447, 8275-8276].

¹¹⁸ AZ annual report for 1999 [8315] notes that this investment constitutes a key business imperative covering patents, trade marks, design registration, copyrights and internet domain name registrations.

¹¹⁹ [9925] and [9959-9960].

to EUR 219 million (USD 237.2 million) during 2000¹²⁰. In its annual report for 1998 AZ observes that as of 1994 its research and development expenditure has risen by 25% per year and that during the same period the number of staff involved in research and development has risen from 3 500 to 6 400¹²¹. By comparison, during 1998 Byk Gulden's entire workforce comprised 7 780 employees¹²² (as against AZ's 58 000 employees in 1999)¹²³.

- (85) Marketing and staff costs: During 1994-2000 AZ's expenditure on marketing and administration rose from SEK 8.7 billion (USD 1.1 billion) in 1994 to USD 6.6 billion in 1999 after which spending fell to USD 5.7 billion in 2000¹²⁴. Byk Gulden's personnel costs were EUR 412 million (USD 346 million) in 1994 after which they fell to EUR 289 million (USD 224 million) in 1995¹²⁵. Thereafter the personnel costs rose to EUR 453 million (USD 492 million) in 2000.
- (86) Moreover, unlike Takeda and Byk Gulden, as from 1994, AZ essentially sold Losec and Losec MUPS through own marketing companies (i.e. not through licensees) in the countries most relevant to this decision (the Benelux countries, Denmark, Germany, Norway, Sweden and the United Kingdom)¹²⁶. The exception is Belgium where AZ has used a licensee (Bio-Therabel). In its annual reports for 1993 and 1998 AZ reports that it changed and renegotiated former licensing arrangements to gain increased influence over marketing operations in several important markets¹²⁷. Takeda, Byk Gulden and Eisai have, however, enlisted licensees in several of the said countries – sometimes in addition to their own marketing companies¹²⁸. Takeda has marketed its lansoprazole products through licensees in Belgium, Denmark, the Netherlands, Norway, Sweden and the United Kingdom¹²⁹. Similarly, Byk Gulden marketed its pantoprazole products through licensees in Belgium, Denmark, Norway, Sweden and the United Kingdom¹³⁰.

(b) Patent litigation involving AZ, Takeda and Byk Gulden

- (87) The chemical formulae of the omeprazole molecule and those of the other PPIs (e.g. the lansoprazole molecule) are similar; specifically, the PPI compounds have similar arrangements of atoms (distinguishing them for example from the H₂ blockers) yielding similar therapeutic effects¹³¹. However, the molecules constituting the active substances in the PPIs are somewhat different in that certain atoms have been replaced by others¹³². Yet in view of the close similarity in chemical formulae, the producers of the latecomer substances lansoprazole, pantoprazole and rabeprazole were very much exposed to patent infringement actions from AZ, as the holder of the patents relating

¹²⁰ [9611, 9718, 9798-9799].

¹²¹ [8211].

¹²² [9720].

¹²³ [8328].

¹²⁴ [8275-8276] and [8485, 8543].

¹²⁵ [9695-9696].

¹²⁶ [7972], [8115-8116], [8188-8189], [8273-8274, 8281].

¹²⁷ [7948, 8281].

¹²⁸ [10050-10064].

¹²⁹ [9182-9185]. See also [3509, 3511, 3516-3517].

¹³⁰ [9186-9190]. See also [3396-3397, 3400-3401].

¹³¹ [244-246, 9193-9195].

¹³² [8810].

to the original active substance within the PPI class and the holder of formulation patents. Such actions were indeed brought by AZ against Takeda (lansoprazole), Byk Gulden (pantoprazole) and Eisai Janssen (rabeprazole) in a large number of countries resulting in overall settlements between AZ and the other PPI manufacturers in 1994 (Takeda) and 1996 (Byk Gulden and Eisai) (see recitals (90), (95) and (95)).

- (88) **[confidential]**¹³³
- (89) AZ indeed brings a number of patent infringement actions against Takeda (including its marketing companies and licensees) in, *inter alia*, France (18 December 1992), Sweden (23 July 1993), the United Kingdom (15 February and 18 May 1994) and Germany (21 March 1994)¹³⁴. AZ invokes infringement of its substance and formulation patents.
- (90) AZ and Takeda reached an overall settlement on **[confidential]**. In the preamble of the settlement¹³⁵, Takeda acknowledged AZ as the pioneer inventor of PPIs from a scientific point of view. **[confidential]**¹³⁶.
- (91) **[confidential]**¹³⁷
- (92) **[confidential]**¹³⁸.
- (93) **[confidential]**¹³⁹.
- (94) AZ brings a number of patent infringement proceedings against Byk Gulden (including its marketing companies and licensees) in *inter alia* Germany (29 March 1995), Sweden (25 September 1995), the United Kingdom (19 and 27 October 1995), Denmark (22 February and 20 March 1996), Norway (3 May 1996) and France (20 May 1996)¹⁴⁰. In all of these actions AZ invokes its substance patent for omeprazole and, in some cases, other rights, such as formulation patents. These infringement proceedings and Byk Gulden's counterclaims result in interim rulings in Denmark and Sweden. In Denmark, AZ's request for an interlocutory injunction is rejected on 30 May 1996¹⁴¹. In Sweden, AZ's request for an interlocutory injunction is granted by the court of first instance on 27 September 1995. The ruling is upheld on appeal later that year¹⁴².
- (95) AZ and Byk Gulden reached an overall settlement agreement on 12 June 1996¹⁴³. **[confidential]**¹⁴⁴

¹³³ **[confidential]**

¹³⁴ [9182-9185].

¹³⁵ A copy of the settlement agreement was produced by AZ in response to a request for information pursuant to Article 11 of Regulation No 17 dated 26 February 2004, after the Oral Hearing. AZ had refused to reply to a similar request by the Commission dated 8 May 2003. See also the joint contemporaneous press release concerning the settlement at [9251].

¹³⁶ **[confidential]**

¹³⁷ **[confidential]**

¹³⁸ **[confidential]**

¹³⁹ **[confidential]**

¹⁴⁰ [9186-9190].

¹⁴¹ [9191].

¹⁴² [9224-9225] and [9227, 9230, 9233-9235].

¹⁴³ [9250].

- (96) AZ's annual report for 1997 observes that AZ and the Japanese pharmaceutical company Eisai agreed in 1996 to terminate a patent dispute concerning the companies' substance patents in respect of omeprazole and rabeprazole¹⁴⁵. The agreement entailed the mutual recognition of the companies' patent rights. The agreement further stipulated that AZ were to receive certain compensation from Eisai based on the latter's sales of rabeprazole. Finally, AZ gained access to certain technologies developed by Eisai, which could be used for future formulations of omeprazole. If these technologies were to be utilised, Eisai would receive certain compensation from AZ.

(c) The competitive environment in certain markets and product development

- (97) In this section reference is made to certain AZ documents which contain information on AZ's competitive strengths and weaknesses (mainly in relation to other PPI producers). These documents – which mainly concern certain national markets relevant to this case – deal *inter alia* with comparisons between AZ's products and other PPIs, as well as general developments as regards the conditions of competition on those markets. Reference is also made to information revealing the three main PPI producers' comparative strengths in terms of product development (R & D pipeline, indications etc.) based on information derived from the said companies' annual reports.
- (98) A document of February 1999 lists – in addition to the key patents surrounding Losec – a number of other intellectual property rights which serve to protect Losec capsules and MUPS¹⁴⁶. First, the document refers to AZ's trade marks for the omeprazole products, such as “LOSEC”, “MUPS”, “PRILOSEC” and “OMEPRAL”, as well as pending applications for “ANTRA” and “MOPRAL” (Losec's brandnames in Germany and France). Second, the document cites AZ's copyright in respect of *inter alia* the Summary of Product Characteristics¹⁴⁷, the FASS¹⁴⁸ listing text and patient leaflet (if any). Third, AZ's design protection is mentioned; for example, there are a number of registered designs protecting the design of the MUPS tablet.
- (99) **[confidential]**¹⁴⁹
- (100) **Germany:** In AZ's annual report for 1994¹⁵⁰, the managing director for AZ's marketing company in Germany observes that comprehensive reforms carried out by the authorities in 1993 to limit healthcare costs led to the stagnation on the German pharmaceutical market but that for “*Astra Germany, however, the trend has been more favourable than for most others. Of the 20 largest pharmaceutical companies, in the market Astra showed the strongest growth. We are managing well against competition for several reasons. This is due to more than just good products and a good reputation. [Often] this is not enough when price [is] the determining factor... We have a highly competent sales force, which is clearly decisive*”. AZ's annual report for 1996 notes that Losec is the largest selling pharmaceutical in the German market and

¹⁴⁴ **[confidential]**

¹⁴⁵ [8062].

¹⁴⁶ [3674].

¹⁴⁷ Such summaries need to be filed as part of an application for a market authorisation.

¹⁴⁸ The publication FASS lists medicinal products in Sweden.

¹⁴⁹ **[confidential]**

¹⁵⁰ [7999].

that it consolidated its position as the leading anti-peptic ulcer drug during 1995. The report further observes that Losec's market share advanced to 36% (from 30%) with sales exceeding those of its closest competitor by more than three-fold¹⁵¹.

(101) **[confidential]**¹⁵²

(102) **[confidential]**¹⁵³

(103) **[confidential]**

(104) **[confidential]**¹⁵⁴

(105) The same document notes that the paramount strategy during the planning period (i.e. 1999-2000¹⁵⁵) is the launch of Losec MUPS and that Losec capsules will be deregistered on 31 December 1998 as part of this strategy¹⁵⁵.

(106) A further post-1998 AZ document¹⁵⁶ concerning Sweden notes that the major strengths of AZ's Losec product are "*The effect, trademark, first product on the market*" whereas "*Perceived as expensive for the society*" is the major weakness. It also contains a price index for 1998 with lansoprazole and pantoprazole priced at respectively 80% and 85% of Losec's price.

(d) R&D pipeline and range of indications

(107) By the end of 1999 AZ had already filed applications for market authorisations for its second-generation branded PPI product Nexium – *in casu* esomeprazole – in Europe and the United States following a development programme involving more than 15 000 patients and covering six indications including short and long term GERD, PUD and H pylori associated ulcers¹⁵⁷. In its 1999 annual report AZ claims that the clinical data shows that Nexium healed more RO patients more quickly than Losec. Nexium was in fact launched during 2000 in several EEA Contracting Parties. Byk Gulden's annual report for the same year (1999) reveals that the estimated launch of the PPI substance expected to succeed pantoprazole is only in 2006¹⁵⁸.

(108) Takeda filed its application for an indication for maintenance treatment of RO early in 1999¹⁵⁹. AZ already received marketing authorisations for this indication in all countries (the Benelux countries, Denmark, Germany, Norway, Sweden and the United Kingdom) relevant to this decision between 1991 and 1997¹⁶⁰. It should also be noted that most of the indications for AZ's Losec capsules (as well as for Losec MUPS) in those countries cover all three or at least two of the available strengths (10,

¹⁵¹ [8058]. It should be reiterated that AZ – e.g. in its annual report – uses a market definition for acid-related gastrointestinal diseases which encompasses both PPIs and H2 blockers.

¹⁵² **[confidential]**

¹⁵³ **[confidential]**

¹⁵⁴ **[confidential]**

¹⁵⁵ [2270].

¹⁵⁶ [2273].

¹⁵⁷ [8295].

¹⁵⁸ [9740].

¹⁵⁹ [9991].

¹⁶⁰ [7407, 7409].

20 and 40 mg)¹⁶¹. By comparison, it was only in the autumn of 1998 that Byk Gulden introduced a second strength (20 mg) medicine containing pantoprazole (in addition to its 40 mg formulation)¹⁶².

(e) Market shares and sales by different operators on the PPI market

- (109) Tables 24-30 in the Annex display the level of sales of oral PPI formulations to pharmacies (in value) in seven EEA Contracting Parties¹⁶³. The top row in each table sets out the size of these sales per year and country. The market shares and total sales of each PPI (omeprazole, lansoprazole, pantoprazole and rabeprazole) are then listed in bold. Finally, the market shares and sales of the individual PPI producers, their licensees, parallel traders and generic producers, as the case may be, are specified, with the exception of minor sellers. Germany is the only country relevant to this Decision in which generic sales took place during the relevant period; indeed, a large number of generic firms launched omeprazole based products after April 1999.
- (110) Throughout the entire period 1991-2000 in the EEA jurisdictions relevant to this decision, AZ has only sold Losec capsules and MUPS tablets through its own marketing companies (see recital (86)). The exception is Belgium where AZ has used a licensee (the Belgian company Bio-Therabel) alongside its own marketing company. **[confidential]**^{164, 165}. As a result, Bio-Therabel's sales have been attributed to AZ.

(f) Prices of comparable PPI products (1991-2000)

- (111) Tables 31-37¹⁶⁶ in the Annex to this Decision show the development in the prices for the respective PPIs. The dosages used (20 mg omeprazole, 30 mg lansoprazole and 40 mg pantoprazole) are comparable formulations based on the dosage recommendation for treatment of general cases of PUD (see recital (68))¹⁶⁷. The tables reveal that AZ's Losec has been – with some exceptions – the most expensive PPI and that Takeda's lansoprazole based products have, generally speaking, been the second most expensive¹⁶⁸.

G. GENERIC PRODUCTS AND THEIR EFFECTS ON NATIONAL HEALTH SYSTEMS AND CONSUMERS

- (112) The abuses in this case concern market access for generic producers as well as market access for parallel traded products on a number of EEA markets.

¹⁶¹ [7406-7419].

¹⁶² [9739].

¹⁶³ [10050-10102, 10115-10118, 10122-10131]. The source of the data is IMS Health.

¹⁶⁴ **[confidential]**

¹⁶⁵ **[confidential]**

¹⁶⁶ **[confidential]**

¹⁶⁷ [6243]. See also (Vol 5, Annex 4.17 AZ Reply).

¹⁶⁸ In a strategy document of 27 January 1999, AZ observes that “[i]n most markets class competitors are marketed at lower prices than Losec” [2412]. National AZ strategy documents for Denmark, the Netherlands and Sweden also reveal that AZ's products are more expensive than the other PPIs in those countries [3698, 2264-2265, 2268-2269, 2273].

- (113) The Community institutions regard access to generic medicines as one of the objectives of Community pharmaceutical legislation and policy¹⁶⁹. Moreover, within their powers, many EEA Contracting Parties have since the beginning of the nineties introduced and are increasingly introducing progeneric mechanisms which oblige or encourage physicians, pharmacists and consumers to respectively prescribe, dispense and purchase cheaper generic products¹⁷⁰.
- (114) These progeneric measures must be viewed in the wider context of a range of cost-containing measures adopted, in particular since the early 1990s, by the public authorities in the Member States. The measures aim to contain rising public expenditure in the form of reimbursement of medicines, the rate of increase of which has exceeded that on health care in general. The cost-containment arrangements include positive and negative lists restricting public reimbursement of pharmaceuticals, prescribing budgets, health economic tests, controls of the wholesalers' and pharmacies' margins and measures intended to influence or fix the prices of medicines to name but a few.
- (115) An AZ document dated 11-13 April 1994 illustrates the cost-containment trend during the 1990s: *“Health care providers continue to become more cost-conscious, with prescribing budgets, reference pricing, and generic substitution of branded products all increasingly common. The result is zero pricing flexibility for pharmaceuticals”*¹⁷¹. Although AZ's reference to “zero pricing flexibility” is an exaggeration (see recitals (116) et seq. below), it reveals the highly regulated and special nature of the pharmaceutical sector. It needs to be emphasised that on the demand side, the key decisions concerning prescription medicines are primarily made by prescribing doctors – subject to the authorities' cost containment measures and in particular the increasing trend towards generic substitution by pharmacies – and not by patients. Moreover, another special feature of the pharmaceutical sector is that it is neither the decision-maker (the doctor and – in certain cases – the pharmacy) nor the end consumer (the patient) but a third party (normally the national health systems) who bears the bulk of the cost for medicines prescribed. Finally, studies of actual prescription behaviour reveal a strong component of inertia and habit on the part of the prescribers¹⁷².

1. SAVINGS FOR NATIONAL HEALTH SYSTEMS RESULTING FROM CHEAPER GENERIC PRODUCTS

- (116) The rationale behind the pro-generic cost-containment measures is the fact that prices for generic products are often much lower (typically by 20-50%) compared to the corresponding original medicines and that such lower-priced generic products entail savings for the national health systems (and, thereby, the taxpayers and contributors to

¹⁶⁹ See inter alia the Commission's Communication of 25 November 1998 (COM (98) 588 final) (in particular p. 15) [7106] and the Council Conclusions of 29 June 2000 (OJ C 218, 31.7.2000, p. 10).

¹⁷⁰ Most of the information contained in this section is based on a number of studies and reports dealing with national systems for pricing, reimbursement and related issues. See study by the Austrian Health Institute, December 2001 [7200]; OECD study, April 2000 [7329]; study by the Social Insurance Institution (KELA) in Finland, 2002 [9104 et seq]; LSE study, 2001 [6884 et seq]; Swedish Government Report, 2000 [6847-6848]; report by National Economic Research Associates, December 1998 [7037] and Finnish Government Bill 165/2002 [7449-7456].

¹⁷¹ [2709].

¹⁷² [7303, 7318].

insurance schemes)¹⁷³, which – through the reimbursement systems – bear the bulk of the cost for medicines. The extent and distribution of these savings resulting from generics depend to a large extent on the Member States’ – sometimes widely – different national rules as regards pricing, reimbursement, incentives for doctors to prescribe generically as well as substitution at the pharmacy level. These differences are also reflected in the widely differing shares held by generic products on the Member States’ overall pharmaceutical market.

- (117) More precisely, the public measures aimed at influencing or even fixing manufacturers’ *prices* are a key determinant of the price effects and savings produced by cheaper generic products. These price-related public measures usually only apply to reimbursable medicines. The reason the authorities are able to influence actual prices (in particular for prescription medicines) even in countries where manufacturers have in principle been free to set their own prices during the bulk of the period relevant to AZ’s behaviour and its effects in this case (e.g. Denmark, Germany, the Netherlands (until 1996), Sweden and the United Kingdom) is related to reimbursement. The public authorities’ pricing decisions are often a condition for reimbursement. National authorities will sometimes only reimburse the medicine up to the price fixed by the authorities. Moreover, in most EEA Contracting Parties price approval does not automatically entail entitlement to reimbursement which requires a separate decision¹⁷⁴.
- (118) More specifically, for publicly reimbursed medicines, authorities influence prices directly and indirectly according to two main methods. Several countries combine both methods. First, the authorities negotiate a reimbursable price with the manufacturers or unilaterally set the reimbursable price based on *inter alia* information provided by the manufacturers. Second, the reimbursable price is fixed according to a so-called reference price system. Recourse to a reference price system normally depends on whether generic products have entered the market (see recital (129) below).
- (119) Under reference price systems products are classified into clusters based on similar therapeutic effects. The health system sets a “reference price” for each cluster based on a relatively low priced product within the cluster. The reference price becomes the maximum reimbursement for all products within the reference category. Manufacturers may be allowed to charge a price above the reference price. However, in that case the patient must pay the excess amount. The system may be accompanied by a system of substitution, which allows or obliges the pharmacy to replace the product prescribed by the doctor (see recital (131) below).
- (120) In EEA Contracting Parties where no reference price system exists, the authorities set the reimbursable price by taking into account a variety of factors such as therapeutic value added, cost-effectiveness, prices for the same or similar products on the domestic or foreign markets (cross-country comparisons) and the R & D costs borne by the manufacturers¹⁷⁵.

¹⁷³ The term “national health systems” is used below in the sense of covering the two main forms of health care systems within the Community: national health service systems (funded by taxpayers) as well as public and private social insurance systems (funded by contributors). See [7211].

¹⁷⁴ See KELA report, p. 5 [9106].

¹⁷⁵ Countries applying cross-country comparisons include Austria, Belgium, Denmark, Finland, France, Greece, Italy, Luxembourg, the Netherlands, Norway Spain and Sweden. See OECD Study, p. 77

- (121) In Belgium¹⁷⁶, the relevant authorities set a maximum approved price for all medicines entering the market until 2001 following assessment of the therapeutic value of the product by comparing it to existing products. Other factors taken into account included cross-country comparisons. In principle, a medicine was only reimbursed if its price did not exceed that of generic alternatives or therapeutically equivalent products already on the market. However, a therapeutically superior product could obtain a higher price. A generic product was reimbursed if its price was at least 16% lower than that of the original product. In June 2001, a reference price system was introduced in Belgium with the aim of increasing the use of generics (which at the time only accounted for 1-2% of total pharmaceutical sales). When introduced, the reference price was set at around 16% below the price of the original product.
- (122) In Denmark¹⁷⁷, a reference price system was introduced in 1993. The reference price was based on the average price of the two cheapest products within the group. In 2001, the reference price system was replaced by a system based on a “reimbursement price”. The reimbursement price must not exceed the average price in eleven specified Member States and the three EEA Contracting Parties.
- (123) In Germany¹⁷⁸, a reference price system has been in place since 1989. In defining the reference price, the relevant authorities have taken into account differences in price between the products within the reference group, health economic considerations, savings targets and the manufacturers’ interest. The aim has been to set a reference price allowing for price competition between products priced below the reference price.
- (124) In the Netherlands¹⁷⁹, a reference price system was established in 1991. The clusters were defined based on mode of action, therapeutic indication, method of administration and adverse effects of the medicines. In 1996, a maximum wholesale price was introduced for all reimbursable medicines based on the average price of comparable products in four specified Member States. The products from these countries were considered comparable if they had the same active substance, strength and dosage form. If a product did not fall into a cluster, the reimbursement price was assessed based on therapeutic value, efficacy, adverse effects and mode of administration.
- (125) In Norway¹⁸⁰, a reference price system was set up in 1993. The reference price used was the lowest price within a group. Since 2000 the Norwegian authorities set a price for all pharmaceutical products, whether reimbursable or not. The reference price system was abandoned in 2001, after which the reimbursable price was defined as the average of the three lowest prices of a basket of prices within the EEA.
- (126) In Sweden¹⁸¹, the price fixed by the relevant authority following negotiations with manufacturers and according to certain criteria (such as therapeutic and health

[7364]; KELA report [9111, 9113, 9116, 9120, 9134, 3138, 9140, 9142, 9151]; Austrian Health Institute Study [7252-7255, 7258, 7260-7263]; Finnish Government Bill 165/2002 [7448-7451].

¹⁷⁶

See KELA report [9113-9116].

¹⁷⁷

See KELA report [9116-9120].

¹⁷⁸

See KELA report [9126-9129]. See also LSE study [6956-6960].

¹⁷⁹

See KELA report [9140-9142]. See also LSE study [6988-6990].

¹⁸⁰

See KELA report [9142-9145].

¹⁸¹

See KELA report [9151-9154].

economic value, R & D costs and prices for corresponding domestic and foreign products) has been a precondition for reimbursement at least during the period 1993-2000. If there were generic products on the market, Sweden applied a reference price system during the period 1993-2002. The reference price was 10% above the cheapest generic alternative.

- (127) In the United Kingdom¹⁸², no overall system of fixed or reference prices has been used during the period relevant to this case. Pricing for non-generic products is in principle free in the United Kingdom. On the other hand, the authorities control reimbursement costs through profit frameworks agreed with the manufacturers. The authorities set prices for generic products which are reimbursable.
- (128) It appears from the foregoing that the bargaining position of pharmaceutical companies vis-à-vis the authorities will, in general, vary depending on the value added and cost-effectiveness of their products in relation to other products. Firms offering breakthrough products with demonstrable advantages over existing medicines are thus, generally speaking, able to extract higher prices from buying organisations whose buyer power is more limited in such situations. For these reasons, significant price differences between different categories of products used within the same therapeutic area give a strong indication as to relative strength in bargaining power vis-à-vis the buying organisations. In this context, firms offering a new breakthrough product such as Losec will, in relation to buyers, normally rely on medical evidence attesting to therapeutic advantages.
- (129) As mentioned several of the relevant Member States in this case (Denmark, Germany (since 1995), the Netherlands (until 1996), Sweden and the United Kingdom) in principle allow manufacturers to set the prices even for their reimbursable products; however, for commercial reasons manufacturers rarely price their products above the reimbursement level fixed by the authorities (whether through a fixed or reference price system), as the difference is covered by the patient (see recitals (133) *et seq* below on patients' so-called co-payments). Under reference price systems a manufacturer of an original medicine that does not align its price downwards towards a reference price set following generic entry will often face (sometimes dramatic) falls in market shares¹⁸³. Thus even in countries where pricing by the manufacturers is theoretically free, the demand becomes more elastic above the reimbursement level since the patient is required to pay the amount exceeding the reimbursement level.
- (130) Apart from rules on pricing and reimbursement, the authorities in the EEA have also attempted to encourage doctors to prescribe generic products rather than the original versions. Such attempts have tended not to involve formally binding rules. Instead campaigns, maximum budgets and guidelines have been applied¹⁸⁴. In the United

¹⁸² See KELA report [9154-9157].

¹⁸³ AZ strategy documents regarding Sweden and Denmark illustrate the pressure on original manufacturers to reduce prices which results from those countries' reference price systems together with generic entry [3667-3668, 3687-3688]. In Belgium, according to information from June 2002, the prices of 52 original medicines were lowered by their manufacturers due to competition and changed rules (as from June 2001) encouraging generic prescribing [6883].

¹⁸⁴ In Germany individual and regional budgets have, since 1993, been set for doctors under systems involving warnings, monitoring and liability for exceeding budgets. In reality, by 2001 no case of repayment had been reported. See KELA report [9127-9128]. In the Netherlands doctors have also been encouraged to prescribe generically. See LSE study [6992-6993]. In Belgium the authorities' measures

Kingdom, at least, such measures appear to have borne fruit with time¹⁸⁵. Since 1999 Norwegian doctors have been obliged to prescribe the lowest price generic product¹⁸⁶.

- (131) Substitution at the pharmacy level constitutes a more significant factor in encouraging generic use. Generic substitution allows or obliges pharmacies to dispense a cheaper product (often a generic product or a parallel imported product) containing the same active substance as the medicine prescribed by the doctor. Therapeutic as opposed to generic substitution allows or requires pharmacies to dispense a cheaper medicine the active substance of which may not be identical to that prescribed. According to a report dating from the end of 1998 therapeutic substitution did not occur in the Community. According to another report describing the situation in the EEA in 2001 (including major changes during the 1990s), therapeutic substitution is possible for certain products in Germany and the Netherlands.
- (132) Generally speaking, most of the countries described above have during the period relevant to this case increasingly tightened their rules and recommendations on generic substitution from optional rules (allowing pharmacies to substitute subject to the doctor's approval) to mandatory rules (obliging pharmacies to substitute unless the doctor opposes it)¹⁸⁷. In particular the Nordic countries have adopted mandatory generic substitution systems (which also cover parallel imported products: see recital (141) below).

2. SAVINGS FOR CONSUMERS RESULTING FROM CHEAPER GENERIC PRODUCTS

- (133) The other final payer of pharmaceutical products – apart from the authorities – is the consumer (i.e. patient) contributing via co-payment (and sometimes full payment) mechanisms. Depending on the national systems regarding, in particular, pricing, reimbursement and co-payment by consumers, the financial burden on the health systems and the consumers is shared in different proportions¹⁸⁸. During the 1990s, patient co-payments have increased as part of the authorities' general cost containment measures¹⁸⁹. As demonstrated, savings made by national health systems also indirectly benefit income-earning consumers contributing to the healthcare systems through taxes or contributions.

¹⁸⁵ in the form of information campaigns and budgetary restraints only began to change the doctors' traditionally antigeneric attitudes as of at least 2001. See LSE study [6925-6926].

¹⁸⁶ In 1985 around 35% of all prescriptions bore a generic name. By 1998 and 2000 this figure had risen to respectively 63% and 71%. See KELA report [9155-9156]. See also LSE study [7022].

¹⁸⁷ See KELA report [9143].

¹⁸⁷ In Denmark generic substitution became possible in 1991 and mandatory in 1997. See KELA report [9116-9120]. In Norway and Sweden this process took place some years later See KELA report [9143, 9152]. By 2001 in Belgium generic substitution by pharmacies was, however, only allowed exceptionally. See LSE study [6927-28]. According to the same study (describing the situation in 2001) Dutch and German pharmacies were offered financial incentives to substitute generic products [6966-6967, 6993]. According to the KELA report (describing the situation in 2001) pharmacies in the United Kingdom are provided with incentives to dispense the cheapest alternative product available [9155].

¹⁸⁸ For example, the share of copayments of the overall cost for reimbursed pharmaceuticals ranges between 18-40% in the United Kingdom, Sweden, Denmark, Finland and Norway. Swedish Government Report SOU 2000:86 [6838-6859]. See also the NERA report (in particular pp. 5-7, 19-20, 27, 80-81, 86-87).

¹⁸⁹ Austrian Health Institute Study [7235]. In Finland the share of copayment of the cost of pharmaceuticals is particularly high (over 50%). Ibidem [7254-7255].

- (134) The EEA Contracting Parties all apply at least one co-payment mechanism.
- (135) First, countries such as Germany, the Netherlands and the United Kingdom apply a *fixed fee* (per item, prescription or according to pack size) system. As the consumer is charged the same fee irrespective of price, generic entry does not entail direct savings for consumers. However, under the German system the consumer still benefits if the price of a generic product is less than the fixed fee.
- (136) Second, in countries such as Belgium, Denmark, Norway and Sweden consumers contribute a *fixed percentage* of the cost of the medicine. Often the fixed percentage varies depending on the type of illness or medicine with lower co-payment rates for more severe conditions. Under this fixed percentage-based system, it is clear that the cheaper the product, the more the consumer saves. Under such percentage based systems generic entry will thus entail savings for consumers.
- (137) Third, some countries apply *high cost protection systems* whereby a limit is set on the consumers' co-payments over e.g. a period of time or per prescription. Sweden and Denmark apply graduated forms of high cost protection systems whereby the share of co-payment borne by the consumer decreases as the total cost of medicines increases and reaches certain predefined spending thresholds over a 12-month period. Under this system, consumers whose annual consumption does not entitle them to full reimbursement benefit from the existence of cheaper generic products¹⁹⁰.
- (138) Fourth, the *amount by which the price of the medicine exceeds the reimbursement price* is borne by the consumers in addition to other forms of co-payment in certain countries (such as Belgium, Germany, the Netherlands and Sweden). Under this system generic entry will normally mean savings for consumers.

H. PARALLEL IMPORTED PRODUCTS AND THEIR EFFECTS ON NATIONAL HEALTH SYSTEMS AND CONSUMERS

- (139) The second abuse in this case also concerns the prevention of access to certain EEA markets for parallel imported products. Parallel imported medicinal products are typically cheaper than the equivalent original branded reference products¹⁹¹. Parallel imported products play their greatest role before patent/SPC expiry which often results in market entry of even cheaper generic products.
- (140) In its Decision of 8 May 2001 concerning Glaxo Wellcome the Commission outlined certain benefits of parallel trade by noting inter alia that "*First, parallel-traded products offer a second source of supply. This is especially important from a consumer's point of view when branded and patented products are involved. Patented products enjoy protection for at least 20 years. In cases where only a few alternatives are available, parallel trade will offer the only source of competition. Second [...] patients benefit directly from parallel trade [...] when they have to pay the full amount of the purchase price themselves or when reimbursement is only partial and is expressed as a percentage of the actual purchase price (in contrast with a flat fee). [...] Ultimately, all patients pay for the national health system. Public health systems*

¹⁹⁰ Regarding the consumers' savings under this system see [7073-7074].

¹⁹¹ According to information from 2000, prices for parallel imported products in Sweden were generally around 10-15% lower than those of the original versions [6859].

are financed via contributions or by general taxes. Any savings made by these schemes via the purchase of cheaper parallel traded drugs indirectly benefit the schemes' members"¹⁹².

- (141) In view mainly of the said cost savings for national health systems, several EEA Contracting Parties (including Sweden, Germany, Norway, Denmark, the Netherlands and the United Kingdom) apply various mechanisms and incentives to promote parallel trade¹⁹³. For example, in Sweden, Denmark and Norway, substitution at the pharmacy level applies not only to generic products but also to parallel-imported products¹⁹⁴, a fact which has resulted in or is expected to result in savings both for national health systems and consumers¹⁹⁵. In other countries (such as the Netherlands and Norway), pharmacies retain a proportion of the price difference when providing the patient with a cheaper parallel-imported pharmaceutical. In the United Kingdom, the reimbursement paid to a pharmacy is reduced if its sales of parallel-imported pharmaceuticals do not meet a percentage threshold.
- (142) Moreover, as mentioned in respect of generic products, the existence of cheaper therapeutically equivalent products (such as generic or parallel imported products) either on the home market or in other EEA markets constitutes a key factor taken into account for price fixing purposes (recital (120))¹⁹⁶. Cheaper parallel imports combined with market forces also exert further downward pressure on the prices of original medicines, especially in high price countries¹⁹⁷. Therefore, to the extent that the reimbursement level falls as a result of price fixing mechanisms and market forces, national health systems benefit in terms of lower expenditure.

I. THE FIRST ABUSE: AZ'S MISLEADING REPRESENTATIONS AS PART OF ITS SPC STRATEGY

1. INTRODUCTION

- (143) In 1993 and 1994, AZ submitted applications to a number of national patent offices within the EEA in order to obtain so-called supplementary protection certificates (SPCs). It did so on the basis of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products ("SPC Regulation")¹⁹⁸. Such certificates effectively extend the basic patent protection for the active substance in a pharmaceutical product.
- (144) The SPC-related competition issue in this case is whether AZ has made misleading representations to national patent offices so as a) to obtain SPCs for longer periods

¹⁹² Recitals 183-186 of Commission Decision 2001/791/EC in Cases IV/36.957/F3 - Glaxo Wellcome, IV/36.997/F3 - Aseprofar and Fedifar, IV/37.121/F3- Spain Pharma and IV/37.138/F3 - BAI, IV/37.380/F3 - EAEPIC (OJ L 302, 17.11.2001, p. 1). See also Case 104/75 de Peijper [1976] ECR 613, paragraph 25.

¹⁹³ Recitals 34 and 52 of Decision 2001/791/EC.

¹⁹⁴ See in respect of Sweden [6866, 7449], Denmark [7450] and Norway [6875; 7450-7451].

¹⁹⁵ See in respect of Sweden [7449], Denmark [7450], Norway [7450-7451] and Finland [7453-7456].

¹⁹⁶ In Denmark and Sweden parallel imported products are included in the therapeutic group where the reference price is based on the lowest priced product(s).

¹⁹⁷ [7065].

¹⁹⁸ OJ L 182, 2.7.1992, p. 1. Regulation as last amended by the 2003 Act of Accession.

than it would have obtained in the absence of the misleading representations or in some other cases b) to obtain SPCs which the patent offices would not even have granted in the absence of the misleading representations. For a proper understanding of the facts, it is helpful to bear in mind that the effective launch of a medicinal product on the market is normally preceded by a series of different administrative decisions and acts.

- (145) The first step is usually the issuing of the “technical” market authorisation by the competent national medicines or health authority pursuant to Directive 65/65/EEC. In Community pharmaceutical law, “market authorisation” commonly refers to the technical market authorisation. The second step is normally the notification of that authorisation to the company concerned and the third step is its publication in the relevant country’s official journal or gazette and/or another official publication (see Article 12 of Directive 65/65/EEC). Beyond the technical authorisation, actual marketing often require price approval. Here too, one can typically distinguish three steps in the process at the time of the various authorisations relating to Losec – the relevant product in this case - during the years 1987 to 1990 in the Member States concerned. First, the national authority approved the price proposed by the pharmaceutical company. Thereafter, it notified its decision to the company. Finally, the decision was published in the country’s official journal or gazette and/or another official publication. In the context of the first abuse, the Commission will refer to the “technical authorisation” or the “technical market authorisation” when referring to the authorisation pursuant to Directive 65/65/EEC.
- (146) More specifically, an AZ document dating from 1994 illustrates Losec’s authorisation process during 1987-1990 in the then twelve Member States¹⁹⁹. According to that internal document, all twelve Member States issued technical market authorisations for Losec whereas ten Member States officially published those authorisations. Seven Member States transmitted a letter containing the agreement of the price. In nine Member States there was a “official listing/official price publication”. The internal document finally lists dates when Losec was given “effective authorisation” in all twelve Member States.

2. THE SPC REGULATION

- (147) A long time typically elapses between the moment at which a company files its application for a basic patent for the active substance (which is the starting point of the patent protection period of 20 years) and the moment at which national authorities issue the authorisations to place the medicinal product containing that active substance on the market. As a consequence, the period during which the patent holder can recoup its research and development investments is typically much shorter than 20 years. Regulation (EEC) No 1768/92 introduced SPCs to offer supplementary compensation for these investments.
- (148) A generic manufacturer cannot launch a generic version without either obtaining the consent of the patent holder or committing patent infringement before the substance patent, extended as the case may be by an SPC, of the original reference product

¹⁹⁹ The document was submitted by AZ to the United Kingdom patent office on 16 June 1994. See 6.119 AZ Reply and [4313].

expires. The effect of the SPC protection is therefore to delay market entry for generic companies. On the other hand, care has been taken to “*strike a balance between the interests of the researchers and those of generic firms, notably in laying down the duration of the protection given by the certificate and the transitional arrangements*”²⁰⁰.

(a) The duration of an SPC (Article 13)

- (149) The SPC takes effect at the end of the lawful term of the basic patent. It lasts “*for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years*” (Article 13 (1)). However, this period can never be longer than five years (Article 13 (2)).

(b) The relevant conditions for obtaining an SPC (Article 3)

- (150) An SPC can be granted “*if, in the Member State in which the application referred to in Article 7 is submitted ... a) the product is protected by a basic patent in force and b) a valid authorization to place the product on the market ... has been granted in accordance with Directive 65/65/EEC ...*”. Article 3 (d) specifies that “*the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product*” (underlining added).

(c) The required contents of an SPC application (Article 8)

The relevant provisions of Article 8 (required contents of an SPC application)

- (151) The application must cite, *inter alia*, “*the number of the basic patent and the title of the invention*” (Article 8 (1) (a) (iii)), “*the number and the date of the first authorization to place the product on the market as referred to in Article 3 (b) [i.e. the technical authorisation in the country where the SPC application is filed] and, if this authorization is not the first authorization for placing the product on the market in the Community, the number and date of that authorization*” (i.e. in the country where the first authorisation was issued) (Article 8 (1) (a) (iv)) underlining added).
- (152) Pursuant to Article 8 (1) (b) of the SPC Regulation, the application must include a copy of the market authorisation under Directive 65/65/EEC as referred to in Article 3 (b) of the SPC Regulation (i.e. the technical authorisation). If that authorisation is not the first market authorisation in the Community, Article 8 (1) (c) of the SPC Regulation provides that the application must also contain “*information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication*” (underlining added).

²⁰⁰

COM (90) 101 final.

The patent offices' practice and the publicity in connection with SPC applications and grants

- (153) On 3 February 1995, the relevant Commission services met representatives from the national patent offices to discuss certain issues which had arisen during the actual application of the SPC Regulation by national patent offices since the Regulation's entry into force on 2 January 1993. It appears from the record of the meeting that the Commission services accepted the principle of self-control on the part of the SPC applicants (set out in Article 10 (5) of the SPC Regulation) in that it accepted that the "*Member States were able to provide that the certificate was to be granted without verification of compliance with the condition laid down in Article 3 (d), namely that the authorization was the first authorization to place a product on the market in the Community (Article 10(5))*"²⁰¹.
- (154) Elements in the file confirm that the practice of the Member States' patent offices was, broadly speaking, to rely – without verification – on the information submitted by the applicants with regard to the *first* marketing authorisation in the EEA²⁰². In the context of verification by the patent offices of the correctness of data submitted in the SPC applications (e.g. correct legal basis and proper copies of market authorisations) the record of the meeting of 3 February 1995 moreover reveals that difficulties arose over what the Member States made public regarding marketing authorisations and that there was no harmonisation of material published in national official publications (e.g. some Member States simply published a reference to the market authorisation without providing many details)²⁰³. Here it can also be mentioned that Article 9 (2) of the SPC Regulation stipulates that notification of an SPC application must be published by the respective patent offices, while Article 11 (1) provides that the fact that an SPC has been granted must be published by the same patent offices. However, a submission by the Finnish Pharmaceutical Industry Federation to the European Federation of Pharmaceutical Industries' Association dated 20 October 1994 refers to "*apparent differences in how the information on SPC-applications and grants is published by the Patent Offices in different countries*" and gives as an example the Swedish patent office which "*often publishes only the chemical name of a compound*"²⁰⁴. The submission notes that a "*further problem recognised by the Finnish members is the difficulty in obtaining information on the date of the first marketing approval for new drugs*".

(d) Transitional regime (Article 19)

- (155) Since Losec obtained its first market authorisation within the Community after 1 January 1985 but before the SPC Regulation entered into force, the transitional provisions contained in Article 19 of the SPC Regulation are applicable to the SPC applications for omeprazole.

²⁰¹ [175], [183].

²⁰² [1097]. See more specifically with regard to the Norwegian patent office at [1210] and, with regard to the Finnish patent office, at [188] and [1657].

²⁰³ [183].

²⁰⁴ [189].

- (156) Pursuant to Article 19(1), “[a]ny product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorization to place it on the market as a medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate” (underlining added). The Member States to which this main rule applies (i.e. where the first market authorisation in the Community must be post-1 January 1985) will be referred to as “1985 countries”.
- (157) Article 19 (1) contains two derogations from the main rule. The competent authorities in Denmark and Germany can only grant the SPC if the first market authorisation in the Community was post-1 January 1988. Germany and Denmark will be referred to as “1988 countries”. In contrast, the authorities in Belgium and Italy can grant the SPC if the first market authorisation within the Community was issued after 1 January 1982. These two Member States will be referred to as “1982 countries”.
- (158) When the SPC Regulation was later incorporated into the EEA Agreement²⁰⁵, for the purposes of Article 3(b) of the SPC Regulation, national marketing authorisations in any of the EFTA States were equated with marketing authorisations pursuant to Directive 65/65/EEC within the Community. Furthermore, Finland and Norway were added to the list of “1988 countries” whereas Austria became a “1982 country”. For Sweden, the main rule prevailed. This meant that it became a “1985 country”.
- (159) It follows from Article 19 (2) that the time limit for SPC applications under the transitional regime was 2 July 1993. Under the EEA Agreement, for Austria, Finland, Norway and Sweden the time limit was 1 January 1995.

3. AZ’S SPC STRATEGY FOR OMEPRAZOLE

- (160) In June 1993 AZ files a first round of SPC applications for omeprazole capsules under Article 19 of the SPC Regulation in seven Member States: one “1982 country” (Belgium), four “1985 countries” (the Netherlands, Luxembourg, United Kingdom and Ireland) and two “1988 countries” (Germany and Denmark).
- (161) In December 1994, AZ files a second round of SPC applications in three EEA countries (Austria, Finland and Norway). In Sweden, AZ had previously filed an SPC application under a national law.
- (162) For a proper understanding of the detailed description of AZ’s SPC Strategy for omeprazole capsules in points (a) to (e) below, it is appropriate to set out some background information on AZ’s internal organisation at the time and the general context of AZ’s SPC applications under the transitional provisions. In 1992 and 1993 AZ’s patent department is responsible for preparing the instructions to the patent agents which will file the SPC applications for the eight AZ products concerned. To that end, AZ must collect information both relating to patents and market authorisations from the relevant companies within AZ, *inter alia* the so-called product companies which formally owned the relevant patents. For omeprazole, omeprazole sodium and felodipine, the product company was AZ’s fully owned subsidiary Hässle. However, AZ’s patent department also had to collect information relating to market

²⁰⁵ The SPC Regulation was incorporated into the EEA Agreement by EEA Joint Committee Decision No 7/94 (OJ L 160, 28.6.94, p. 138). See also [1213-1217], [1309-1320] and [1334 *et seq.*].

authorisations for those three Hässle products from AZ's local marketing companies in the countries concerned. In this process, a patent liaison team at Hässle acted as the intermediary between AZ's patent department and the local marketing companies. For AZ's other five products concerned by the SPC applications, the relevant product companies were three other companies within the AZ group. Finally, AZ's patent department could only send the instructions to the patent agents after they had been signed by the relevant product companies within AZ, i.e. the companies which formally owned the patents.

(a) AZ's preparation of its SPC applications for omeprazole

The internal preparatory memoranda

- (163) ***Memoranda of 21 December 1992 and 25 January 1993:*** On 21 December 1992²⁰⁶ AZ's patent department sends a memorandum to the product companies (including Hässle). The memorandum includes lists containing data both on the patents and on market authorisations relating to products for which the patent department considers that SPCs "*could be possibly obtained*". The patent department asks the product companies to verify the information provided. On 25 January 1993²⁰⁷, AZ's patent department sends a further memorandum containing updated lists for the products in respect of which SPC applications under the transitional rules are considered "*possible*". The information on "*First EC reg. date*" states "*87*" for omeprazole (including omeprazole sodium). The information on national "*Reg. date*" in respect of omeprazole in Luxembourg gives "*87*" for omeprazole (including omeprazole sodium). For France April 1987 is provided as the national "*Reg. date*" for omeprazole. AZ's patent department asks the product companies concerned to verify the information.
- (164) ***Memoranda of 16 March 1993:*** The first of three memoranda dated 16 March 1993 (all drafted in Swedish and sent by the same AZ patent department expert to Hässle) contains draft instructions to be signed by Hässle and then sent by the patent department to the patent agents filing in the SPC applications for omeprazole. The draft instructions include a box regarding the "*first market registration in an EC country*". In this box "*France... april 1987*" is written. Right above this box is written: "*For DE and DK, the patent department considers that an application is not possible as the first market registration in the EC was before 1988*"²⁰⁸.
- (165) This is confirmed by AZ's patent department in a second memorandum of 16 March 1993 to Hässle which contains draft instructions for the SPC applications for omeprazole sodium (a derivative of omeprazole which is the active substance in the injectable version of Losec)²⁰⁹. The box regarding "*the first market registration in an EC country*" refers to "*Luxembourg ... January 1988*" and right above this box is written: "*SPCs [for omeprazole sodium] in DE and DK may therefore be valuable as no SPC can be obtained for omeprazole capsules in both these countries*".

²⁰⁶ [3269].

²⁰⁷ [3241].

²⁰⁸ [2445].

²⁰⁹ [3238].

- (166) AZ's patent department sends a third memorandum dated 16 March 1993 to Hässle containing advice for *inter alia* the SPC applications for omeprazole sodium. In this memorandum, AZ's patent department repeats that it intends to apply for an SPC regarding omeprazole sodium and it observes: “[a]n advantage is that in all countries such a SPC would extend further than the protection for the basic substance [i.e. omeprazole] and would also include Denmark and Germany”²¹⁰. Regarding another product, felodipine, the memorandum states that “you [i.e. the addressee of the memorandum] have stated that the first registration in the EC is Denmark in December 1987. Please check that the date is really correct, as a first registration not before 1988 would mean that we can apply also in DE and DK. Certain countries apparently think that a registration is complete only when the price negotiations have been concluded. Could this apply to Denmark?”. As regards omeprazole, the memorandum then concludes that SPCs which extend the protection until April 2002 should be obtainable only in Belgium, the United Kingdom, Ireland, Luxembourg and the Netherlands. This memorandum explicitly mentions November 1987 as the market authorisation date in Luxembourg for omeprazole and April 1987 as the market authorisation date in France for omeprazole.
- (167) **Memorandum of 29 March 1993:** Two weeks later, in a memorandum of 29 March 1993 (in Swedish) to Hässle containing draft instructions for the omeprazole applications²¹¹, AZ's patent department advocates for the first time an argument according to which – for Denmark and Germany only – the relevant date under Article 19 is situated after 1 January 1988. In the relevant box, April 1987 in France is still noted as “the first market registration in an EC country” but some words are added: “for the applications in DE and DK, see above”. The commentary above that box explicitly states: “For the applications in DE and DK the patent department will argue before the respective patent offices that the first valid registration in the EC took place only after 1 January 1988”. No specific date is mentioned in this memorandum nor is any explanation given as to the reasoning that would underpin the argument that the decisive date is situated after 1 January 1988 for Germany and Denmark. The memorandum also cites “Okt 1987” as the market authorisation date for Luxembourg.
- (168) **Memorandum of 30 March 1993:** This memorandum (in Swedish) from Hässle to AZ's patent department starts as follows²¹²: “Thanks for your memo dated 930329. There are still certain points which are not clear as regards countries such as Luxembourg, France and Denmark. In the said countries price negotiations must be completed and officially published before a product can even be marketed. That date we consider to be decisive. We will obtain the same information from the other countries, in order to determine dates according to the same criteria in the various countries.” The author then says that she will identify a number of types of dates for the various countries: 1) “the authority's ... approval of the registration application (probably called “marketing approval”)”; 2) “when the communication was received by the company”; 3) “when the communication was officially published (equivalent to official gazette)”; 4) “whether price approval is required”; 5) when this was notified to the company” 6) “When was the price officially published”. This is the first time AZ

²¹⁰ [3231-3232].

²¹¹ [2442]. See also the decision of 6 May 1993 containing handwritten annotations added to the memo of 29 March 1993 [2439].

²¹² [3212-3213].

refers to the last of the said dates – i.e. the official price publication – as being “decisive”.

- (169) The author also gives a first, albeit incomplete, overview of the approval procedures of omeprazole in Luxembourg and France as well as felodipine in Denmark²¹³. A common thread that connects these three approval procedures is that the technical authorisation date was in all cases before 1 January 1988 (15 April 1987 in France and 16 November 1987 in Luxembourg for omeprazole and 29 December 1987 for felodipine in Denmark).
- (170) For Luxembourg, the author of the memorandum quotes a specific date – 16 November 1987 – for the “market registration” and notes further that “*I do not know yet*” the date of official publication of the approved price. She explains that the Luxembourg authorities approved the price on 17 December 1987 and informed AZ about this approval on 31 December 1987 so that the product “*could not be marketed before 88-01-02 at the earliest which was the first working day*”. Hässle had received this information on 22 March 1993 from AZ’s marketing company in Belgium (which was also responsible for AZ’s business in Luxembourg at the time)²¹⁴.
- (171) For France, the author recalls that the market registration took place in April 1987. She goes on noting that “*the price negotiations were completed in the spring of 1989 after which the product could be marketed. The result of the price negotiations was published in ‘Journale Officielle (sic) de la République Française’ 1988-11-22 [the author must have meant 1989]*”²¹⁵.
- (172) **Memorandum of 7 April 1993:** On 7 April 1993, the author of the 30 March 1993 memorandum provides AZ’s patent department with updated information on the basis of new input concerning Luxembourg and France²¹⁶. This further input was transmitted to Hässle by AZ’s Belgian marketing company on 5 April 1993 and by the French marketing company on 6 April 1993.

²¹³ The memorandum notes with regard to felodipine in Denmark: “...market registration took place 87-12-29 (=1) The letter was received by Astra Denmark 88-01-04 (=2). The registration was published 88-01-21 (=3) in *Statstidende* and the price was made public 88-02-29 (= 5+6) in “*Specialitetstaksten*” No pharmacy would sell felodipine without knowledge thereof”. The bracketed figures refer to the six steps quoted at recital (168).

²¹⁴ For the market authorisation (“*autorisation de mise sur le marché*”), AZ’s marketing company in Belgium had in a letter dated 22 March 1993 given the patent department the exact number (“455/87/11/0446”) and legal basis (“*loi du 11 avril 1983 portant réglementation de la mise sur le marché et de la publicité des spécialités pharmaceutiques et des médicaments préfabriqués*”) [3225]. As to the price approval, it had also mentioned the legal basis (“*règlement grand-ducal du 17 août 1983*”) and had provided the letter of 17 December 1987 by which the authorities had notified Astra-Nobel pharma (AZ’s Belgian subsidiary acting on behalf of AZ at the time) of their price approval. A stamp on the letter indicates that the letter was received on 31 December 1987 [1562, 3226]. At that point in time, AZ’s patent department and Hässle according to AZ [6.70 AZ Reply] had not yet received the letter showing that Astra-Nobel Pharma (AZ’s Belgian subsidiary acting for AZ in Luxembourg at the time) had submitted its price proposal on 8 December 1987 and had asked the price approval to become effective as of 8 February 1988 (“*Par la présente, nous vous notifions le prix ex-usine que nous comptons appliquer pour les grossistes grand-ducaux ... Conformément à votre législation, nous appliquerons ce prix à partir du 08 février 1988*”) [573, 1511, 3226].

²¹⁵ [3222].

²¹⁶ [3214].

- (173) In the information regarding Luxembourg, reference is now made to a “*copy of an official paper, dated March 1998* [the author must have meant 1988], *listing the authorized products in Great-Duchy of Luxembourg*”²¹⁷. The cover page of this “paper” contains the title “*Spécialités pharmaceutiques – Liste des spécialités pharmaceutiques admises à la vente dans le Grand-Duché de Luxembourg*” (“*Pharmaceutical specialities – List of pharmaceutical specialities approved for sale in the Grand-Duchy of Luxembourg*”) (hereinafter the “List”)²¹⁸. The cover page of the List also mentions a company called “*CEFIP sàrl Luxembourg*” as editor and contains a reference to the last modification of this List (“*modification au 24.2 comprise*”). A copy of page 246 of the List is attached to the memorandum; both the Losec capsule (omeprazole) and injectable (omeprazole sodium) versions appear on it (together with several other products). A date appears at the top left hand corner of page 246: “*21/03/88*”. The information relating to the listed products does not include their price. Even if only the cover page and p. 246 are provided, it appears that the List itself is a computer printout of several hundreds of pages listing medicinal products considering that p. 246 enumerates 23 products in alphabetical order starting with the letters “Lo”.
- (174) For France, the only new information is that the technical market authorisation from 15 April 1987 was published in the French official journal (JORF) on 9 July 1987. The correct date of publication of the price approval is now also stated: 22 November 1989 in JORF.

AZ’s decision of 6 May 1993

- (175) On 6 May 1993 Hässle adopts – based on the patent department’s proposal – the decision on the instructions for the SPC applications for omeprazole. The signature of the person making the proposal on 5 May 1993 and the signature of Hässle’s President on the following day in fact appear on the draft instructions dated 29 March 1993 from the patent department to Hässle (see recital (167))²¹⁹. However, handwritten annotations (in Swedish) have been added on the decision. It is not clear whether the annotations emanate from the patent department or Hässle.
- (176) The first annotation concerns the box in the final decision of 6 May 1993 entitled “*first market registration in an EC country*”. In this box “*France*” and “*15 April 1987*” are stated²²⁰. This box further states that “*for the applications in DE and DK, see above*”. This in fact refers to the following text in the decision: “*For the applications in DE and DK the patent department will argue before the respective patent offices that the first valid registration in the EC took place only after 1 January 1988*”. However, in the decision a handwritten annotation now instructs that “*Luxembourg March 1988 to be cited as first in EC*”. This annotation is in fact an instruction to replace “*France*” and “*15 April 1987*” by “*Luxembourg*” and “*March 1988*” in “*the first market registration in an EC country*” box. As explained, “*March 1988*” (see recital (173)) appears on the cover page of the List issued by the Luxembourg editor CEFIP.

²¹⁷ [3227].

²¹⁸ [3229].

²¹⁹ [2439]. The decision is signed by one person making the proposal and the managing director, both from the “product company” (i.e. the non-operating Astra subsidiary AB Hässle which owns the relevant omeprazole patents) [2440].

²²⁰ “15” is a handwritten annotation.

- (177) Other handwritten annotations (in Swedish) appear in the section citing the “first market registration” dates and numbers for twelve countries. One annotation reads: “FR: 22 November 1989 to be cited!” and is an instruction to use this date and not the originally proposed “April 1987” as market registration date in France. Another annotation reiterates the instruction to cite March 1988 as the market registration date for Luxembourg and overrules a reference to “Oktober 1987” (which is a mistaken reference to the technical authorisation date mentioned before, i.e. 16 November 1987).
- (178) Finally, the day before signing the final decision regarding the SPC application for omeprazole, the President of Hässle signs the final decision for the SPC application for omeprazole sodium²²¹. This document again contains references to the fact (as in the first draft decision for omeprazole sodium of 16 March 1993) that it may be valuable to obtain SPCs for omeprazole sodium in Denmark and Germany “*as no SPCs can be obtained for omeprazole capsules in these two countries*”. On the cover page, the first marketing authorisation for omeprazole sodium is said to have taken place in Luxembourg in “January 1988” (corrected by hand as being “26 Feb.”)²²².

(b) AZ’s instructions to patent agents

- (179) **Instructions for the first round of SPC applications:** On 7 June 1993 AZ’s patent department sends identical instructions to seven of the patent agents which are to file the SPC applications for omeprazole capsules in the first round²²³. Based on the requirements in Article 8 of the SPC Regulation, these patent agents are instructed to: a) use “March 1988” as the “First authorization in the E.C” and b) use “445/87/11/0446” as the number of that authorisation. This number features on the competent Luxembourg Minister’s technical authorisation dated 16 November 1987. Moreover, AZ instructs its agents to enclose a copy of the patent specification, a copy of the first authorisation in the country where the application is to be lodged, information regarding the “Legal Provision” and a “Notice of authorization from Official Publication in Luxembourg”. The “Legal Provision” enclosed with the instructions is “Law governing the placing on the market and publicity relating to pharmaceutical specialities and premanufactured medicines in *Mémorial A 1983, p. 702 and 938*”²²⁴, which in fact is the basis for the technical authorisation in Luxembourg of 16 November 1987. The “Notice” comprises the front page and page 246 of the Luxembourg List. In other words, the date and the notice in the instructions both relate to a document from March 1988 (the List) whereas the number (“445/87/11/0446”) and the “Legal Provision” relate to the technical authorisation of 16 November 1987.

²²¹ [2452].

²²² AZ was apparently not aware that the authorisation and publication dates for Losec capsules (containing omeprazole) and the injectable version (containing sodium salt) were identical.

²²³ Instructions from Astra AB (patent department) to patent agents in Belgium [7470-7487]; the Netherlands [7488-7496]; the UK [7497-7512]; Denmark [7540bis-7551]; Germany [7568-7640]; Luxembourg (via France) [7641-7647] and Ireland [7648-7662].

²²⁴ Instructions from Astra AB (patent department) to patent agents in Belgium [7486]; the Netherlands [7495]; the United Kingdom [7512]; Denmark [7551]; Germany [7639]; Luxembourg (via France) [7646] and Ireland [7661].

- (180) The final instructions no longer limit the use of “*March 1988*” to Denmark and Germany (as initially envisaged in the decision of 6 May 1993) but extend it to all the other five countries in which the first round of applications were filed (“first round countries”) as well. Minutes of an internal AZ meeting on 15 November 1994 reveal that this was done “*for the sake of consistency*”.
- (181) It furthermore appears from the instructions in respect of the first round of applications that in the data on France, AZ has replaced the official price publication date “22 November 1989” (as stated in the decision of 6 May 1993 on the instructions for applications) in the “*MARKETING AUTHORIZATIONS IN THE E.C.*” section with the slightly later date “*27.11.1989*”. However, in the box stating the number of this authorisation, AZ has stated the numbers which relate to the technical authorisation of 15 April 1987²²⁵.
- (182) Apart from the information on Luxembourg and France, the instructions of 7 June 1993 provide the date and number of the “*MARKETING AUTHORIZATIONS IN THE E.C.*” in respect of Belgium, the Netherlands, the United Kingdom, Denmark, Germany, Ireland and Greece. Both the dates and numbers (unlike the dates given for Luxembourg and France) relate to the technical authorisation²²⁶. For Portugal a date (“August 1988”) which even precedes the technical authorisation is cited. For Spain “N/a” is indicated.
- (183) ***Instructions for the second round of SPC applications:*** On 18 November 1994 AZ instructs its patent agents in Austria, Finland and Norway to file the SPC applications for omeprazole capsules in these three EEA countries²²⁷. As explained above (see recital (158)), marketing authorisations under those countries’ national legislation had become relevant for the purposes of the SPC Regulation. As a result, both AZ’s instructions to the patent agents and the subsequent application forms refer to the first authorisation within the “*EEA*” and not only the “*Community*”²²⁸.
- (184) The instructions in respect of the second round of applications are essentially similar to the ones AZ sent in the context of its first round of SPC applications (see recitals (179)-(182)). However, the second round of instructions contains the date and the number for the first marketing authorisation in the EEA only, instead of listing the dates and the numbers for the first marketing authorisations in ten Member States. Moreover, the more specific date of “*21.03.1988*” is quoted as the first marketing authorisation in Luxembourg. As in its first round instructions, AZ submits “*445/87/11/0446*” (i.e. the number of the technical authorisation of 16 November 1987) as the number of the Luxembourg authorisation. It also encloses the List as the relevant “*notice*” of this authorisation and the “*Law governing the placing on the market and publicity relating to pharmaceutical specialities and premanufactured medicines in Mémorial A 1983, p. 702 and 938*” as the “*Legal Provision*”. As noted, this legal basis in fact relates to the technical authorisation in Luxembourg of 16 November 1987.

²²⁵ [619].

²²⁶ [365, 383-384, 623, 696-697, 765-766, 811-812, 2440-2441, 3241, 3269, 4313].

²²⁷ Instructions from Astra AB (patent department) to patent agents in Norway [7513-7523]; Austria [7524-7540] and Finland [7552-7567].

²²⁸ See [7513], [7524], [7552], [7669-7671], [7710-7711] and [7737-7738].

(c) AZ's first round of SPC applications (June 1993)

- (185) Apart from the agent in Luxembourg, all six other patent agents follow AZ's instructions when filing their applications during the period 12-30 June 1993, although some of them express doubts about the "March 1988" date. Some patent offices accept this date without raising questions. Others reject it. In one case, it means that AZ does not obtain any SPC protection at all. In some cases it leads to the grant of an SPC of shorter duration than hoped for. The following recitals give a detailed account of the SPC applications in the various countries.

The 1982 country (Belgium)

- (186) The Belgian patent agent files the Luxembourg date "March 1988" and the number of the Luxembourg technical authorisation in line with AZ's instructions of 7 June 1993. On 20 July 1993, AZ's patent agent in Belgium requests AZ to supply the "*exact date (not only the month) of the grant of the Luxembourg marketing authorization*"²²⁹. On 26 August 1993, the patent agent informs AZ that, following a request from the patent office, AZ needs to provide the patent agent with "*the exact date of the grant of the Luxembourg market authorization*"²³⁰.
- (187) On 10 September 1993, AZ informs the patent agent that "[a]s regards the exact date of the grant of Luxembourg marketing authorization, we refer to the date of publication in "*Spécialités Pharmaceutiques*", which is the date that in our opinion should be used for the purpose of this application. This date is 21 March 1988". AZ also informs the agent that AZ's Belgian subsidiary will provide the agent with "*the requested documents*"²³¹. On the same day, AZ's Belgian subsidiary provides the patent agent with a "*copy of the Luxembourg registration 16-11-1987*"²³².
- (188) On 29 September 1993, the Belgian patent agents informs AZ that "[w]ith respect to the date of the Luxembourg authorisation, please note that the date is the date mentioned on the authorisation as such, ie November, 1987. This approach has been used by other companies for which we filed SPC application in Luxembourg. Without instruction to the contrary, we will use November 16, 1987 as grant date of the marketing authorisation in Luxembourg". Accordingly, on 30 September 1993 AZ files the Luxembourg technical authorisation date²³³.
- (189) On 4 October 1993, the patent agent informs AZ of the filing mentioning "*November 16, 1987 as being the grant date of the Luxembourg marketing authorization*"²³⁴. The patent office accepts this as the relevant date and accordingly grants an SPC expiring on 16 November 2002²³⁵. On 25 November 1993, AZ is informed by the patent agent of the patent office's decision and that the SPC obtained "*can be maintained in force up to November 16, 2002*"²³⁶.

²²⁹ Vol 7, Annex 6.3.20 AZ Reply.

²³⁰ Vol 7, Annex 6.3.21 AZ Reply.

²³¹ Vol 7, Annex 6.3.22 AZ Reply.

²³² Vol 7, Annex 6.3.24 AZ Reply.

²³³ Vol 7, Annexes 6.3.25 and 26 AZ Reply.

²³⁴ Vol 7, Annex 6.3.27 AZ Reply.

²³⁵ [3063].

²³⁶ Vol 7, Annex 6.3.29 AZ Reply.

- (190) The SPC in Belgium was set aside by the relevant Belgian court on 25 September 2002²³⁷.

The 1985 countries (the Netherlands, Luxembourg, the United Kingdom and Ireland)

- (191) *The Netherlands*: AZ applied for SPCs for both omeprazole and omeprazole sodium, citing “March 1988” supported by the List in both applications.
- (192) On 26 November 1993 the Dutch patent agent informs AZ by two identical letters (concerning respectively omeprazole and omeprazole sodium) that the patent office has doubts whether the List regarding the marketing authorisation in Luxembourg is the publication of the marketing authorisation in the Official Luxembourg journal as required by Article 8 (1)(a)(iv) of the SPC Regulation. The Dutch patent agent also informs AZ that the patent office “*objects against the imprecise date indication of the Luxembourg marketing authorisation (“March 1988”). It seems that this date pertains to the month in which the above “Liste” was published, rather than the actual date of the grant of the marketing authorization*”²³⁸.
- (193) On 16 December 1993, AZ sends two identical letters concerning omeprazole and omeprazole sodium to the patent agent mentioning that “[t]he date 21 March 1988 is stated on the top of the second page of [the List]”, that “[t]he actual grant of the marketing authorisation ... took place on 16 November 1987”, that “[i]n [AZ’s] opinion, the date 21 March 1988 is relevant for the purpose of Article 8 (1) (a) (iv) of the SPC Regulation” but that “both dates can be put forward to the Examiner”²³⁹.
- (194) The patent office relies on the Luxembourg technical authorisation date of 16 November 1987 and therefore grants an SPC for omeprazole expiring on 15 November 2002²⁴⁰.
- (195) The evidence on the file does not support AZ’s claim that when it became aware of its allegedly genuine mistake, in 1996, it took legal advice and was told that nothing could be done to correct the duration of the SPC²⁴¹.
- (196) AZ claims in its Reply to the Statement of Objections that the head of AZ’s patent department sought the advice of internal and external lawyers on 14 October 1996²⁴². In that Reply, AZ does not even claim that the internal and external lawyers advised the head of the patent department “*that nothing could be done to correct the duration*”. Nor does AZ provide any evidence of such advice.
- (197) Admittedly, at a meeting in London on 11 December 1996, AZ’s Dutch patent agent informs *inter alia* the head of AZ’s patent department that there is “[n]o legal possibility to go back to the [Dutch patent office] and make corrections”²⁴³. At the London meeting, AZ decides not to take action vis-à-vis the Dutch patent office (by

²³⁷ 6.196 AZ Reply.

²³⁸ Vol 7, Annexes 6.3.30-31 AZ Reply.

²³⁹ Vol 7, Annexes 6.3.32-33 AZ Reply.

²⁴⁰ [3064].

²⁴¹ AZ reply to letter of facts, p. 60.

²⁴² 6.153 AZ Reply [11258].

²⁴³ See handwritten notes taken at the meeting [4489-4490].

for example informing it about the ongoing legal proceedings in Germany [concerning the validity of AZ's SPC for omeprazole there])²⁴⁴. AZ further decides at the meeting that the Dutch patent agent should provide an "opinion" of the situation in the Netherlands including a risk assessment²⁴⁵. The meeting furthermore decides that *inter alia* the head of AZ's department is to evaluate the need to involve "Schaper" for the Netherlands. It appears that Mr Schaper is a lawyer at the Dutch law firm de Brauw²⁴⁶. Yet, as mentioned in the previous recital, AZ claims in its Reply to the Statement of Objections that it had already by that point in time sought advice from internal and external counsel.

- (198) Moreover, a communication dated 29 January 1997 from AZ's Dutch patent agent to AZ reveals that the patent agent has undergone a change of heart following the London meeting as to whether AZ ought to approach the Dutch patent office²⁴⁷. As the reason for his "feelings of doubt" the patent agent states that "*it is an unsatisfactory situation wherein on the one hand a (possibly) wrong date of first authorization in the EEC does not constitute a nullity ground for granted [SPC] but on the other hand neither patentee nor third parties have certainty about the real "legal" duration of the [SPC]*"²⁴⁸. The patent agent explains that he has raised the problem with the person responsible for SPCs at the Dutch patent office. The patent office official confirms that there was no provision in the Dutch Patents Act for a correction of a SPC that had been granted. But according to the account by AZ's patent agent "*the absence of said proviso does not necessarily mean that a correction is formally impossible. In this respect [the patent office official] agreed with me that a situation wherein a legal uncertainty exists, for which apparently no legal solution is provided, should be corrected*". On the basis of the information obtained by the patent agent from the patent office he suggests "*to formally request the Dutch Patent Office for a "certificate of correction"*".
- (199) In AZ's reply to its patent agent dated 10 February 1997, the author states that she is "startled" to learn that the patent agent had contacted the patent office "*after what we agreed at our meeting in London*"²⁴⁹. The author states that she does "*not agree with [the patent agent] that we should file a request for certificate of correction. I see absolutely no point in us taking action where the outcome must be regarded as unpredictable and in the worst case scenario unwanted*". She furthermore observes that she had discussed the patent agent's proposal with the head of AZ's patent department who "*agrees with me that we should not at this point take any action vis-à-vis the Dutch [patent office]*".
- (200) It also emerges from a fax dated 11 October 1996²⁵⁰ from the head of AZ's patent department in Sweden to an AZ subsidiary in the Netherlands that AZ had acknowledged – back in 1993 – that it might lose six months SPC term in the Netherlands in the event that its agent was instructed to provide the date of the technical authorisation in France (i.e. 15 April 1987): "*This possibility was evaluated as far back as 1993*". The fax further shows that AZ had concluded back in 1993 that

²⁴⁴ See the typewritten minutes of the London meeting [4493]. See also the handwritten notes [4490-4491].

²⁴⁵ [4493].

²⁴⁶ [4477].

²⁴⁷ [4494-95].

²⁴⁸ [4494].

²⁴⁹ [4517].

²⁵⁰ [4474].

the loss of six months SPC protection for omeprazole was the “*only risk*” that AZ had to fear if the patent office were to detect the existence of the French date.

- (201) In 2002, Merck Generics BV (a company affiliated to the complainant), Multipharma and Centrpharm filed applications to the Dutch patent office for a declaration that the SPCs would expire with effect from 15 April 2002²⁵¹. On 29 October 2002, the Dutch patent office found that the correct date of the expiry of the SPC was 15 April 2002.
- (202) **Luxembourg:** AZ’s SPC application for omeprazole is transmitted to the patent office both via a French and a Luxembourg patent agent. AZ has also instructed the French agent to file an SPC application for omeprazole sodium in Luxembourg.
- (203) On 10 June 1993, the French agent warns AZ that “*there are some risks that the Patent Office of Luxembourg considers that the OMEPRAZOLE and its salts [e.g. omeprazole sodium] are the same product*”²⁵². By letter of 11 June 1993, AZ encloses the technical market authorisations for omeprazole and omeprazole sodium in Luxembourg (both dated 16 November 1987) and informs the French agent that “[i]t should be emphasized that even though the enclosed Luxembourg authorizations [for omeprazole and omeprazole sodium] are dated 16 November 1987, it is our opinion that the date of publication in “*Spécialités Pharmaceutiques*” (i.e. 21 March 1988) is the relevant date for the purpose of Article 3(d) of the SPC Regulation. Consequently, you are instructed to refer to this latter date as the date of first authorization within the EC. We are of the opinion that no further argumentation is required at this stage”²⁵³.
- (204) On 17 June 1993, the French patent agent instructs the Luxembourg patent agent to file the applications for omeprazole and omeprazole sodium in Luxembourg by using “*not the date indicated on the market autorisation (16 November 1987 in this case) but the date of publication in the official journal “Spécialités Pharmaceutiques” of Luxembourg, that is to say 21 March 1988*” and that “*although this position is debatable we ask you to comply with these instructions*”²⁵⁴.
- (205) On the same day the French patent agent contacts AZ to enquire whether the dates used in SPC applications for other products already filed on behalf of AZ have to be changed in the light of the instructions for omeprazole capsules. The French patent agent writes: “*... your instructions to refer on the [SPC application] forms to the dates of publication in “Spécialité Pharmaceutique [i.e. the List] of the Authorizations and not to refer to the date which is mentioned on the Authorizations by themselves. We would like to know if these instructions would apply to all the SPC that you have yet ordered to file. We draw in particular your attention on the fact that we have yet filed one of the SPC, the SPC related to FOSCAVIR. As you did not instruct us to indicate as date of the first Authorization in the EC, the date of the official publication, we have indicated the date mentioned on the Marketing Authorization by itself*”²⁵⁵.

²⁵¹ 6.189, 6.191, 6.193 AZ Reply.

²⁵² Vol 7, Annex 6.3.17 AZ Reply.

²⁵³ Vol 7, Annex 6.3.18 AZ Reply.

²⁵⁴ Vol 7, Annex 6.3.19 AZ Reply.

²⁵⁵ [2883-2884].

- (206) AZ replies on 21 June 1993 that its instruction of 7 June 1993 is only applicable in respect of omeprazole and omeprazole sodium²⁵⁶.
- (207) Before that – on 16 June 1993 – the Luxembourg patent agent has already filed an incomplete SPC application²⁵⁷. On the application form “Luxembourg” has been cited as the country of the first Community authorisation (“*the first market authorisation in the Community*”). The number cited is “445/87/11/0446”. To this extent, the agent follows AZ’s instructions. However, the agent does not file the List; it simply notes that a copy of the Luxembourg authorisation (“*copie de l’autorisation luxembourgeoise*”) will be forwarded later. Nor does the agent file “*March 1988*”. There is a handwritten annotation “*16 November 1987*” specifying the date of the Luxembourg authorisation. It is, however, not entirely clear whether this handwritten annotation is made by the Luxembourg patent agent or the patent office. A letter from the French patent agent to AZ dated 2 August 1996 suggests that the Luxembourg patent agent, based on his knowledge from contacts with the Luxembourg authorities in a previous case, may have added the “*16 November 1987*” himself²⁵⁸. A subsequent AZ memorandum dated 9 September 1996 shows that it was indeed the patent office that made the addition²⁵⁹. This memorandum which deals with the authorisation history for omeprazole in a number of countries, describes the Luxembourg procedure which followed the initial submission of the application on 16 June 1993 as follows: “*1. Application 1993-06-16. No date of authorisation in LU indicated (space on application form left blank). LU authorisation stated as first in EU. Copy of LU authorisation document noted as missing, to be submitted later. 2. Letter from agents 1993-06-10 requesting copy of LU authorisation 3. Response 1993-06-11: copy of LU authorisation enclosed, instruction not to use date on authorisation but 1988-03-21. (...) 6. Copy of LU authorisation filed 1993-09-22, question of correct date not commented in accompanying letter from agent. 7. Official confirmation of receipt of application sent to Astra from French agent 1994-01-14, unclear when issued by LU authority. Confirmation is in form of signature on application form, a copy of which is sent to applicant. On this copy, the date “16.11.87” is filled in by hand (by authority, according to [French] agents) as date of LU authorisation. 8. SPC issued 1994-05-04*”. The expiry date of the Luxembourg SPC obtained is 16 November 2002²⁶⁰.
- (208) AZ’s account in the preceding recital shows that on 11 June 1993, at the request of the French patent agent, AZ – in addition to submitting the List in its instructions of 7 June – provides the Luxembourg technical authorisation to the French patent agent together with an instruction not to use the date thereon (16 November 1987) but the date “1988-03-21”. However, it is clear from the above that the Luxembourg patent agent does not fully comply with the instructions as neither the date nor the List are initially filed. The Luxembourg technical authorisation is not filed with the patent office before 22 September 1993. As in the other Benelux countries, AZ thus eventually provides the Luxembourg technical authorisation to its patent agents and the patent office but not with the French technical authorisation of 15 April 1987.

²⁵⁶ [2882]. Also at [3614].

²⁵⁷ [355-356].

²⁵⁸ See [2495] and [3607].

²⁵⁹ [2495].

²⁶⁰ [3064].

- (209) **The United Kingdom:** AZ's SPC application goes in stages. Initially, its patent agent submits "*March 1988*" supported by the List as the relevant date without any further explanation²⁶¹. The patent office however asks for a precise date²⁶². In its response, AZ explains that the relevant technical authorisations "*bear the date 16th November 1987*" and that "*21st March 1988*" may be used instead of "*March 1988*"²⁶³. The patent office replies that the correct date is 16 November 1987²⁶⁴.
- (210) However, AZ decides that it will continue to argue in favour of the "21 March 1988" date not just in order to obtain a longer SPC protection in the United Kingdom (and the other 1982 and 1985 countries) but also in order to preserve its chances to obtain an SPC at all in the 1988 countries (such as Germany and Denmark). In an internal memorandum of 14 February 1994²⁶⁵, the head of AZ's patent department writes: "*We are working hard to receive as long SPC ... as possible for Losec in the different European countries. One argument we are enhancing is that the definition of "Market authorization" is not clear under EC-law or at national levels ... We are at the moment trying for [the date the authorities have decided a price and published the price and the fact that the product is authorised to be reimbursed] as it gives as longest SPC-time and the possibility to at all maintain the SPC in Germany and receive an SPC in Denmark*".
- (211) The head of AZ's patent department requests Hässle to obtain information about effective launch dates for Losec in all countries and adds: "*Specifically inform me if we sold Losec in any EU state prior to having the price negotiations concluded in that country*". On 3 March 1994 Astra Luxembourg replies as follows²⁶⁶. As "*First sales (official launch)*" it cites "*11 March 88 Losec® 20 mg caps. + I.V.*". In respect of "*Price agreement (not published)*" it mentions "*17 Dec 87 Losec® caps + I.V.*". Just beside the information on the price agreement "*1987*" appears as a handwritten annotation. On 17 May 1994, Hässle seeks confirmation from Astra Luxembourg concerning certain data (e.g. the precise date for official publication of the agreed price) but not on the launch date. On 18 May, Astra Luxembourg replies by resending the fax dated 3 March 1994²⁶⁷.
- (212) On 30 May 1994, Hässle again seeks confirmation from Astra Luxembourg that the "*Official publication of price*" was "*21 March 1988*"²⁶⁸. On 8 June 1994, Astra Luxembourg replies that the "[p]rice agreement" was "*17 Dec 1987, not published*"²⁶⁹. Regarding "[l]etter concerning agreed price" the fax states "*not published – 17 Dec. 1987*". The fax finally refers to an "[o]fficial publication of authorization" published in the "*Mémorial*" sometime in "*March 1988*".
- (213) On 16 June 1994, AZ's patent agent lodges a new submission with the patent office²⁷⁰. Attached to the submission is a table covering different steps in the authorisation

²⁶¹ [7716].

²⁶² [397]; see also [2497].

²⁶³ [367].

²⁶⁴ [2467].

²⁶⁵ [2957].

²⁶⁶ [3027]. Spelling mistakes corrected.

²⁶⁷ Vol 8, Annex 6.3.37G AZ Reply [14202].

²⁶⁸ [2946-2947].

²⁶⁹ [3028].

²⁷⁰ [4152].

procedure for omeprazole in various countries²⁷¹. The table lists 15 April 1987 as the technical authorisation for France and 21 March 1988 as “official listing/official price publication” for Luxembourg. The submission itself acknowledges that “*the Luxembourg Minister of Health sent two letters dated 16th November 1987 indicating grant of market authorizations for Losec (capsules and for injection)*” and that “*information that the marketing authorization was approved was published in ‘Mémorial’ on 4th December 1987*”. It then goes on to justify – for the first time – why 21 March 1988 is the relevant date under Article 19 of the SPC Regulation:

“In practice, it is not possible to market a medicinal product until it appears in the Ministry of Health’s list of drugs that have received marketing authorisations. New drugs will not be prescribed by doctors or dispensed by pharmacists until they have received this list. The list published by the Luxembourg Minister of Health, “Spécialité Pharmaceutique”[...] was published on 21st March 1988. This is the date from which marketing could effectively commence in Luxembourg. First sales in Luxembourg took place at the end of March 1988. It is accordingly submitted that 21st March 1988, the date when as a practical matter the medicine could first have been placed on the market in the EEC, is the relevant date [...]”²⁷².

- (214) It follows from this submission: (a) that the patent agent presents the date appearing in the top lefthand corner of page 246 of the List (i.e. the page where Losec appears) as the date at which this List has been published; (b) that he contends that the products cannot be marketed “*as a practical matter*” before the publication of this List and (c) that he asserts that Losec has been marketed for the first time in Luxembourg “*at the end of March 1988*”.
- (215) The patent office does not accept AZ’s new submission and indicates that it regards “*the earliest date of issue of a national marketing authorisation*” as the relevant date²⁷³.
- (216) In a third stage, AZ accepts that the patent office bases its decision on 15 April 1987, i.e. the date on which Mopral (the French brand name for Losec) received technical authorisation in France. It adds that this amendment is without prejudice to its interpretation of Article 19 of the SPC Regulation in the 16 June 1994 letter²⁷⁴. On 30 September 1994, the patent office grants the SPC with reference to the French technical authorisation date. The expiry date of the SPC is 14 April 2002²⁷⁵.
- (217) A few months later, AZ observes that “*in England the scrutiny of SPC applications has been much more rigorous*” than in Germany and that it was “*decided (without prejudice), to amend our application and request that the term run from the French authorization*” because “[t]hereby we have retained the possibility to argue with full force for the SPC in Germany in connection with possible future court proceedings”²⁷⁶.
- (218) **Ireland:** The Irish patent office is not satisfied with the “March 1988” date²⁷⁷. It states, by letter of 10 August 1995²⁷⁸, that there is no date of first Community authorisation

²⁷¹ See 6.119 AZ Reply and [4313].

²⁷² [4154].

²⁷³ [4161].

²⁷⁴ [4161].

²⁷⁵ [3064].

²⁷⁶ [2428], [4154].

²⁷⁷ [7690-7695].

²⁷⁸ [2479, 2498].

on the request form filed by AZ's patent agent and, moreover, that the List does not indicate the first marketing authorisation. On 17 October 1995 AZ's patent agent in the United Kingdom gives the Irish patent agent detailed particulars on the authorisation dates in Luxembourg and France (including the technical authorisation of 15 April 1987)²⁷⁹. By letter of 26 October 1995 the Irish patent agent proposes a less comprehensive reply so as not to “unduly complicate matters”²⁸⁰. Accordingly, in its response of 23 November 1995, AZ's patent agent files a submission explaining the relevant dates as well as adducing arguments in favour of the 21 March 1988 date²⁸¹. It states, *inter alia*, that “*Omeprazole capsules first received technical approval in the EU in France on April 15, 1987. However, other requirements, in particular agreement on price, were not fulfilled until November 22, 1989, at which point authorisation to market in France, was achieved. In Luxembourg, technical approval for omeprazole capsules was given on November 16, 1987. Effective authorisation to place the product on the market in Luxembourg was achieved on March 21, 1988 ...*”. In June 1996, the Irish patent office grants the SPC for omeprazole with reference to the French technical marketing authorisation. The expiry date of the SPC obtained is 15 April 2002 (with the substance patent for omeprazole expiring on 8 August 1999)²⁸².

The 1988 countries (Denmark and Germany)

- (219) **Denmark:** On 30 November 1994, AZ withdraws its SPC application²⁸³ based on the Luxembourg March 1988 date. As a result, the omeprazole substance patent in Denmark expires on 11 April 1999²⁸⁴. At a meeting held in Copenhagen on 15 November 1994, AZ explains that “[i]n Denmark the patent office informally pointed out that they did not consider Luxembourg as the first authorisation. They intended to argue as GB, with which the authority has good and close contacts in SPC matters (see also the Plendil [AZ medicine containing felodipine] file) ...”. AZ further observes that “DK ... came up with a different formal reason to reject the application and thereby avoid a dispute as to the ‘first country’”, that “on reflection, we decided that it was best not to do battle in DK, i.e. to preserve the arguments in Germany” and finally that “following discussions with our Danish representatives, we therefore decided to withdraw the Danish applications and make it look as if it is due to our mistake in citing the patent number”²⁸⁵.
- (220) The record of the meeting also summarises AZ's SPC strategy for omeprazole as implemented until then: “*Decisive for all [omeprazole and omeprazole sodium cases] is the date considered to be the first market approval ... We have chosen to argue that this is first when also the price is approved. Therefore, the first authorisation for omeprazole is Luxembourg in March 1988 and we have, accordingly, also applied in DE and DK for which January 1988 apply as transitional rules. This would not have been possible if we had considered as the decisive point in time the date of the first official approval, which was France April 1987*”. The record goes on: “*For the other*

²⁷⁹ Vol 8, Annex 6.3.60 AZ Reply.

²⁸⁰ Vol 8, Annex 6.3.61 AZ Reply.

²⁸¹ [368-370]; [2479].

²⁸² [3064].

²⁸³ [7665]-[7668].

²⁸⁴ [3063].

²⁸⁵ [2428].

countries where the transitional rules did not pose a problem but where we for the sake of consistency used the Luxembourg approval we are convinced that we, if necessary, in connection with possible SPC disputes will be able to revert to the French date on account of the uncertain state of the interpretation of new legislation at the time of the filing of the applications”.

- (221) **Germany:** AZ’s German patent agent files the application according to AZ’s instructions from 7 June 1993²⁸⁶. Afterwards he queries whether the reference to “*March 1988*” is sufficient²⁸⁷. The application form shows that “21” has been added by hand to the typewritten date “*März 1988*”. On 10 November 1993, the patent office approves AZ’s application based on the date 21 March 1988. The expiry date of the SPC thus obtained is 21 March 2003²⁸⁸.
- (222) On 18 June 1996, a generic manufacturer, ratiopharm, brings proceedings before the Federal Patent Court against AZ. It claims that the omeprazole SPC for Germany should be invalidated on the grounds that the first technical Community authorisation was issued before 1 January 1988, namely on 15 April 1987 in France. It is the first time that AZ has had to defend its SPC Strategy in court proceedings.
- (223) In its first submission of 9 October 1996²⁸⁹, AZ points out that “*all the circumstances which determine the point in time of the introduction of a pharmaceutical to the market must be included in the interpretation of [the SPC Regulation]*” and that “[*t*]hat point in time depends (also) on the pricing provisions – especially so in France and Luxembourg”. It claims that back in 1993 “[the head of AZ’s patent department] ... did not know otherwise when he filed his application also in Germany” and that “[h]e had asked all the national subsidiaries in the Community for the necessary information and obtained legal advice, especially also from France and Luxembourg”. According to AZ, “*he was reassured in believing that March 21, 1988, being the date of publication of the authorization of circulation, including the ministerial price fixing, granted for Luxembourg on November 16, 1987, was the decisive date for the first authorization to put on the market ...*”. Another passage reads: “*It was only by publication of the ministerial price fixing on March 21, 1988 that the whole procedure of approval was terminated, from [the head of AZ’s patent department] point of view, and the product could be marketed as a refundable product (at fixed price) from then on only*”.
- (224) It emerges from contemporaneous internal AZ documents that AZ knew by that time that Losec had been marketed in Luxembourg prior to the alleged publication of the List. A document from 19 August 1996 mentions 1 February 1988 as effective launch date²⁹⁰. In another document from 9 September 1996²⁹¹, AZ’s representative mentions the same date (1 February 1988) as well as 11 March 1988 (with a question mark) as the launch date and observes that “[p]ublication of list by Health Ministry seemingly not awaited [before launch]”. She identifies three problems: “1. *Both grant and publication of grant before 1988-01-01... 2. 1987-11-16 as basis for SPC (despite*

²⁸⁶ [7678-7689].

²⁸⁷ [4538].

²⁸⁸ [3064].

²⁸⁹ [1555-1557]. Also at [358].

²⁹⁰ [2911]. Also at [4619].

²⁹¹ [2495-2496].

efforts to have 1988-03-21 accepted)... 3. Launch of product before publication of list”.

- (225) In its submission to the Federal Patent Court of 4 April 1997²⁹², AZ repeats that “[the head of AZ’s patent department] *assumed that the product could be marketed legally only as of the publication of the ministerial price fixing on March 21, 1988*” and that its “*reasons for stating March 21, 1988 as the time of the first authorization in the Community are understandable even though, in the final analysis, February 8, 1988 is the date which is decisive for the fixing of the price*”²⁹³. Here AZ clearly refers to its letter of 8 December 1987 by which it submitted its price proposal to the Luxembourg authorities and announced its intention to apply that price as of 8 February 1988 in accordance with Luxembourg law. The proposal was confirmed in the Luxembourg authority’s price approval by a letter of 17 December 1987 (see recital (170)).
- (226) AZ’s argument before the Federal Patent Court differs from the arguments its patent agent in the United Kingdom had used in the 16 June 1994 submission to the patent office in the United Kingdom in at least two respects. AZ now claims that publication in the List was a “*legal*” requirement for effective marketing of Losec in Luxembourg, not just a requirement “*as a practical matter*”. It also now assimilates the List to a publication which includes the ministerial price approval. It should be recalled that AZ’s subsidiary in Luxembourg had informed AZ on 3 March and 8 June 1994 that the price approval decision of 17 December 1987 had not been published (see recital (212)). In addition, AZ states categorically that it now thinks that the date 8 February 1988 is “*decisive for the fixing of the price*”.
- (227) On 12 June 1997 the Federal Patent Court revokes AZ’s omeprazole SPC on the ground that the first technical Community marketing authorisation is the French date 15 April 1987²⁹⁴. AZ appeals the decision to the Federal Court of Justice. On 8 May 1998, the head of AZ’s patent department informs the patent offices in the Benelux countries and Finland about this appeal by the same standard letter²⁹⁵: “*Proceedings have been brought against [AZ] for the revocation of the parallel SPC in Germany. [AZ] were unsuccessful in those proceedings at first instance, but the matter is under appeal to the Federal Supreme Court. A number of important issues of the interpretation of regulation 1768/92 arise in those proceedings, and [AZ] is accordingly seeking a reference to the European Court of Justice on those questions. It is anticipated that the decision of the ECJ on any questions referred to it may have a bearing on what the correct date was from which the term of the [Belgian, Dutch and Luxembourg] SPC should have been calculated*”. In the letter to the Belgian, Dutch and Luxembourg patent offices the following formula is then used: “*The purpose of this letter is accordingly to notify the Patent Office of the existence of current litigation in another member state, and that it is [AZ’s] intention to abide by any ruling of the ECJ and notify your office of the effect such ruling has on the term of the [Belgian, Dutch and Luxembourg SPCs respectively]*” whereas the letter to the Finnish patent office reads: “*The decision of the [Court of Justice] is likely to have a direct effect on the situation in Finland, where (should the findings be made against [AZ]) very similar questions of the validity of the [SPCs] would arise*”. The head of the

²⁹² [911]. Also at [560].

²⁹³ [914].

²⁹⁴ [285-300].

²⁹⁵ [574-575];[4529] (English versions at [1517-1518] and [4527-4528]); [576-577] and [1003-1004].

patent department also writes that AZ's view is "*that, for the purposes of [...] [the SPC] regulation, the first marketing authorisation within the Community was effective as of 21 March 1988, when all authorisations necessary to enable the product to be placed on the market in the first member state (Luxembourg) had for the first time been granted*".

- (228) Before the Federal Court of Justice, AZ reiterates its belief in the decisiveness of the date under pricing law for the purposes of Article 19 of the SPC Regulation and states that this is and always has been AZ's belief: "*Therefore, [AZ] was – and still is – convinced that, when the actual marketing of a medicinal product not only is conditional upon the marketing authorisation but also upon an approval under pricing law, “marketing authorisation” under [Article 19 of the SPC Regulation] can only refer to a situation where also the second condition (i.e. approval under pricing law) is fulfilled.*"²⁹⁶. AZ also claims that there was no reason for AZ or its patent agents to enter into deeper discussions or even raise the contentious issue with the patent offices. In respect of the Netherlands AZ however claims that it did explain to its patent agent the above legal provision (Article 19 of the SPC Regulation) based on the decisiveness of the authorisation pursuant to pricing law in Luxembourg.
- (229) On 1 February 2000, the Federal Court of Justice refers a number of issues relating to the interpretation of the SPC Regulation to the Court of Justice of the European Communities²⁹⁷. One of them is whether the expression "*first authorisation to place ... on the market ... in the Community*" before certain dates stated in Article 19 (1) of the SPC Regulation refers to an authorisation within the meaning of Directive 65/65/EEC (i.e. the technical authorisation) or to another authorisation granted later relating in particular to the prices of the medicinal product²⁹⁸.
- (230) A few months before, on 21 October 1999, the head of AZ's new intellectual property department (previously head of AZ's patent department in Sweden) writes to AZ's new London-based CEO²⁹⁹: "*In 1993, I proposed [to AZ's head of R & D and its head of legal affairs] how we should handle the [SPC] strategy for Losec in Europe. I underlined the uncertainties involved but promised to develop an argumentation for our interpretation of the EU directive (the author must mean “Regulation”) that would at least ensure our case being heard at the ECJ in Luxembourg*". He then proposes "*that an Action Team be set up at [AZ's London headquarters] to lead [and] co-ordinate our activities. [Mrs A] from my function and myself would be very pleased to actively participate in the team*". He goes on: "*If successful we would then have all generic products on the German market withdrawn until expiry of the SPC and moreover we would indeed secure all the other EU markets where we have SPCs until 2002-2004*". A subsequent email from a senior director of AZ in Sweden to the new CEO of the new parent company (AstraZeneca Plc) refers to the memo from 21 October 1999 and reads as follows³⁰⁰: "*I am coming back to the issue of managing the future process regarding the interpretation of the SPC transitional rules outlines in [the head of the patent department's] MEMO of October 21 ... As proposed by [the*

²⁹⁶ [4135-4136]. Also at [5420].

²⁹⁷ OJ C 163, 10.6.2000, p. 18.

²⁹⁸ In its judgment of 11 December 2003, the Court ruled that it is the technical market authorisation which is relevant for the purpose of Art. 19 of the SPC regulation. See Case C-127/00 *Hässle AB v ratiopharm GmbH*, [2003] ECR I-14781, in particular paragraph 79.

²⁹⁹ [3770-3771, 4213].

³⁰⁰ [4215, 5180].

head of AZ's patent department] *we need to assemble an action team and such team has to be managed from [AZ's HQ in London]*". The email ends as follows: "[AZ's CEO], *I kindly ask you to nominate the right people suitable to lead as well as to join this team in order for us to quickly start the important work needed to get our SPC back in Germany. This will also have great impact on the SPC status in many other European markets*". Such an action team is indeed quickly set up based on an instruction by the new AZ CEO from 1 November 1999³⁰¹. As regards the subsequent SPC-related activities directed from AZ in London it may be mentioned that handwritten notes by an inhouse counsel regarding mainly the German SPC case refers *inter alia* to the following: "*Luxembourg system unclear: March 1988 launch*"³⁰².

- (231) Despite the revocation of the SPC, AZ sues a number of companies that enter the German market following the expiry of the omeprazole substance patent on 3 April 1999³⁰³. The file contains evidence of the following suits in connection with which AZ has invoked the SPC³⁰⁴: 23 April 1999 against Azupharma and 5 May 1999 against ratiopharm and Merckle as well as actions brought against Stada Pharm on 3 August 1999, Merck Dura GmbH on 4 August 1999 and Hexal, 1 A Pharma, Dolorgiet and Aliud on 11 and 14 February 2000. A considerable number of generic omeprazole versions obtained marketing authorisation in Germany as from 12 April 1999 (see recital (73)).

(d) AZ's second round of SPC applications for omeprazole (December 1994)

- (232) In December 1994, AZ's patent agents start the second round of SPC applications in Austria³⁰⁵ (a 1982 country), Finland³⁰⁶ and Norway³⁰⁷ (both 1988 countries) on the basis of AZ instructions of 18 November 1994 (see recitals (183) and (184)). From the outset, it should be noted that Losec was authorised for marketing in Sweden and actually launched in that country on 5 February 1988³⁰⁸ and on 28 February 1988 respectively³⁰⁹.

The 1982 country (Austria)

³⁰¹ [5180]. In this context reference can be made to a number of other documents showing the involvement of AstraZeneca Plc in the SPC Strategy. See [5381] and [5037].

³⁰² See handwritten notes found in Shaun Grady's office [5019-5036]. The note contains *inter alia* the following elements: "MP 11/1/00 ... German SPC" ... "UK picked up the French authorisation first... weakness ... Do get an SPC for UK but ½ year shorter ... " [5021] ... "Blgm & NL SPC not counted from the French so may be ½ year too long & subsequently shortened" [5022] ... "Luxembourg system unclear : March 88 launch" [5022]. The notes refer to number of persons involved in connection with the German case: "Mike Rance "Chris Major", "Roger Bollon", "MJR", "Jim Attrige", "Steve Brown", "MN", "TMCK" [5023-5024].

³⁰³ [3790] referring to five companies against which proceedings were brought by AZ. Another document (handwritten notes) refers to 12 companies against which proceedings were brought by AZ [5021, 5026]. See also [5184].

³⁰⁴ [5286-5301], [5130-5143] and [5145-5167]. See also [5139-5140, 5163-5164, 5184].

³⁰⁵ [7737-7741]. See also [1008].

³⁰⁶ [7669-7677].

³⁰⁷ [7710-7712].

³⁰⁸ [4359].

³⁰⁹ [3322].

- (233) The Austrian patent agent initially questions AZ's instructions, in particular the "21.03.1988" date, and requests additional information to be able to explain "*why the date on the marketing authorization is not the relevant date of the first authorization to place the product on the market in the community since we would have to explain this inconsistency to the Austrian patent office*"³¹⁰. However, the patent agent eventually submits "21. März 1988"³¹¹. The Austrian patent office later grants the SPC on the basis of that date and expiring on 24 August 2005.

The 1988 countries (Norway and Finland)

- (234) **Norway:** On 21 December 1994, AZ's patent agent files an SPC application for omeprazole in line with AZ's instructions. On 14 April 1997, the Norwegian patent office grants the SPC for omeprazole based on the "21.03.1988" date, therefore expiring on 21 March 2003³¹². On 2 October 1998, the complainant informs AZ that it has applied for market authorisation for an omeprazole-based product³¹³. On 17 December 1998 the complainant challenges the patent office's decision before the Oslo City Court, claiming that the first technical authorisation for omeprazole capsules has taken place in France on 15 April 1987, i.e. before 1 January 1988³¹⁴. The complainant wins its action before the Oslo City Court, after which AZ brings the case before the appeals court which stays the proceedings pending the outcome of the case before the Court of Justice concerning AZ's SPC for omeprazole in Germany³¹⁵.

- (235) In its reply of 12 February 1999³¹⁶, AZ again justifies its use of the Luxembourg date of 21 March 1988 and the List on the ground that Losec could not be marketed before that date:

"The patent division received information through subsidiaries of the Astra Group in the EU member states, and found that the first member country to complete all necessary permits for bringing the omeprazol product to market was in fact Luxembourg, and that this occurred on 21 March 1988, when permission (which at the time also comprised the necessary price approval) was published. Before that date, the omeprazol product could not be brought to market anywhere in the EU, nor in any country where the EEA version of the Council Directive had been implemented ... It is however the subsequent publication of 21 March 1988 in the Luxembourg Health Department's list of drugs that have been permitted for sale, and which thus had obtained approval of their price, that was the last necessary condition for Losec to be brought to market in Luxembourg".

- (236) As to what AZ knew about the authorisation procedure for Losec in Luxembourg at the moment of the submission of 12 February 1999, reference is made to the faxes from AZ's Luxembourg subsidiary from 1994 (see recitals (211)-(212)) as well as the two internal AZ documents from 19 August and 9 September 1996 (see recital (224)). Moreover, reference is made to a list dated 23 February 1998 referring to the approval and launch dates of the various omeprazole-based products, in which the "*Launch*

³¹⁰ [4521]. See the exchange of notes between the Austrian patent agent and Astra AB at [4519-4522].

³¹¹ [7737].

³¹² [3064].

³¹³ [6538].

³¹⁴ [310]. Also at [1464]. A few days earlier, AB Hässle and Astra Norge AS bring proceedings against ScandPharm claiming infringement of AB Hässle's SPC [6511].

³¹⁵ Scrip No 2693 7 November 2001, p. 3.

³¹⁶ [1477-1488].

Date” for “*Omeprazole capsules 20 mg*” in Luxembourg is cited to be “1988-02-01” and the “*Original Approval Date*” is listed as 16 November 1987³¹⁷.

- (237) Moreover, before the Norwegian patent office, AZ does not mention the decision of 5 February 1988 enabling marketing in Sweden (see recital (232)). In contrast to its position in the German court proceedings, AZ no longer concedes the point that “February 8, 1988” is the decisive date for the fixing of the price in Luxembourg.
- (238) In later pleadings of 20 May 1999³¹⁸, AZ claims that the Luxembourg decision of 17 December 1987 authorising sales with effect from 8 February 1988 was “*not sufficient to enable Losec to be brought to market in Luxembourg*” because the approved prices for medicinal products first had to be reported to wholesalers and retailers and that “[AZ’s] *understanding is that no list comprising Losec with an indication of the price was published before 21 March 1988, and that the ‘Liste des Spécialités’ ... published on that date also comprised a list where Losec was entered with its price*”.
- (239) In connection with these proceedings in Norway, the complainant in this case was also engaging in correspondence with the Luxembourg authorities³¹⁹. Based on this correspondence the complainant contests that the publication of this List was necessary for the effective launch of Losec. Referring to letters of 17 February and 2 June 1999 obtained from the Division de la pharmacie et des médicaments of the Luxembourg Direction de la santé³²⁰, the complainant argues that the List was – at the relevant point in time (March 1988) – nothing more than an unofficial document issued by one of the CEFIP³²¹ wholesale members, namely *Comptoir Pharmaceutique Luxembourgeois*. According to the letter dated 17 February 1999 “[t]he dates on the documents *LISTE DES SPECIALITES PHARMACEUTIQUES ADMISES A LA VENTE DANS LE GRAND-DUCHE DE LUXEMBOURG* are not of any importance. This is only an unofficial list of all products authorised in Luxembourg and it appears every three months”³²². On 2 June 1999, the Luxembourg pharmacy and medicines department informed the complainant that “*it is not possible to send [the complainant] a copy of the ‘Liste des Spécialités Pharmaceutiques Admises à la Vente dans le Grand-Duché de Luxembourg’ of December 1987 or June 1988, because this official list did not exist at that time. A convention between the luxemburgish government and CEFIP in order to give them these exclusive rights was only signed in 1990, beginning on June 15th 1990. Former to this convention an unofficial list was published by the wholesaler Comptoir Pharmaceutique Luxembourgeois on behalf of CEFIP in order to inform the pharmacists on the products that are authorized and available on the market. CEFIP had used our database in order to publish their list but we never controlled this publication because it was not official and also contained other informations*”³²³.

³¹⁷ [3316, 3320].

³¹⁸ [1505].

³¹⁹ 6.172 AZ Reply.

³²⁰ [302, 1081].

³²¹ CEFIP is a company owned by the *Syndicat des Pharmaciens* and the *Groupement des Grossistes Repartiteurs Luxembourgeois en Produits Pharmaceutiques* which, according to the complainant, represent around half of Luxembourg’s pharmacists and pharmaceutical wholesalers.

³²² [302].

³²³ [1081].

- (240) Moreover, the complainant's record of oral explanations on 4 June 1999 by the head of Comptoir Pharmaceutique Luxembourgeois SA further makes the situation in Luxembourg even more clear³²⁴. According to the record in 1988 the wholesaler Comptoir Pharmaceutique Luxembourgeois also produced a second type of unofficial list on behalf of CEFIP, namely a twice-yearly price list which was updated fortnightly. The price list included approved products even before they had received price approval from the Luxembourg Office des Prix. The record observes that the price list became official in 1990. As regards the Liste des spécialités pharmaceutiques admises à la vente dans le Grand-Duché de Luxembourg, the record observes that in 1988, the publication was published on an irregular basis, although it was meant to appear on a quarterly basis. Its purpose was to keep doctors, pharmacies and pharmaceutical companies updated on approved pharmaceuticals. The record furthermore notes that the List of March 1988 "*must have had about 500 pages since the products starting with "L" appears on p. 246. On the top left hand corner of this page is a date 21/03/88. [The Head of Comptoir Pharmaceutique Luxembourgeois] believed that this date was the date of printing of the March 1988 LIST, which comprised all products approved by 24 February 1988*"³²⁵.
- (241) In its submission of 20 May 1999 to the Oslo City Court, AZ does not explicitly deny the existence of a price list. Indeed AZ submits a page from a list entitled "*Liste Luxembourgeoise des Prix Pharmaceutiques*" containing an entry on Losec capsules ("*LOSEC GELULES 20 MG [illegible text] RR ARTICLE ENTREGISTREE MAIS PAS EN STOCK*") and gives 16 January 1988 as the date for the Losec entry³²⁶. Yet, AZ still observes before the Oslo City Court that its "*understanding is that no list comprising Losec with an indication of the price was published before 21 March 1988 and that the Liste published on that date also comprised a list where Losec was entered with its price*". AZ claims that this information was based on statements made to AZ's Luxembourg lawyer at the time by the director of CEFIP (who published the Liste)³²⁷. It admits that it "*does not have the complete Liste ... or any part thereof comprising the price for Losec*" although "*lengthy efforts have been made to procure this document...*"³²⁸.
- (242) On 29 June 1999, the Oslo City Court revokes the SPC granted by the Norwegian patent office on the ground that the first technical market authorisation occurred before the cut-off date for Norway³²⁹.
- (243) **Finland:** On 30 December 1994, AZ's Finnish agent also files "*21.3.1988*" as the first marketing authorisation in the EEA and the Finnish patent office grants an SPC based on that date, therefore expiring on 21 March 2003³³⁰.
- (244) On 21 December 1998, Merck Generics Oy, an associated company of the complainant, lodges an appeal³³¹ in the Helsinki District Court against the patent office's decision on the grounds that the first technical market authorisation date had

³²⁴ [1079-1080]. See also [5502].

³²⁵ [1080].

³²⁶ [5502, 5507].

³²⁷ 6.174 AZ Reply.

³²⁸ [1507].

³²⁹ [1210-1217]; see also [3448].

³³⁰ [3064].

³³¹ [1633].

taken place before 1 January 1988³³². In its submission of 25 February 1999³³³, AZ repeats *verbatim* the statement made on 12 February 1999 (quoted at recital (235)) before the Oslo City Court³³⁴.

- (245) In a subsequent submission by AZ of 30 June 1999, AZ states the following³³⁵: “[T]he defendant withholds the opinion that LOSEC couldn’t be marketed in Luxembourg before March 21, 1988. Before that date LOSEC hasn’t been marketed either in Luxembourg or in another EEA country. Both the defendant and the plaintiff have tried to obtain a full copy of the “Liste” and tried to find out the publications legal status in Luxembourg. It seems like the situation in Luxembourg was quite unclear”. The Helsinki District Court has now stayed the proceedings in the light of the pending request from the Federal Court of Justice to the Court of Justice of the European Communities for a preliminary ruling (see recital (229)).

(e) AZ’s SPC application for products other than omeprazole

- (246) At around the same time as AZ handed in its first and second round SPC applications for omeprazole capsules, it filed applications for several other products under the transitional provisions of the SPC Regulation³³⁶. For omeprazole sodium, AZ relies on the same Luxembourg data and the same SPC Strategy as it did for omeprazole capsules. For its other products AZ files the technical authorisation dates. For felodipine it uses the date of publication of the technical authorisation.

Omeprazole sodium

- (247) For omeprazole sodium, the first technical market authorisation in the EEA takes place in Luxembourg on 16 November 1987 (even though AZ initially thought that it took place in January or February 1988) (see recital (178)). In its SPC applications in Belgium, Ireland, Germany, Luxembourg, the Netherlands, Denmark, the United Kingdom, Finland, Norway and Austria, AZ nevertheless refers to “March 1988” or (in the second round) “21 March 1988” (as it did for omeprazole capsules). In Sweden and France³³⁷, which are 1985 countries, AZ cites the technical authorisation on 16 November 1987³³⁸. In subsequent court proceedings in 1999 concerning omeprazole, AZ submits that the date given in the Swedish application “*is an error*” due to the unclear situation resulting from Sweden’s entry into the Community³³⁹. As regards France, AZ states in the same proceedings that the French patent agent did not follow AZ’s instructions³⁴⁰.
- (248) As part of AZ’s preparations during 1998 for its omeprazole sodium application in Belgium, an email dated 7 August 1998 was sent to the head of AZ’s patent

³³² A few days earlier, AB Hässle has initiated legal actions against ScandPharm and Merck Generics Oy [6676], notably on the basis of AB Hässle’s Finnish SPC omeprazole.

³³³ [1639].

³³⁴ [964]. Also at [1643].

³³⁵ [1339]. See also 6.181 AZ Reply.

³³⁶ [3761].

³³⁷ See respectively at [401] and at [2484]. Also at [399].

³³⁸ [3670].

³³⁹ [1507].

³⁴⁰ [1507]; [2891].

department³⁴¹. The email raises a number of problems linked to the omeprazole capsule application from 1993: “*If we in our letter to the patent office in BE state that if they choose a date other than 21.03.88 ... this might have implications on our Losec Capsule SPC ... in Belgium ... My question is: Is it enough to indicate that there may be implications or should we raise France and its date 15/4 1987 in greater detail?*”. The AZ employee making the proposal reverts with a new email of 19 August 1998 to the head of AZ’s patent department which includes, *inter alia*, the following proposal³⁴²: “*We submit an application which is as similar to the capsule one as possible, i.e. with the same claim as to the date: 21/3 1988 in LU as the first date. This is done to avoid introducing different dates which may be perceived as misleading. An important difference is on the other hand that we add the ‘legal provision’ which contain the rules on pricing. This was not part of the application for the capsule SPC in BE*”. The email goes on with further proposals regarding the strategy: “*We submit (within the near future) [to the Belgian patent office] a ‘declaration’ which describes the pricing situation, i.e. describing the dates which may be applicable. This will be an expanded version of your letter of 8 May [1998] (see recital (227)). Here we refer to the letter by Astra of 8 December 1987... (see recital (225)). We also refer to the reply we received which is dated 17 December 1987 (see recital (170)).*”

Felodipine

- (249) Felodipine is the active substance in a number of cardiovascular medicines (e.g. Plendil). The first technical market authorisation for Plendil was issued by the relevant Danish authority on 29 December 1987³⁴³. An AZ stamp dated 4 January 1988 also appears on this authorisation which indicates it was received by AZ Denmark on this date. The technical authorisation of 29 December 1987 was published in the Danish official journal (the *Statstidende*) on 21 January 1988³⁴⁴. Effective marketing of pharmaceutical products in Denmark requires listing in the so-called *Specialitetstaksten*³⁴⁵. Plendil was listed in the *Specialitetstaksten* on 29 February 1988, as AZ knew already in late March 1993³⁴⁶ (see footnote 213 at recital (169)). The function of listing in *Specialitetstaksten* is also explained in a submission by AZ dated 16 September 1993 (see recital (251)).
- (250) AZ files its SPC applications for felodipine in largely the same countries and at around the same time as those for omeprazole: a first round in June 1993 in Belgium, the Netherlands, Luxembourg, the United Kingdom, Germany and Denmark, and a second round in November-December 1994 in Austria, Finland and Norway. It relies on the date at which the first technical market authorisation (in Denmark) was *published*, i.e. 21 January 1988. In the filing in Ireland in October 1993, however, reference is made to the technical authorisation date of 29 December 1987³⁴⁷.

³⁴¹ [3627].

³⁴² [3628].

³⁴³ [943].

³⁴⁴ [420, 550-551].

³⁴⁵ [535-536].

³⁴⁶ [1297].

³⁴⁷ [403-404].

- (251) The Dutch and Irish patent offices consider the relevant date to be the technical authorisation on 29 December 1987 and they both issue SPCs based on that date³⁴⁸. The patent office in Denmark (a 1988 country) also considers the technical authorisation date to be relevant. It therefore rejects AZ's felodipine application. The Danish Patent Appeal Court upholds the patent office's decision³⁴⁹. It should be noted that in a memorandum of 16 September 1993, two external counsel enlisted by AZ in Denmark³⁵⁰ not only argue in favour of the date at which the technical authorisation was officially published but, in addition, explicitly reject the price approval date (i.e. the original basis of the SPC Strategy for omeprazole capsules for which applications had been submitted around three months before) as irreconcilable with Article 19 of the SPC Regulation. Indeed, the memorandum concludes that “[i]t is our opinion that the effective date of the marketing authorization underlying an SPC must relate to the date on which the authorization not only exists in the abstract, but is notified to the applicant as well as to third parties. This date will be the date of publication in the official Gazette. As actually the applicant cannot enjoy the benefits of the authorization before listing in Specialitetstaksten an alternative would be to refer to such date. Such reference, however, is not reconcilable with the wording of [the SPC Regulation] and Directive 65/65”. This memorandum was not only submitted to the Danish patent office but also to the Finnish patent office³⁵¹.
- (252) The patent offices in Belgium (1982 country), the United Kingdom, Luxembourg and Austria (1985 countries) as well as Norway and Finland (1988 countries) also issue SPCs based on 21 January 1988³⁵². Germany (1988 country) relies on the date of delivery to AZ of the technical authorisation (i.e. the stamped date 4 January 1988)³⁵³.
- (253) As in the case of the omeprazole applications, the felodipine applications were centralised by AZ in Sweden³⁵⁴.

Other products

- (254) For all other products (five in all) falling under the transitional provisions of the SPC Regulation, AZ filed the date of the technical authorisation as the first date of authorisation within the Community (and EEA)³⁵⁵. More specifically, this is the case

³⁴⁸ In Ireland, in its own words “*AB Hässle chose not to apply this interpretation, but referred to the marketing authorization date, since the question of the date in Ireland did not of course have any relevance to the question whether a protection certificate could be issued, only to the question of its duration*”[1297-1298].

³⁴⁹ [419-436].

³⁵⁰ [532].

³⁵¹ [1660-1661]. In Finland, the patent agent added on 15 June 1995: “*With reference to the arguments put forth in the said memorandum [the Danish memorandum of 16 September 1993] we note by way of conclusion that the relevant date for the marketing authorisation on which an SPC is based is the date when the marketing authorisation not only exists in an abstract sense but when it is notified both to the applicant and to third parties. This date is the date of publication in the official journal, i.e. in this case 21 January 1988. An alternative date given in the memorandum is the date when Astra Denmark received the notification of the market registration ...*”. As pointed out in recital (252), the Finnish patent office accepts this reasoning.

³⁵² [942, 944-947, 5585].

³⁵³ [940], [944-946]. It may be noted that AB Hässle cites the number (“6499”) of the grant of 29 December 1987 in its applications based on 21 January 1988 [550, 940, 943].

³⁵⁴ [1297].

³⁵⁵ 6.79-80 AZ Reply.

for *budesonide* (the active substance in a number of asthma medicines variously called Spirocort or Pulmicort Turbohaler), *bambuterol* (the active substance in Bambec), *remoxipride* (the active substance in Roxiam) and a combination substance consisting of *felodipine and metoprolol* (the active substance in Logimax)³⁵⁶. AZ's reliance on the technical authorisation dates clearly follows from a comparison between the technical authorisation decisions by the relevant Danish authority and the applications filed by AZ. In all these cases, the first technical authorisation (all of them in Denmark) occurred after 1 January 1988. The technical authorisation dates thus enabled AZ to obtain SPCs in the 1988 countries.

*J. THE SECOND ABUSE – THE SELECTIVE CAPSULE DEREGISTRATION
COMBINED WITH THE SELECTIVE TABLET/CAPSULE SWITCH AS PART OF
AZ'S LOSEC POST PATENT STRATEGY*

1. INTRODUCTION

- (255) Under its “Losec Post Patent Strategy” (hereinafter “LPPS Strategy”), AZ plans a series of measures including the selective withdrawal from the market and deregistration of the market authorisation of Losec capsules combined with the launch of a tablet version of Losec capsules (Losec MUPS). In line with the LPPS Strategy, a number of AZ's national marketing companies elaborate national strategy documents in the course of 1998 or 1999 under instructions from AZ's central headquarters in Sweden.
- (256) It emerges from AZ's internal documents that two key aims of the LPPS Strategy are to prevent or at least delay the market entry of generic versions of omeprazole and to obstruct parallel trade in Losec capsules.
- (257) For a proper understanding of AZ's LPPS Strategy, it is first necessary to describe the relevant legal EU and national frameworks (section 2 below) in their form at the time relevant to the behaviour which is the subject of this decision. The relevant parts of AZ's internal documents and subsequent related actions will then be described (section 3 below).

2. THE LEGAL FRAMEWORK

- (258) Directive 65/65/EEC – the cornerstone of Community pharmaceutical legislation at the time relevant to this decision – provides that a medicinal product may be marketed in a Member State only after authorisation has been obtained from the competent authority in that Member State. To that end, the applicant must submit a series of data and documents, listed in Article 4 of Directive 65/65/EEC, including, the results of pharmacological and toxicological tests and clinical trials. The primary purpose underlying the requirement of a marketing authorisation is to safeguard public health, i.e. to ensure the quality, safety and efficacy of the medicines placed on the Community market. This objective must be attained by means which will not hinder the development of the pharmaceutical industry and trade in medicinal products within the Community (second recital of Directive 65/65/EEC).

³⁵⁶ For these five active substances see [468-492].

(a) The simplified market authorisation procedure for generic products

- (259) However, point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65, as amended by Directive 87/21,³⁵⁷ provides for a number of simplified procedures, one of which is used by manufacturers of generic versions of original reference products which are already on the market. This simplified procedure is hereinafter referred to as the “generic procedure”. Under the generic procedure, the generic applicant does not have to supply the results of pharmacological and toxicological tests and of clinical trials, and may rely instead on data submitted in respect of a “reference” product which has already been authorised³⁵⁸.
- (260) The generic procedure strikes a balance between the interests of innovative and generic producers. On the one hand, the purpose is to relieve applicants for marketing authorisations of the obligation to carry out pharmacological and toxicological tests and clinical trials³⁵⁹. In this way it enables the generic manufacturer to bring to the market cheaper medicines which are therapeutically equivalent to the original versions without having to go through the entire market authorisation procedure. On the other hand, the competent authority can only authorise the marketing of a generic medicinal product after the innovative company has enjoyed a period of protection for the data to which the generic applicant must refer. This was considered appropriate in order to ensure that innovative firms are not placed at a disadvantage (second recital in the preamble to Directive 87/21/EEC). It should also be stressed that one of the principal objectives of the generic procedure is to avoid the repetition of tests on humans or animals unless absolutely necessary (fourth recital).
- (261) In order to place a generic version of an original medicine on the market via the generic procedure, a generic manufacturer must, pursuant to point (8) (a) (iii) of the third paragraph of Article 4, fulfil three cumulative conditions.
- The generic version must be “*essentially similar*” to the original reference product;
 - The so-called *data exclusivity* has expired. The data exclusivity protects the preclinical and clinical data which the manufacturer of the original reference medicinal product has filed with a view to obtaining his market authorisation. This data exclusivity lasts for six or ten years from the moment the manufacturer of the original reference product obtains his first marketing authorisation in the Community;

³⁵⁷ OJ L 15, 17.1.1987, p. 36.

³⁵⁸ The final subparagraph of point 8(a) also contains a so-called “hybrid abridged procedure”. Under that procedure, where the medicinal product is intended for a different therapeutic use from that of the other medicinal products marketed or is to be administered by different routes or in different doses, the applicant is required to provide only the results of such pharmacological and toxicological tests and clinical trials as are appropriate in the light of the difference in therapeutic use, route of application or dose from the other medicinal products marketed (the fresh data are referred to as “bridging data”). Otherwise, the applicant relies upon the data relating to the reference product which it is required to specify under point 8(a)(i) or (iii). The hybrid abridged procedure is therefore intermediate between the abridged and the normal procedure as regards the evidential burden which it imposes on the applicant.

³⁵⁹ See Case C-368/96 *The Queen v the Licensing Authority, ex parte Generics and Others* [1998] ECR I-7967, paragraphs 4 and 69. See also Case C-223/01 *AstraZeneca A/S v Laegemiddelstyrelsen*, [2003] ECR I-11809, paragraphs 42 and 52.

- The original reference medicinal product “*is marketed*” in the Member State where the generic application is filed.

(262) It should be pointed out that in the context of the second abuse in this case the third requirement, namely the requirement that the product “is marketed”, was particularly relevant. At the time that AZ implemented its conduct in 1998, there was some uncertainty as to the interpretation of this requirement. In subsequent litigation before the Court of Justice, AZ argued that the requirement means that the reference market authorisation must be in force not only at the time a generic application is filed but also at the time when the authority decides on the generic application. However, in its judgment in 2003 the Court of Justice ruled that it is sufficient for the purposes of processing a generic application that the reference market authorisation is in force at the time the generic application is filed (see recitals (307), (310), (838) and (840)).

(b) The conditions for marketing parallel imported products

- (263) Directive 65/65/EEC cannot apply to a medicinal product covered by a marketing authorisation in one Member State which is being imported into another Member State as a parallel import of a product already covered by a marketing authorisation in that other Member State, because the imported medicinal product cannot, in such a case, be regarded as being placed on the market for the first time in the Member State of importation³⁶⁰. National authorities must grant a parallel import licence if the product to be imported has the same active ingredients and therapeutic effects as the existing reference product, and complies with the requirements relating to quality, efficacy and safety³⁶¹.
- (264) Traditionally, a parallel import licence in principle has relied on an existing market authorisation issued in accordance with Directive 65/65/EEC. However, in a few recent judgments³⁶², the Court of Justice has clarified that, where the reference market authorisation issued under Directive 65/65/EEC is deregistered by the authorisation holder for reasons other than the protection of public health, there do not appear to be reasons under Articles 28 and 30 of the Treaty to justify the automatic cessation of the validity of an existing parallel import licence.

3. AZ’S LOSEC POST PATENT STRATEGY

- (265) Points (a) to (h) below describe the development of the LPPS Strategy, from the early preparation at AZ’s central headquarters to the national strategy documents which AZ’s marketing companies drew up in line with an AZ’s LPPS Strategy document from 29 April 1997. Point (i) describes the results that AZ achieved in implementing these strategies against generic producers and parallel traders.

³⁶⁰ Cases 104/75 De Peijper, and C-201/94 Smith & Nephew and Primecrown [1996] ECR I-5819.

³⁶¹ Case C-94/98 The Queen, ex parte Rhône-Poulenc Rorer Ltd and May & Baker Ltd v The Licensing Authority [1999] ECR I-8789.

³⁶² Cases C-172/00 Ferring Arzneimittel GmbH v Eurim-Pharm Arzneimittel GmbH [2002] ECR I-6891, C-15/01 Paranova Läkemedel AB and Others v Läkemedelsverket [2003] ECR I-4175, and C-113/01, Paranova Oy [2003] ECR I-4243.

(a) The early preparation for the LPPS strategy (1996)

- (266) It appears from minutes of an internal management meeting (“*Marketing Advisory Council*”) on 9 August 1996 that AZ is working on “*a full pre and post patent strategy for Losec which will be ready during September*”³⁶³. The minutes also reveal “*a possible strategy for MUPS in Europe which has been discussed with Astra Hässle, legal affairs, the patent department and Astra UK*”. An enclosure to the minutes contains a reference to the essence of the future MUPS Strategy: “*Introduce MUPS and withdraw capsules ...*”. A reference to “*Parallel importation*” is listed under “*Other considerations*”. At this stage, however, a Losec MUPS/Losec capsule switch is deemed “*unlikely*” by AZ.
- (267) A memorandum of 20 December 1996 on the LPPS Strategy addressed by the managing director of AZ’s Swedish marketing company – who is also AZ’s regional director for the Nordic countries at the central level and the person in charge of AZ’s “*central marketing team*” – to the managing directors of AZ’s marketing companies in Norway and Denmark contains a standard agenda used for meetings held during the autumn of that year with the ten largest marketing companies within the AZ group. The agenda contains a number of questions, including questions on how generics will penetrate the markets under “*a do-nothing scenario*”: “*How will Losec® and generics be reimbursed*” ... “*What legal ways in your market do you see to disturb/delay generic approval/introduction and how much time would that buy you?*”³⁶⁴.

(b) The LPPS Strategy document (29 April 1997)

- (268) In its LPPS Strategy document of 29 April 1997³⁶⁵, AZ notes that the omeprazole substance patents or SPCs will expire in most major markets in the time period 1999-2004. The document specifies that “*in some countries, e.g. Germany, Denmark, Norway ... the substance patent will expire in 1999, meaning that such markets will be open to generic competition and sales/price erosion in 2 years from now, which will affect the price levels in these countries as well as other countries in these regions, Europe in particular*”. It goes on to note that “*in a do nothing scenario, we project a sales decay of Losec, following patent expiry, to 20-30% in 2006 of peak sales year 2000*”.
- (269) Under the heading “*Purpose of Losec Post Patent Strategy*”, AZ states that “*the primary aim of the Losec post patent strategy is to identify approaches/key actions to minimize sales erosion following patent expiry and, importantly, to develop/launch products with significant medical benefit/differential to compete with cheap generic omeprazole/H2RA’s and to retain price and volume*”. This statement refers to AZ’s long-term aim to ensure a successful transition from the omeprazole-based Losec products to a new generation of anti-ulcer products based on a new active substance (later named “esomeprazole”). This aim is clear from the subsequent heading “*Basic principles of the Losec Post Patent Strategy*” where AZ visualises and describes the three basic “principles” – in fact three phases – of the LPPS Strategy³⁶⁶.

³⁶³ [2565].

³⁶⁴ [3723-3725].

³⁶⁵ The strategy is an Astra Hässle document [3324]. Also at [4387].

³⁶⁶ See also [4416-4453].

- (270) In the first phase, AZ intends to “[d]iversify Losec® during its patent life by introducing bioequivalent line extenders offering practical benefit”. Losec MUPS is mentioned as one such extender of Losec capsules. The idea is to “protect some sales short/mid term after expiry through customer loyalty/use habits, in particular in the absence of generic product solutions”.
- (271) The second phase scheduled around the period of patent expiry (1999-2004) is of key importance in this case. In this phase, AZ wants to “delay generic introduction through technical and legal hurdles” because “[e]very day of protected sales of Losec® is worthwhile considering the huge sales volume projected at patent expiry”. AZ observes further: “[c]reating such barriers is a major priority and include a range of actions”. There are six categories of such “actions”:
- (a) “document protection”;
 - (b) “upgrade of product quality”;
 - (c) “secure additional offensive/defensive patents”; “broaden the base of intellectual property rights”;
 - (d) “establish a comprehensive surveillance programme to identify ... suppliers of generic omeprazole”;
 - (e) “prepare and take firm and immediate legal action (e.g. infringement of formulation patents) against companies introducing generic omeprazole”.
 - (f) “consider total switch of Losec® capsules for tablets (e.g. MUPS) where local substitution rules would make such an action effective”.
- (272) AZ sees this last action as “probably relevant for markets with early patent expiry considering the timing of [esomeprazole] market availability (e.g. ... Denmark, Norway, Germany)”. AZ specifies that “[o]ver 30 markets have so far requested the file” but that “Losec MUPS will not be filed in Italy and Spain”. It repeats that “Losec® MUPS will play a vital role in the early patent expiry markets, where a total switch from capsules is considered in order to try and protect sales from major, early decay after expiry”. AZ describes Losec MUPS as a “high-tech” tablet which is “bioequivalent to the Losec® capsule”, whilst providing “some practical benefits (eg dispersibility, simpler / calendarized packaging) .
- (273) The third phase involves the introduction of “patent protected products with clinical benefit/significant differential over generic omeprazole”. AZ describes this introduction of a new generation product as the “most important and critical part [of the LPPS Strategy]” and its purpose is to generate “longer term revenue after expiry of the [omeprazole] patent”. Phases one and two are described as “relevant for the short/medium term period after expiry”. In a speech before AZ’s senior management in October 1999, the head of AZ patent department confirms that the aim of the strategy “is to slow down generic market penetration to give time for the new esomeprazole ... ”.³⁶⁷

- (274) Other internal documents confirm the existence of the LPPS Strategy. Among a set of slides, one slide entitled “*Lossec Maximum Term Defence*” states that national action plans are to be elaborated and approved centrally by AZ and that the aim of the “*IP strategy*” is to “*delay generic penetration of the markets by aggressively defending the patent rights in order to gain time for [the successor product referred to in the third and final phase of the LPPS Strategy, later calledesomeprazole]*”³⁶⁸. AZ is also concerned about parallel imports. AZ indeed asks itself how it could “*prevent importation to the EU states of low-priced Danish (or German) omeprazole*” (underlining in original text). Another (undated) set of AZ slides which also refers to “*Project Maximum Term*”) advocates: “*... File a patent-cloud of mixtures, uses, formulations, new indications, and chemistry ... This would possibly slow down and create uncertainty*” (see third action (c) listed at recital (271))³⁶⁹.

(c) The MUPS Strategy

- (275) The file contains a number of other documents which deal specifically with the second phase “*total switch*” action, i.e. the core of the so-called “MUPS Strategy” which forms an integrated part of the LPPS Strategy (hereafter “MUPS Strategy”).
- (276) **[confidential]**³⁷⁰
- (277) AZ observes further that its marketing companies in most countries have commented that they will only withdraw the capsule over time and that “*this depends on market acceptance of MUPS after launch and a desire to limit patient/prescriber confusion*”. AZ’s marketing companies in Austria, the Netherlands and the US are reported to wish to make both products available. Many other companies envisage a gradual withdrawal for various reasons: Belgium (“*depending on acceptance*”); Germany (“*limit potential confusion*”); Denmark and Ireland (no reason given); France (“*Class competition, market acceptance of capsule*”); Italy (“*run down inventory stocks*”); Portugal (“*inventory run out*”) and Sweden (“*acceptance*”). For the Netherlands both options (parallel marketing and gradual withdrawal) are considered (“*competitive advantage it needs to be EU decision*”). Only two companies recommend immediate withdrawal: Greece (“*limit potential confusion; pricing; preference for tablet*”) and Norway (“*strong launch message*”).
- (278) **Minutes from an internal meeting of 18 September 1997 (“Lossec MUPS i Europa – Brain storming”)**: It emerges from these minutes³⁷¹ that AZ’s senior management in Sweden, including its CEO, had requested a draft pan-European MUPS Strategy to be delivered by 3 October 1997. The minutes refer to the need to evaluate the consequences of a total switch to MUPS under the respective national regulatory rules (“*Regulatory rules on a country-by-country basis relevant for total MUPS switch*”) and raise questions like: “*How can we exploit*³⁷² *these [rules] and where? Shall the capsule be withdrawn or shall it be maintained*”. Two AZ inhouse counsel are assigned this evaluation task. Another member of AZ’s senior management is assigned the task of preparing country-by-country plans regarding the expiry of the patents.

³⁶⁸ [3943-3948]. See also [3780, 3785-3787, 3793, 3797].

³⁶⁹ [3804].

³⁷⁰ **[confidential]**

³⁷¹ [3551].

³⁷² The verb “utnyttja” (“exploit”) is used in the original Swedish version.

- (279) **MUPS Strategy document of 25 September 1997:** AZ states in this document that “*The plan, at least in Europe (save IT; ES and possibly PT and GR), is to convert all sales from the capsule to MUPS*”³⁷³.
- (280) **Draft MUPS Strategy document of 3 October 1997:**³⁷⁴ AZ states that Losec line extenders (MUPS being the first major such extender) “*serve the primary purpose of [inter alia] putting more resource and time pressure on companies developing omeprazole copies/generics*”. The marketing strategy is to launch MUPS “*in all European countries with a few exceptions*” and to base the launch on a “*total switch, at a rate judged to be possible/appropriate in the individual market*”. AZ adds that “*Losec MUPS is seen predominantly as a major line extender to protect business and is not expected to generate major incremental sales*”. The launch of Losec MUPS is expected to “*vitalise the Losec® brand and the switch strategy is intended to increase the protection of the Losec® brand (vs future generics) and make the brand more competitive against class competition*”.
- (281) This MUPS Strategy document contains a section entitled “*Legal and regulatory considerations of a withdrawal and de-registration of Losec® capsules when Losec® MUPS is authorised*”. Under this heading, AZ notes that once the capsules will have been withdrawn “*the authorizations for the capsule can consequently be surrendered*”, except in Sweden³⁷⁵. AZ states that “*the consequences of this from a regulatory and legal viewpoint will be further investigated*”. Among the “[i]ssues that need clarification”, AZ makes a clear distinction between generic products and parallel imports. It asks whether manufacturers of generic omeprazole capsules might continue to be “*able to obtain authorisations for capsule formulations*” even after the Losec capsules have been withdrawn and deregistered. AZ also asks: “*Will generic substitution in pharmacies be possible, i.e. can generic omeprazole capsules be dispensed if the prescription is for Losec® MUPS?*”. AZ decides to investigate this issue further “*country by country*”. For parallel imports, AZ believes that “*the authoritative answer will very likely depend on a ruling from the [Court of Justice]*”. Among the general Community law aspects which require clarification, AZ mentions “*competition law (articles 85 and 86)*” as well as “*free movement of goods (articles 30 and 36)*”.
- (282) Under the heading “*Supply strategy*”, AZ takes the view that “[m]arkets with early patent expiry or having special strategic needs (e.g. Sweden) should be prioritized regarding delivery of Losec® MUPS in the wallet pack” which is said to be “*unique and attractive*”. Under the final heading “*Recommendation*”, AZ advocates a “*Total switch*”, considers it “*important that the first launch of Losec® MUPS does not occur in a low price market*” and that Losec MUPS “*not be launched in Italy/Spain*” at all. AZ also sees the need for the “*strongest possible legal defense in all markets to defend Astra from generic competition regardless of formulation*”.

³⁷³ [3933].

³⁷⁴ [3553]. Also at [3050] (with handwritten annotations), [3307] and [4408].

³⁷⁵ AZ will in fact surrender the market authorization in Sweden. See also the minutes of Astra AB Board of Directors Meeting of 25 February 1998 which state that “since the approval for Losec capsules in many countries depend on the Swedish registration, it is, however, necessary to transfer the reference registration to another country before the approval of the capsules can be removed” [2628-2629].

- (283) **MUPS Strategy document from 22 October 1997 (“Consequences of MUPS strategy – interim report”)**:³⁷⁶ In this document, the two inhouse counsel mentioned in the minutes of the meeting of 18 September 1997 (see recital (278)) are optimistic as to the possibilities to prevent parallel imports as a consequence of the capsule deregistration: “*If Astra’s capsule registration is surrendered, it will in many cases appear from the national rules on parallel import licences that such licences for the capsules cannot be upheld. This could follow, for example, from the fact that the parallel import licence per definition depends upon the existence of a valid license for an original product, or from a requirement that the imported product should be “the same” as the original one. There are indications that several of the Scandinavian authorities generally would take this position*”.
- (284) Like the MUPS Strategy document of 3 October 1997, the interim report of 22 October 1997 is more pessimistic as to the possibilities to block market access for generic omeprazole capsules. AZ states that “*Since the MUPS applications are based on the capsule data, we will not be able to withdraw the capsule documentation even if the authorization of the capsules will be surrendered in European countries*”. From this AZ draws the conclusion that “*it will be possible for the generic competitors to refer to Astra’s capsule data, provided that they can show that there is essential similarity between their product and the product which is on the market, i.e. MUPS*”. Nonetheless, AZ refers to ongoing investigations with a view to identifying “*if there are any discrepancies between the European health authorities in deciding on essential similarity and the documentation needed for generics*”.
- (285) Referring to the Community rules on free movement of goods, the inhouse counsel note that “[i]n cases of this type, it will always be important for the manufacturer to be able to show that his strategy does not amount to an artificial partitioning of markets. It can, for example, be important to show that registrations for the new formulations have been sought in all EU countries or that there are objective reasons for not doing so”.

(d) Losec/H199 scenario (29 April 1998)

- (286) The “*Losec/H199 [AZ’s internal designation of esomeprazole] scenario*” dated 29 April 1998 also sets out the three phases of the Losec Post Patent Strategy defined in the LPPS Strategy document of 29 April 1997³⁷⁷. Under the heading “*major uncertainties/issues around post patent*” the document specifies in respect of the envisaged MUPS switch that the “*formulation conversion is not precedented*”.

(e) Draft paper for gastrointestinal therapeutic area team meeting 4 December 1998 (30 November 1998)

- (287) A document from 30 November 1998 entitled “*Draft paper for GI TA team meeting 4 December 1998*” deals with the 1999-2002 time horizon³⁷⁸. It contains information on AZ’s regulatory actions of which “*the overall aim [is] to prevent or delay generic entry*”.

³⁷⁶ [3562].

³⁷⁷ [4416-4453].

³⁷⁸ [4378 *et seq.*].

- (288) After having referred to the three conditions for assessing “essential similarity” (i.e. one of the three conditions for approval under the generic procedure), AZ then notes that *“in some countries ... the Health Authorities will even require the generics to comply with the same specification as the originators specification approved in that country. AZ’s reference to “the originator’s specification” includes data concerning inter alia the active substance and the final (or “finished”) medicinal product which the originator company has filed to obtain its original market authorisation.*
- (289) AZ thereafter reports a) that *“In this respect, a technical file with expert statement regarding the quality of omeprazole vs. the quality of generic omeprazole on various markets has been compiled”*; b) that *“the technical file will be sent to the Health Authorities in advance of generic approval to alert the Health Authorities of the bad quality of some of the generics on the market”* and c) that *“the aim is to slow down the evaluation procedures for generics and strengthen the platform for legal action if a generic of inferior pharmaceutical quality should be approved”*.
- (290) Still under the heading “Essential similarity”, AZ further reports: *“To strengthen the product quality, Astra are investigating the possibility to improve specifications for Losec on national bases. The limits for the omeprazole finished product specifications will be tightened as much as possible in each country of importance. This will put pressure on the generics when they have to comply with the omeprazole specifications”*. The type of tightening of product specifications to which AZ refers can be effected by applications to the competent national authorities under a special type of procedure (“variations procedure”) used when a company wishes to modify or update its market authorisation³⁷⁹. In the 30 November 1998 document, AZ observes that the tightening of product specifications and the submission of a technical file, *“has been commenced in ... Norway, Finland and Denmark”*.

(f) The gastrointestinal Franchise Plan (12 May 1999)

- (291) The *“GASTROINTESTINAL FRANCHISE PLAN Horizon 1-3 1999-2007 and beyond”* (hereafter “GI Franchise Plan”) of 12 May 1999³⁸⁰ covers AZ’s long term strategy for the whole gastrointestinal therapeutic area, i.e. not only the anti-ulcer market. **[confidential]**
- (292) It is time horizon 1 (1999-2002) which is of particular interest for this case. The GI Franchise Plan copies *verbatim* parts of the November 1998 document but contains more detail on the actions already taken as well as on the actions to be undertaken or pursued during the period 1999-2002.
- (293) According to the GI Franchise Plan, the overall aim of the regulatory actions is *“to prevent or delay generic market entry for generic omeprazole by prolonging the market exclusivity of Losec or by requiring generic companies to include more data/documentation in their applications to get market authorisation”*³⁸¹. This almost

³⁷⁹ For marketing authorisations obtained under the mutual recognition procedure, variations take place pursuant to Commission Regulation (EEC) No 541/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorization granted by a competent authority of a Member State. OJ L 55, 11.3.1995, p. 7.

³⁸⁰ [3132-3172].

³⁸¹ [3146].

literally copies a statement from the 30 November 1998 document. The GI Franchise Plan mentions three “principles”, the third one being to “*increase technical, biopharmaceutical and quality hurdles for generics*”. The 30 November 1998 document similarly reads: “*increase hurdles for generics e.g. bio-equivalence standards, product quality including monographs, complicated formulations etc*”.

- (294) In the GI Franchise Plan, AZ takes stock of “*actions already taken*” as well as of “*actions during 1999-2002*”. Attachment 3 to the Plan lists these regulatory actions, specifies to which country each of them applies and gives initiation and completion dates on a quarterly basis for each of them. For the purposes of this case, three actions are mentioned. First, AZ plans to “*continue processes initiated and described above, including submission of technical file in Germany, Denmark, Holland, UK, Belgium and Sweden*”. Second, AZ also announces that “*Lossec specifications will be upgraded as a further hurdle against generic omeprazole products*”. Third, AZ intends to “*monitor regulatory impact of the Lossec MUPS switch on generic/parallel imports and generic substitution*”. In its 30 November 1998 document, AZ had stated: “*a survey is ongoing to capture the different national Health Authorities interpretation of the regulatory impact of the MUPS/capsule switch*” and it had noted that “[t]he impact on generic, parallel importers and generic substitution is investigated”. Attachment 3 to the GI Franchise Plan situates the initiation date for this monitoring in the fourth quarter of 1998 and its completion date in the fourth quarter of 1999 for all countries.

- (295) **[confidential]**

(g) The adoption by AZ of national LPPS Strategy documents

- (296) Several of AZ’s marketing companies drafted national strategy documents in line with the general strategy documents emanating from AZ’s headquarters. This was the case in at least Finland³⁸², Norway (October 1998)³⁸³, the Netherlands (October 1998)³⁸⁴, Denmark (November 1998)³⁸⁵ and Sweden (February 1999)³⁸⁶. A fax of 29 May 1998 from AZ’s central headquarters advocates these national strategies in order to “*secure as far as possible that generics do not enter the field*”³⁸⁷. The fax clearly shows that the elaboration of the national Finnish, Danish and Norwegian LPPS Strategy documents are centralised by AZ in Sweden.
- (297) AZ is aware that Lossec is probably the most costly item on certain national health budgets (through the reimbursement system) and that consequently generic market entry would give the public authorities room to make savings³⁸⁸. AZ is also aware that existing Danish and Swedish – and for Norway planned – national regulations provide for reimbursement on the basis of the cheapest among a group of therapeutically

³⁸² For Finland, the Commission has a copy of Astra Hässle minutes of a meeting held on 25 March 1998 with representatives the Finnish marketing company. These minutes are entitled “Post Patent Strategy for Astra Finland” [4622].

³⁸³ [2277].

³⁸⁴ [2262].

³⁸⁵ [3683].

³⁸⁶ [3664].

³⁸⁷ [3706-3707].

³⁸⁸ [2617]. According to Scrip (No 2546 7 June 2000, p. 6), in 1999 Lossec was the top selling medicine in Denmark (USD 25 million) and Sweden (USD 119 million), the second best selling medicine in Norway (USD 25 million) and the fourth best selling medicine in Finland (USD 12 million).

equivalent medicinal products³⁸⁹. An internal Astra memo from AZ headquarters to AZ's Nordic regional manager of 3 February 1998 entitled "*Regional report Nordic Region*" states the following: "*In the other Nordic countries we expect very little in terms of dramatic changes in Finland, whereas both in Norway and Denmark, the authorities are very active in trying to curb the rising costs of pharmaceuticals. In Denmark it is expected that the government will introduce new measures during the spring, such as mandatory price reduction. Negotiations are currently ongoing with the Danish government in order to try to minimise the negative impact of new laws. Especially therapeutic substitution must be avoided at all costs*"³⁹⁰.

- (298) The first paragraph of AZ's LPPS Strategy document for Denmark ("*LOSEC PATENT STRATEGY Denmark*") from 2 November 1998³⁹¹ states that "*If we do not counteract generic competitors, we will lose 75% of our market within a year*". Further on AZ Denmark describes the market dynamics resulting from generic entry in general: "*A generic product is normally launched on the Danish market [at] a price 10-20% lower than the price of the original product, depending on the status of reimbursement. After a certain adjustment period in which the company offering the original product makes the necessary price reductions, the difference in price will in most cases narrow down to approximately 5%, which is on the minimum limit to avoid [generic substitution]. The speed of the market penetration of a generic product depends on how effectively the products are marketed, the price strategy and not least how fast and consequent the company of the original product narrows the price difference. If a generic product is allowed to maintain a price difference above the minimum limit in 2-3 months, this product will probably have achieved a market share of 30-50%. The larger the price difference, the faster the generic products grow simply due to the substitution rules. If the large price differences persist during a long time, the habits regarding prescription of the [general practitioners] will be permanently influenced in favour of the generic product. All history shows that if this happens it is very hard to make the [general practitioner] return to the original product even though the price difference is reduced ... There is a risk, that the relatively peaceful competition on the Danish market between the original and generic products could be disturbed in the future by the international generic companies ...*".
- (299) Under the heading "*THE "DO NOTHING" SCENARIO*", AZ Denmark notes that "[i]f we do nothing, the consequences will be a substantial loss of sales and profit ... If we are not allowed to reduce Losec price, we will have lost our market in 3-6 months. The new reduced price level will also have impact on the price setting for [esomeprazole]. Generic omeprazole could be a reality from July 1999, if formulation patents do not hold up in court". AZ estimates that during 1999-2001 it will lose almost DKK 290 million in Losec and esomeprazole sales if generic omeprazole is allowed to enter the market. It further expects "*the market share of Losec in value to decrease dramatically if generic peroral [i.e. oral administration] omeprazole enter the market. Total omeprazole market share will probably be quite stable, but a big part of the Losec market share will most likely be taken over by generics in 2000-2001. [Esomeprazole] is scheduled for launch August 2000. It will be very difficult to launch [esomeprazole]*

³⁸⁹ See Norwegian strategy document from Astra Norge AS [2283, 2295]; Swedish strategy document [3667-3668]; Danish strategy document [3687-3688].

³⁹⁰ [2753-2754].

³⁹¹ [3684].

successfully, since Astra by this time will not be the market leader and the price gap between [esomeprazole] and generics will be large”.

- (300) The Norwegian LPPS Strategy document (“LOSEC PATENT STRATEGY ASTRA NORGE AS”) from 23 November 1998³⁹² notes that “[i]n Norway, the price is set by SLK [i.e. the Norwegian Medicines Control Agency], primarily based on the cheapest comparable drug on the market. If there are no generics on the market at that time we expect no difficulties in obtaining price and reimbursement at a level comparable to the price of Losec® at that time, if that price is not significantly higher than the price of [esomeprazole] in other EEA member states. If there are generics on the market, however, the price might be set according to the price of generics. We expect this to exclude the product from being launched. Alternatively, the price might be set equal to the (lowest) price in EEA member states. Under such circumstances reimbursement may constitute a hurdle ... It is therefore critical that both price is set and reimbursement is granted before the entrance of generics”. Concerning the introduction of esomeprazole, AZ Norway points out in the same vein that “[r]eimbursement is the definite key to success, and price will be the major issue. The ‘cut cost wind’ blowing through the administration shows us that ‘good enough’ is a reason to stop reimbursement for new and better products”. AZ Norway expects a 50% price fall to “sweep Losec® off the market with a few exceptions” and estimates the absence of generic competition during 1999-2003 to be the equivalent of NOK 1015 million. The Norwegian strategy document is attached to a letter of 22 October 1998 from AZ’s Norwegian marketing company to one of AZ’s Swedish subsidiaries (Astra Sverige AB) which states that “the first draft version [of the Norwegian Losec Patent Strategy) was submitted to Astra Hässle on August 15, 1998 and an updated version resubmitted October 1, 1998”³⁹³.
- (301) The Swedish LPPS Strategy document (“LOSEC® DEFENSE STRATEGY – SWEDEN”) from 26 February 1999³⁹⁴ notes that “[b]oth from a marketing and regulatory perspective the capsules are replaced with MUPS® from January 1, 1999”. It further notes that “[t]he next step will be conversion from Losec MUPS® to [esomeprazole]” and that “[i]t is of the utmost importance that [esomeprazole] can be marketed without generic omeprazole being available for the longest period possible ... The idea is to maximize the speed of conversion [to esomeprazole] not to optimize the omeprazole sales”.
- (302) It appears from the foregoing that the national LPPS Strategy documents are essentially directed against generic capsules (in line with AZ’s general LPPS, MUPS and GI Franchise Plan Strategies). However, the national LPPS Strategy documents – like the general MUPS Strategy – also address the issue of parallel trade in Losec capsules. The deregistration of the Losec capsules is seen as the means to stop parallel trade in Losec capsules. The Norwegian LPPS Strategy document expects that “[c]apsule licence withdrawal will be effective from November 1, 1998” and that the conversion will “mimic the situation that has already taken place during the MUPS® introduction by Astra Denmark”. It is therefore expected “that parallel trade of

³⁹² [2295].

³⁹³ [2276].

³⁹⁴ [3676].

*Losec® capsules will gradually cease and be virtually non existing from February 1, 1999*³⁹⁵.

- (303) In addition to the tablet/capsule switch and capsule deregistration, the national Nordic LPPS Strategy documents also contain references to other types of regulatory actions to be adopted to slow down the regulatory approval of generic products³⁹⁶. Such actions are similar to the ones listed notably in the LPPS Strategy of 29 April 1997 (see recital (271)).

(h) The implementation by AZ of the Losec post patent strategy

- (304) The tablet/capsule switch during 1998 combined with the capsule deregistration materialises as follows in the four Nordic countries. Tablet launch is quickly followed by capsule deregistration in *Denmark* (launch on 9 March 1998; AZ's request for deregistration on 19 March 1998 and deregistration as of 6 April 1998), *Finland* (respectively 20 May 1998, 28 September 1998 and 1 October 1998) and *Norway* (respectively 1 September 1998 (10/40 mg), 1 November 1998 (20 mg), 12 October 1998 and 1 December 1998). For *Sweden* the time lag is somewhat longer: tablets are introduced on 2 February 1998 (20 mg) and 1 August 1998 (10/40 mg); AZ requests the deregistration on 20 August 1998 and obtains it as of 1 January 1999³⁹⁷. It should be recalled that in three of these countries, there is an early expiry of the substance patent (Denmark: April 1999) or a risk that the SPC protection will be revoked (Finland and Norway: substance patent without SPC also expiring in April 1999)³⁹⁸.
- (305) In Germany, where AZ runs the risk of losing its SPC protection for omeprazole in April 1999, it launches tablets on 1 December 1998 and withdraws the three capsule formulations during respectively March 1999, October 1999 and December 2002. In the Netherlands, AZ launches tablets in May 1999 and withdraws the capsules in December 1999. In the United Kingdom, AZ launches the tablets on 27 September 1999³⁹⁹, initially withdraws the capsules (September/October 1999) but reintroduces them in December 1999⁴⁰⁰, apparently because pharmacists are not able to endorse a prescription for capsules by providing tablets⁴⁰¹. In Belgium, AZ brings the tablets to the market on 1 December 2000 and withdraws the capsules in September 2001 and September 2002. In Ireland, AZ launches the tablets on 1 November 1999 and withdraws the capsules on the same date. As at 13 December 2002 deregistration of capsules has not taken place or has not been requested in any other country apart from the four Nordic countries⁴⁰².

³⁹⁵ [2284].

³⁹⁶ See [3678] for Sweden, [2282, 2289 and 2294] for Norway, [3684] for Denmark and [4622] for Finland.

³⁹⁷ On all those dates, see notably [7402-7403].

³⁹⁸ In Sweden, the national SPC expired only in February 2002.

³⁹⁹ [7399 *et seq.*].

⁴⁰⁰ [6733].

⁴⁰¹ See Scrip No 2494 of 1 December 1999, p. 4. See Pharmaceutical Journal Vol 263 No 7071 p. 778 of 13 November 1999 (at www.pharmj.com/Editorial/19991113/clinical/losec.html).

⁴⁰² [7403]. An internal AZ email dated 20 January 2000 informs that it is only in certain Nordic countries that AZ has withdrawn and deregistered the capsule and that the other Member States “do not make the product available on the market” even if the registration is still in force [3897].

- (306) All the countries where AZ launches Losec tablets are – at least at the time of the launch – traditionally regarded as high price countries in the EEA, with Belgium at the edge between high and low price countries⁴⁰³. AZ has not launched the Losec tablets in France, Greece, Luxembourg, Portugal, Italy, Spain or Austria, even though the tablets have received market authorisation in those Member States (except for Italy and Portugal) during 1997-2001⁴⁰⁴. AZ accepts that – with the exception of Austria and France - the decision not to launch Losec MUPS in those countries was taken centrally⁴⁰⁵. In those countries, substance patent and, as the case may be, SPC protection for omeprazole capsules either expired much later than in the countries where tablets were launched or such protection was not available at all to AZ⁴⁰⁶. Finally, it should be mentioned that AZ’s market authorisations of Losec MUPS in all EEA countries have been based on the hybrid abridged procedure (see footnote at the end of recital (259))⁴⁰⁷.

(i) The effects of AZ’s Losec post patent Strategy

Denmark

- (307) **Generic authorisations:** On 23 February 1998, i.e. just a few weeks before the deregistration of Losec capsules, the complainant files a market authorisation application for its 20 mg generic version of Losec, which the Danish Medicines Agency (“DMA”) approves on 30 November 1998. On 27 April 1999, AZ appeals against the DMA’s decision. It argues that the generic procedure under Directive 65/65/EEC (point (8)(a)(iii) of the third paragraph of Article 4) requires not only that the original reference product (*in casu* the capsule) “*is marketed*” at the point in time when a generic manufacturer files his application (*in casu* 23 February 1998) but also at the later point in time when the national authority decides on that application (*in casu* 30 November 1998). It does admit that “*the original marketing authorization ... would normally ... in most cases*” remain in force “*where a commercial market exists for the product*”⁴⁰⁸.
- (308) In its defence of 22 June 1999⁴⁰⁹, the DMA argues that AZ’s “*reasons for introducing Losec entero tablets and withdrawing Losec entero capsules from the market are largely commercial as this hinders competitors from applying for marketing authorization for capsules in accordance with the [generic] procedure ...*”
- (309) Pending AZ’s appeal procedure before the Danish regional court, the complainant launches its generic product in June 1999. However, in October the same year AZ notes: “*We DO manage to hold back generic competition ... In for example Denmark a generic company has sold all in all TEN packages of omeprazole. Of these, AstraZeneca bought seven for our testing! In Norway, Finland ... there is to date no*

⁴⁰³ See [7126, and in particular 7127-7128]. See also [7054, 7050] and [7329].

⁴⁰⁴ [7410-7411].

⁴⁰⁵ 7.143-147 AZ Reply to SO [11360-11361].

⁴⁰⁶ Patent/SPC protection expiry in France (April 2004), Austria (August 2005), Italy (March 2010) and no such protection in Spain, Portugal and Greece.

⁴⁰⁷ [7410-7411].

⁴⁰⁸ [1199].

⁴⁰⁹ [1202, 1204]. Also at [1810].

*generic competition ...*⁴¹⁰. In January 2000 AZ succeeds in obtaining an injunction against the marketing of the complainant's product by invoking its formulation patent (see recitals (16) and (22)). It obtains similar injunctions against GEA/Hexal (March 2001) and Biochemie (October 2003)⁴¹¹.

- (310) On 30 September 1998, the DMA rejects an application for a generic omeprazole product filed under the generic procedure on the grounds that it is filed after the deregistration of AZ's capsules on 6 April 1998 and that it, as a consequence, fails to meet the requirement that the reference product "is marketed" within the meaning of point (8)(a)(iii) of the third paragraph of Article 4 of Directive 65/65/EEC. The Danish regional court subsequently (on 23 May 2001) asks the Court of Justice to clarify the interpretation of certain issues concerning the requirement in Directive 65/65/EEC that the reference product "is marketed"⁴¹². On 25 May 2001 ratiopharm receives a market authorisation in respect of a generic omeprazole capsule product, with reference to AZ's MUPS tablets⁴¹³; however, ratiopharm is obliged to provide the results of certain extra tests (so-called "bridging" data) (see footnote 358).
- (311) **Parallel trade:** An AZ Denmark board document describes the effects on parallel trade in Losec capsules of actions previously implemented as part of the MUPS Strategy: *"In March 1998 Losec MUPS was introduced and in April Losec capsules was withdrawn from the market. This meant exclusion of all omeprazole parallel import. In July Losec reached the best result so far ..."*⁴¹⁴. The LPPS Strategy document for Norway confirms that AZ succeeded in ending parallel imports of capsules into Denmark (see recital (302) as well as table 25 in the Annex).

Sweden

- (312) **Generic authorisations:** On 29 December 1998, i.e. three days before the deregistration of Losec capsules takes effect, the complainant obtains from the Swedish Medical Products Agency ("SMPA") a market authorisation for its generic omeprazole capsule and launches the product in May 2000⁴¹⁵.
- (313) At AZ's request, on 17 November 2000, the Stockholm City Court issues an injunction against the sale of that generic product. The injunction is based on AZ's Swedish SPC for omeprazole sodium (i.e. the active substance in the injectable version of Losec), which was obtained under the SPC Regulation and which is valid until 15 November 2002⁴¹⁶. The reason the injunction is not based on AZ's national Swedish SPC for omeprazole is due to the fact that, following AZ's deregistration of Losec capsules with effect from 1 January 1999, the Swedish patent office decides to revoke

⁴¹⁰ [3775, 3777].

⁴¹¹ 7.237(ii) AZ Reply.

⁴¹² Case C-223/01 AstraZeneca v Laegemiddelstyrelsen).

⁴¹³ According to AstraZeneca Plc's reply dated 13 December 2002 to the Commission's request for information pursuant to Article 11 of Regulation No 17 [7404].

⁴¹⁴ See [3692]. The document also contains the following sales data for the period 1995-1998 on Losec parallel imports in Denmark: DEK 257 000 (1995); DEK 27 million (1996 and 1997) and DEK 12 million (1998) [3686]. See also [10074] and [2624, 2625].

⁴¹⁵ On all these dates, see in particular AZ's reply to the Commission's request for information pursuant to Article 11 of Regulation No 17 [7404]

⁴¹⁶ Injunction in case T 7961-00 Aktiebolaget Hässle v. Scandinavian Pharmaceuticals-Generics Aktiebolag [5803, 5809].

AZ's national SPC for omeprazole (with 4 February 2003 as expiry date)⁴¹⁷. However, AZ's appeal before the patent appeals court is successful based on the argument that the new market authorisation for Losec MUPS is sufficient to keep in force AZ's Swedish national SPC for omeprazole⁴¹⁸. It is only in January 2003 that two other generic producers (Biochemie and ratiopharm) receive market authorisations⁴¹⁹. In February 2003, these two producers launch their generic omeprazole capsule versions. AZ brings legal proceedings against them alleging infringement of AZ's formulation patent.

- (314) **Parallel trade:** Shortly after its request of 20 August 1998 to deregister the capsules as of 1 January 1999 (see recital (304)), AZ asks the SMPA by phone on 27 August 1998 about the effect of a deregistration on parallel imports of capsules. On 1 September 1998, the SMPA effectively decides that Losec capsules are deregistered as of 1 January 1999 and that, as a result, the parallel import licences for capsules are revoked⁴²⁰.
- (315) The previous year – on 11 September 1997 – AZ had already approached the SMPA with two questions: 1) “*will companies be able to parallel import Losec capsules with reference to MUPS?...*” and 2) “*If the answer is no, will the existing parallel importers be forced to cease sales immediately?*”⁴²¹. On 25 September 1997⁴²², the SMPA replies to the first question that under the national statutory provisions, a basic condition for parallel imports is that there exists a market authorisation for the reference product (the “*directly imported medicinal product*”) in Sweden and that there is thus no basis for the parallel trade licences in the absence of a marketing authorisation for the directly imported medicinal product. With regard to the second question, the SMPA explains that it can decide that certain sales of the parallel imported products may continue unless the withdrawal of the authorisation is related to reasons of health and efficacy. At the request of the parallel traders, the SMPA, following its decision on 1 September 1998 to deregister the capsules, decides that the parallel trade licenses remain in force for a further six months, i.e. until 30 June 1999⁴²³.
- (316) A number of parallel traders appeal the SMPA's decision to revoke the parallel trade licences to the Uppsala County Court claiming that such a revocation is incompatible with Articles 28 and 30 of the Treaty. This court rules in the parallel traders' favour by judgment of 7 December 1998⁴²⁴. However, AZ's appeal before the Administrative Court of Appeal (judgment of 26 February 1999) is successful⁴²⁵. Table 29 in the Annex reveals a rapid contraction in sales and market shares from 1998 to 1999 and 2000 suffered by the major parallel traders in Losec in Sweden.
- (317) The parallel traders bring their case before the Swedish Supreme Administrative Court. That Court suspends the judgment of the Administrative Court of Appeal with

⁴¹⁷ [5803].

⁴¹⁸ [5807].

⁴¹⁹ [7404, 7742, 7747].

⁴²⁰ [7428]. See also [5791].

⁴²¹ [5916].

⁴²² [5917].

⁴²³ [7145].

⁴²⁴ [5842].

⁴²⁵ [2173].

effect as of 1 June 1999⁴²⁶ and refers the issues to the Court of Justice. On 8 May 2003 the Court of Justice rules as follows: “*Article 28 EC and Article 30 EC preclude national legislation under which the withdrawal, at the request of its holder, of the marketing authorisation of reference of itself entails the withdrawal of the parallel imports of the medicinal product. However, those provisions do not preclude restrictions on parallel imports of the medicinal product in question if there is in fact a risk to the health of humans as a result of the continued existence of that medicinal product on the market of the importing Member States*”⁴²⁷.

- (318) A recent study has estimated the savings from parallel trade in Losec capsules in Sweden since the issuance of the first parallel import licence for 20 mg capsules in January 1997 (to Cross Pharma), taking account of the entry of further parallel importers and the launch of Losec MUPS⁴²⁸. The study breaks the savings for the period 1997-2000 into three parts. First, a saving of SEK 75 million per year derived from parallel import prices being 18-25% lower than the price of the original capsules before the parallel imports began⁴²⁹. Second, savings of SEK 13 million per year achieved from the lowering by AZ of its price for capsules by 10% (which the report assumes was aimed at meeting the lower parallel import prices). Third, savings of SEK 83 million per year due to AZ setting the price of Losec MUPS tablets 23% below AZ’s original capsule price (a price strategy which the report assumes is caused by the cheaper parallel imports). According to a study by the Riksförsäkringsverket (Swedish National Insurance Board) pharmaceutical costs fell by 1-1.5% in 1999 as a result of parallel trade⁴³⁰.
- (319) AZ’s national LPPS Strategy document for Norway shows that AZ was aware that its tablet/capsule switch and capsule deregistration action in one country where the strategy was implemented earlier (*in casu* Sweden) could affect its chances of achieving its result in a second country (*in casu* Norway) where the MUPS Strategy was implemented later (“*The issue is further actualized by the possible legal conflict between P.I. traders and the Swedish Health Authorities on the cancellation of the capsule license in Sweden. If the Swedish case is brought to the courts a negative impact may be assumed in Norway*”)⁴³¹.

Norway

- (320) **Generic authorisations:** Before the deregistration of Losec capsules takes effect, the complainant submits an application for generic omeprazole capsules. It obtains the market authorisation on 1 November 1999 and launches its generic product the same month⁴³². However, as in Denmark, a court injunction based on AZ’s formulation patent prohibits the marketing of the generic product in May 2000. The ruling is

⁴²⁶ Submission by the Swedish Government of 23 April 2001 to the Court of Justice in Case C-15/01 *Paranova Läkemedel a.o.* [7146].

⁴²⁷ Case C-15/01, *Paranova Läkemedel a.o.*, ECR [2003] I-4175.

⁴²⁸ [7085-7088].

⁴²⁹ One of the committees set up by the Swedish counties (which finance the reimbursement of pharmaceuticals in Sweden) notes in 1997 that replacing AZ’s original capsules with Cross Pharma’s parallel imports involves a saving for the patient of SEK 25-100, and twice as much for the Swedish health system [6741b].

⁴³⁰ [7078].

⁴³¹ [2284].

⁴³² [7404].

upheld by the Oslo City Court in November 2001⁴³³. On 2 July 2001 another generic omeprazole capsule product receives market authorisation by the Norwegian Medicines Control Agency (“NMCA”)⁴³⁴.

- (321) **Parallel trade:** Parallel imports of Losec capsules into Norway fall drastically from 1998 onwards (see table 28 in the Annex)⁴³⁵. They however do not cease, as envisaged by AZ in its Norwegian LPPS Strategy document from November 1998. In fact, the NMCA allows the parallel importation of Losec capsules to continue with reference to AZ’s market authorisation for Losec MUPS, as the MUPS authorisation is based on the capsule authorisation⁴³⁶.

Finland

- (322) **Generic registrations:** In May and August 2002 respectively, two omeprazole generic versions receive market authorisation in Finland⁴³⁷.
- (323) **Parallel trade:** On 8 October 1998, the Finnish Medicines Agency (“FMA”) notifies Paranova Oy, a parallel importer of Losec capsules, that it has revoked the parallel import licence as of 30 September 1998 because AZ has obtained the deregistration of its capsules. Paranova Oy brings a legal action against this revocation. This ultimately leads the Högsta Förvaltningsdomstolen (the Supreme Administrative Court) to refer questions to the Court of Justice which are largely similar to those which the Swedish Regeringsrätten had submitted to the same Court of Justice⁴³⁸. Indeed, for the relevant parts, the Court’s ruling in the Finnish Paranova case is similar to its ruling in the Swedish Paranova case (see recital (317)). Market share data show that parallel imports of Losec capsules ceased in 1999 and 2000⁴³⁹.

II. LEGAL ASSESSMENT

A. THE LEGAL FRAMEWORK: ARTICLE 82 OF THE TREATY AND ARTICLE 54 OF THE EEA AGREEMENT

- (324) Article 82 of the Treaty prohibits, as incompatible with the common market, any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it, insofar as it may affect trade between Member States. Article 54 of the EEA Agreement contains the same prohibition with regard to the EEA⁴⁴⁰. In

⁴³³ Scrip No 2693 7 November 2001, p. 3.

⁴³⁴ [7404].

⁴³⁵ According to information provided by the complainant parallel imports of Losec capsules amounted to NOK 77 million in 1998, NOK 8 million in 1999 and NOK 26 million in 2000 [5464].

⁴³⁶ See Scrip No 2494 of 1 December 1999, p. 4.

⁴³⁷ On all these dates, see in particular AZ’s reply to the Commission’s request for information pursuant to Article 11 of Regulation No 17 [7402-7404].

⁴³⁸ Case C-113/01, Paranova.

⁴³⁹ [10251].

⁴⁴⁰ Under Article 5 of Council Regulation (EC) No 2894 of 28 November 1994 concerning arrangements for implementing the Agreement on the European Economic Area “*the Community rules giving effect to the principles set out in Articles 85 and 86 [now Articles 81 and 82] of the EC Treaty [...] shall apply mutatis mutandis*” (OJ L 305, 30.11.1994, p. 6). The case law of the Court of Justice and the Court of First Instance in relation to interpretation of Article 82 of the Treaty applies equally to Article 54 of the

Article 54 of the EEA Agreement the reference to “*trade between Member States*” is replaced by a reference to “*trade between Contracting Parties*” and the reference to competition in “*the common market*” is replaced by a reference to competition in “*the territory covered by the ... [EEA] agreement*”.

- (325) It should be remembered that the existence of a dominant position means that, irrespective of the reasons which have led to such a position, the dominant undertaking or undertakings have a special responsibility not to allow their conduct to impair genuine undistorted competition on the common market.⁴⁴¹ This special responsibility also means that the onus is on such companies to behave in a way which is proportionate to the objectives they seek to achieve⁴⁴². This implies that conduct which may be permissible in a normal competitive situation may amount to an abuse if carried out by dominant firms. Undertakings in a dominant position may be deprived of the right to adopt a course of conduct or take measures which are not in themselves abuses and which would even be unobjectionable if adopted or taken by non-dominant undertakings.
- (326) The concept of abuse is an objective concept relating to the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.⁴⁴³ Similarly, the Court of Justice has held that the strengthening of the position of an undertaking may be an abuse and prohibited under Article 82 of the Treaty, *regardless of the means and procedure* by which it is achieved, and even irrespective of any fault⁴⁴⁴.
- (327) Whilst the fact that an undertaking is in a dominant position cannot deprive it of its entitlement to protect its own commercial interests, and whilst such an undertaking must be allowed the right to take such reasonable steps as it deems appropriate to protect those interests, such behaviour cannot be allowed if its actual purpose is to strengthen this dominant position and abuse it.⁴⁴⁵ Conduct that may otherwise be permissible even on the part of a dominant undertaking may be rendered abusive if its purpose is anti-competitive, in particular if it is part of a plan to eliminate

EEA Agreement. See Article 6 of the EEA Agreement, Article 3 (2) of the EEA Surveillance and Court Agreement, as well as Case E-1/94 of 16.12.1994, paragraphs 32-35.

⁴⁴¹ See Case 322/81 *Michelin v Commission* [1983] ECR 3461, paragraph 57; Joined Cases C-395/96 P and C-396/96 P *Compagnie maritime belge and others* [2000] ECR I-1365, paragraph 85; Case T-83/91 *Tetra Pak v Commission* [1994] ECR II-755, paragraph 114.

⁴⁴² See Joined Cases T-191/98 and T-212/98 to T-214/98 *Atlantic Container Line AB and others v Commission* [2003] ECR II-3275, paragraph 1120.

⁴⁴³ Case 85/76 *Hoffman-La Roche* [1979] ECR 46, paragraph 91.

⁴⁴⁴ See Case 6/72 *Europemballage and Continental Can v Commission* [1973] ECR 215, paragraphs 27 and 29; Case T-128/98 *Aéroports de Paris v Commission* [2000] ECR II-3929, paragraph 170 (emphasis added).

⁴⁴⁵ Case 27/76 *United Brands v Commission* [1978] ECR 207, paragraph 189; Case T-65/89 *BPB Industries and British Gypsum v Commission* [1993] ECR II-389, paragraph 69; upheld on appeal in Case C-310/93 P [1995] ECR I-865.

competition⁴⁴⁶. The acquisition of a right may amount to an abuse for the purpose of Article 82 if that right is acquired by an undertaking in a dominant position⁴⁴⁷.

- (328) The use of public procedures and regulation, including administrative and judicial processes, may also, in specific circumstances, constitute an abuse, as the concept of abuse is not limited to behaviour in the market only⁴⁴⁸ and misuse of public procedures and regulations may result in serious anticompetitive effects on the market. The fact that in such cases the effects in the market may be dependent on further action by public authorities is not decisive to exclude the existence of an abuse. Even when the behaviour is implemented in the market, the effect of exclusionary practices is often dependent on the subsequent reaction of other operators in the market (such as purchasers).

B. THE RELEVANT PRODUCT MARKET

1. SUMMARY OF AZ'S ARGUMENTS

- (329) In its Reply to the Statement of Objections, AZ argues that the Commission wrongly identifies the relevant markets in this case as being a number of national markets for oral prescription PPIs. In AZ's view, H2 blockers exercised a significant competitive constraint on PPIs throughout the relevant period in the markets concerned. In arriving at this conclusion, AZ essentially relies on the following four sources of evidence⁴⁴⁹.

(a) Medical evidence

Mode of action

- (330) AZ argues that the Statement of Objections overstates the importance of the mode of action for market definition purposes. In AZ's view, it is the therapeutic qualities of different classes of medicines which primarily determine prescriber behaviour⁴⁵⁰.

Therapeutic use

⁴⁴⁶ See for example Case C-62/86 *AKZO v Commission* [1991] ECR I-3359, paragraph 72 and Case T-111/96 *ITT Promedia v Commission* [1998] ECR II-2937, paragraph 30, as part of the Commission's arguments.

⁴⁴⁷ Case T-51/89 *Tetra Pak v Commission* [1990] ECR II-309, paragraph 23 and *ITT Promedia*, paragraph 139.

⁴⁴⁸ Case C-395/96 P and C-396/96 P *Compagnie maritime belge and others*, paragraphs 82-88; Case T-111/96 *ITT Promedia*; Commission Decision 92/262/EEC in Case IV/32.450 - *French-West African shipowners' committees* (OJ L 134, 18.5.1992, p. 1). Besides, in the examination of the possible abusive nature of contacts by undertakings with public authorities, the Court of Justice has drawn a distinction between requests from the public authorities in areas where they would have no margin of manoeuvre to act upon the request and "a simple attempt to influence the authority concerned in the exercise of its discretion". Case C-395/96 P and C-396/96 P *Compagnie maritime belge and others*, paragraph 82.

⁴⁴⁹ Unless otherwise stated, AZ's arguments, as they appear below, derive from AZ's reply of 3 December 2003 to the Statement of Objections. "AZ reply to letter of facts" refers to AZ's reply of 21 January 2005 to the Commission's letter of facts of 23 November 2004.

⁴⁵⁰ See also AZ reply to letter of facts, pp. 7, 12-13.

- (331) AZ claims that the Commission fails to take account of the fact that the vast majority of patients suffering from acid-related gastrointestinal diseases were treated in the primary care sector. Primary care clinicians viewed PPIs and H2 blockers as substitutes. In the early 1990s, prescriptions of PPIs were almost exclusively written by specialists and only for the more serious conditions.
- (332) AZ contends that the therapeutic superiority of PPIs was only recognised towards the end of the 1990s. Safety and potency fears related to Losec, the strong established position of the incumbent therapy (H2 blockers), as well as the general inertia characterising prescribing practice and the slow dissemination of clinical data explain, in AZ's view, the very limited use of PPIs by primary care physicians during the early 1990s, as well as the slow acceptance even among specialists.
- (333) The Commission's approach is simplistic in referring only to clinical perspectives at a single point in time after the end of the alleged period of dominance, when the evidence is clear in AZ's view that the period from 1991 to 2000 saw radical changes in the clinical approaches adopted. For each condition (PUD, GERD, RO, NSAID-induced ulcers and non-ulcer dyspepsia), AZ claims that it was only in the second half of the 1990s that PPIs became widely accepted.
- (334) AZ criticises the Commission for using an overly strict demarcation between various diseases and conditions considering that most prescriptions within the acid-related gastrointestinal field are written by general practitioners on a non-investigated basis rather than by specialists following an endoscopic investigation of the patient. Most doctors used an experimental approach involving a "step-up" procedure (starting with less potent medicines such as antacids) or a "step-down" approach (starting with the most potent medicines). AZ observes that in particular primary care physicians continue to view antacids, H2 blockers and PPIs as part of a continuum of acid neutralising and suppressing therapies of varying degrees of potency.
- (335) AZ argues that the Statement of Objections exaggerates the size of the patient population for which PPIs are needed and that such a patient population cannot, in any case, be isolated. AZ moreover claims that the incidence rate for a disease or condition in one country cannot be extrapolated to other countries. AZ furthermore claims that it has advanced the most relevant and compelling evidence on substitutability, namely evidence of actual prescribing practice⁴⁵¹.

(b) Contemporaneous business documents

- (336) In AZ's view, its internal contemporaneous documents (such as its Business Planning Commentaries) as well as the views then expressed by Glaxo and other observers contradict the Commission's assessment. In particular, the views expressed at the time confirm that H2 blockers and PPIs were competing products.
- (337) AZ asserts that the Commission, by relying on its Business Planning Commentaries (submitted as part of its Reply to the Statement of Objections), would appear to be accepting the probative value of AZ's evidence⁴⁵².

⁴⁵¹ AZ reply to letter of facts, p. 13.

⁴⁵² See 4.67 AZ Reply and AZ reply to letter of facts, p. 10.

(c) IMS report

- (338) According to AZ, the IMS report shows that PPIs and H2 blockers were, in fact, prescribed to a large cohort of patients on fundamentally the same medical grounds over the relevant period⁴⁵³.
- (339) AZ notes that both H2 blockers and PPIs were prescribed for the same micro-diagnoses, even if there are minor exceptions. There is a general trend across the different countries to prescribe more PPIs over time; however, this increase remains very gradual. There are very few instances of micro-diagnoses and countries where all patients with a certain micro-diagnosis are only (or almost uniquely) treated with PPIs towards the end of the period considered⁴⁵⁴.
- (340) In AZ's view, the fact that the PPI market has expanded in relative terms does not rule out the possibility that H2 blockers provide a significant competitive constraint.
- (341) In any case, AZ takes the view that volume (in particular measured in terms of the number of prescriptions) is a better reflection of competition in the pharmaceutical market than sales measured by value (on which the Commission primarily relies). The volume of H2 blocker sales remained relatively stable throughout the period, notwithstanding the entry of PPIs, with only a gentle decline in volumes during the second half of the 1990s in most countries. More specifically, AZ states that competition between PPIs and H2 blockers is for prescriptions and that, as a result, market share measured by volume is a much more informative measure of the outcome of that competition than market shares measured in value⁴⁵⁵. AZ also observes that the IMS Report uses "treatment days" as a measure when analysing market volume. This measure describes the actual number of days of treatment of a given type of therapy and is therefore the sales measure that most closely reflects patient usage⁴⁵⁶. AZ finds it noteworthy that in many countries the volume of treatment days for H2 blockers also increased⁴⁵⁷.
- (342) In its reply to the letter of facts AZ furthermore contends that the IMS data on which the Commission relies in its letter of facts (see recital (393)) do not support the relevant conclusions⁴⁵⁸. This is so, in AZ's view, as the IMS data in question relate to shares of PPI and H2 blocker prescriptions by micro-diagnosis – i.e. volume-based data - and do not include price or sales information⁴⁵⁹.

(d) Lexecon study

- (343) According to AZ the Statement of Objections overstates the importance of the price factor. First, the pharmaceutical sector is subject to a high degree of price regulation resulting in low cross price elasticities among branded products. Second, there is usually very limited price sensitivity on the part of the decision makers (i.e. the

⁴⁵³ See also AZ reply to letter of facts, p. 19.

⁴⁵⁴ See also AZ reply to letter of facts, pp. 15-16.

⁴⁵⁵ AZ reply to letter of facts, p. 15.

⁴⁵⁶ AZ reply to letter of facts, p. 15.

⁴⁵⁷ AZ reply to letter of facts, p. 15 (IMS Report, page 4).

⁴⁵⁸ AZ reply to letter of facts, pp. 15-17.

⁴⁵⁹ AZ reply to letter of facts, p. 16.

doctors) in pharmaceutical markets. Finally, the Commission failed to take into account the power of national buying organisations. AZ argues that competition in the pharmaceutical sector mostly takes place through non-price factors such as detailing activity to doctors, advertising in medical journals, funding of clinical studies, the dissemination of the findings of clinical studies to doctors, mailings to doctors, introduction of new presentation forms and a widening of the indications for which products can be prescribed.

- (344) In any case, the fact that prices for PPIs have generally been higher than those of H2 blockers over the same period does not mean that there is no scope for substitution between the products. The appropriate test would involve an assessment of substitution as a result of changes in relative prices, not an analysis of absolute price differences between products.
- (345) According to AZ, restrictions on the freedom to price mean that there will be very limited price variation over time. In AZ's view, price variations for individual brands will be mostly achieved through the introduction of new presentation forms that might have a different price per day of treatment. Moreover, AZ claims that price variation at the molecule (or category) level will on the other hand mostly be driven by composition effects due to the entry of new drugs.
- (346) In view of these features, AZ claims that the "SSNIP (small but significant non-transitory increase in price) test" needs to be refined. AZ claims that it has carried out such a refined SSNIP test taking account of the consensus approach in the economic literature, basing its assessment on a careful analysis of the available evidence on therapeutic substitution, prescribing patterns and changes in prescriptions due to changes in relative prices, advertising activity, entry of new products and other factors affecting sales.
- (347) AZ has commissioned a study undertaken by the economic consultant Lexecon. The study is an econometric estimation of the impact of specific competitive variables on the substitution among PPIs and H2 blockers in Germany and the United Kingdom⁴⁶⁰. AZ claims that the Lexecon study supports the hypothesis that H2 blockers constituted a significant constraint on PPIs in Germany and the United Kingdom.

Germany

- (348) The study's baseline model for Germany estimates the impact of different competitive factors on Losec's market share over time (in a market including PPIs and H2 blockers). Losec's market share is computed as the share of total days of treatment. The competitive factors include: (i) the price of Losec (excluding parallel trade versions); (ii) the (average) price of H2 blockers (excluding parallel trade versions); (iii) the entry of competing PPIs; (iv) the (average) price of competing PPIs, (v) the entry of generic omeprazole; (vi) the (average) price of generic omeprazole; (vii) details of Losec; (viii) (aggregate) details for H2 blockers; (ix) (aggregate) details for other PPIs; (x) details for generic omeprazole; (xi) the number of presentation forms

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The Lexecon study is based on IMS data from September 1991 to December 2000 for Germany and the United Kingdom (the only countries under consideration for which the requisite data is available). In the baseline regression of the study "Losec market share" is defined as the share of total days of treatment, which includes days of treatment with PPIs and H2 blockers.

for Losec (a new presentation is defined here as a new strength, e.g. 10 mg, 20 mg or 40 mg for Losec or a new presentation form, i.e. MUPS instead of capsules); (xii) the number of presentation forms for competing PPIs and (xiii) a time trend (capturing other relevant factors such as “word-of-mouth” among doctors and patients and the cumulative effect of detailing and advertising activity).

- (349) The main results of the study for Germany, as cited by AZ, are as follows. First, the entry of generic omeprazole had a very significant negative effect on Losec’s market share (a 30% lower market share in volume for Losec following generic entry as well as a cross price elasticity of 0.876 indicating that a 10% decrease in the relative price of generic omeprazole would trigger a 8.76% decrease in Losec’s market share). Second, competing PPIs constituted a very significant constraint on Losec’s market share (a lower market share by 13.3% in volume for Losec following entry of competing PPIs as well as a cross price elasticity of 0.58 indicating that a 10% decrease in the relative (average) price of competing PPIs would trigger a 5.8% decrease in Losec’s market share). Third, competing H2 blockers also caused a significant competitive constraint on Losec’s market share (a cross price elasticity of 0.22 indicating that a 10% decrease in the relative (average) price of H2 blockers would cause a 2.2% decrease in Losec’s market share). Fourth, the variable capturing the effect of the number of presentation forms for Losec and competing PPIs on Losec’s market share is not statistically significant and the same is true for the variables concerning detailing activity (i.e. promotional visits to doctors) for competing PPIs and H2 blockers. Fifth, the short-term impact of the detailing activity of Losec on Losec’s market share is negative. Sixth, the model also finds a significant (and positive) effect of long-term detailing activity (as captured by the time trend), so the results seem to indicate that while detailing has a long-term effect, it does not seem to also have an immediate effect.
- (350) AZ observes that Lexecon also ran a number of specification checks to assess whether the results might change if some of the underlying assumptions in the baseline model were adjusted. The results were found to be substantially stable.

The United Kingdom

- (351) The study contains an econometric study for the United Kingdom using the same competitive factors as for Germany, with the exception of the omission of variables for generic omeprazole (as such entry took place only after the relevant period) and the inclusion of a variable capturing the entry of the generic H2 blocker ranitidine in January 1997. AZ divides the results of the study into five parts.
- (352) First, H2 blockers were the main competitive constraint on Losec’s market share before the entry of generic ranitidine in January 1997 (cross price elasticity equal to 0.5 before January 1997). Moreover, Losec’s prices had a statistically significant effect on the market share of H2 blockers throughout the entire period. In addition, Losec’s market share increased after generic ranitidine was introduced partially because of the significant decrease in promotional activity for ranitidine after a generic ranitidine version became available.
- (353) Second, Losec sales do not seem to be negatively affected by the reduction in the (relative) price of ranitidine after 1997. AZ considers that the likely explanation for

this apparent anomaly reflects the generally low price elasticity in the United Kingdom because of the institutional features on the demand side.

- (354) Third, the analysis shows that short-term detailing of Losec had a positive effect on Losec's market share (a 10% increase in detailing increased Losec's market share by 4.2%).
- (355) Fourth, the increase in presentation forms for competing PPIs over time had a negative impact on Losec's market share. Moreover, the entry of competing PPIs had a negative effect on the market share of H2 blockers and a decrease in the (relative) price between competing PPIs and H2 blockers had a negative effect on the market share of H2 blockers, supporting AZ's thesis that PPIs and H2 blockers form part of the same market.
- (356) Fifth, all the variables implicitly captured by the time trend (e.g. "word-of-mouth" among doctors and patients) had a strong (and statistically significant) effect on Losec's market share.
- (357) AZ observes that Lexecon also ran a number of specification checks to assess whether the results might change if some of the underlying assumptions in the baseline model were adjusted. The results were found to be substantially stable.

2. RELEVANT PRODUCT MARKET – THE COMMISSION'S ASSESSMENT

- (358) In this section, the available information on the characteristics, use, sales and prices as well as other factors relevant to the competitive relationship between PPIs, H2 blockers and other medicines used for the treatment of acid-related gastro-intestinal diseases or conditions will be assessed in greater detail in points (a)-(f) below.

(a) The Commission's Notice on the definition of the relevant market

- (359) First, the Commission Notice on the definition of the relevant market for the purposes of Community competition law⁴⁶¹ ("the Notice on market definition") states that "*the main purpose of market definition is to identify in a systematic way the competitive constraints that the undertakings involved face*". More specifically, the objective is "*to identify those actual competitors of the undertakings involved that are capable of constraining those undertakings' behaviour and of preventing them from behaving independently of effective competitive pressure*" and "*demand substitution constitutes the most immediate and effective disciplinary force on the suppliers of a particular product, in particular in relation to their pricing decisions*".
- (360) Second, the Notice on market definition provides that an "*analysis of the product characteristics and its intended use allows the Commission, as a first step, to limit the field of investigation of possible substitutes*" but that this is not sufficient to determine whether two products are demand substitutes. Moreover, the Notice states that "*functional interchangeability or similarity of characteristics may not provide in themselves sufficient criteria because responsiveness of customers to relative price changes may be determined by other considerations also*". The type of evidence

⁴⁶¹ OJ C 372, 9.12.1997, p. 5.

relevant to assess whether two products are demand substitutes includes “*evidence of substitution in the recent past*”. When this type of evidence is available “*it will normally be fundamental for market definition*”. In defining the relevant product market, the Commission relies, in respect of all relevant years and jurisdictions, on such fundamental “*evidence of substitution*” in the form of IMS data, the validity of which is not contested by AZ.

- (361) Finally, the Notice on market definition states that supply-side substitutability may also be taken into account when defining markets in those situations in which its effects are equivalent to those of demand substitution in terms of effectiveness and immediacy (i.e. that suppliers are able to switch production to the relevant products and market them in the short term without incurring significant additional costs or risks in response to small and permanent changes in relative prices)⁴⁶².

(b) *Specific features of competition in the pharmaceutical sector*

- (362) While the Notice on the definition of the relevant market comprises all industrial sectors the assessment of the case in question needs to take due account of features specific to the pharmaceutical market differentiating this sector from other industries. One specific feature of the pharmaceutical market is the existence of a classification system in which products, i.e. medicines, are grouped according to their functional interchangeability, i.e. therapeutic indications. Furthermore, the market for pharmaceutical products is characterised by a high degree of public regulation, including the marketing authorisation as well as pricing and reimbursement rules of medicinal products. In addition, the demand side is characterised by a low degree of involvement by patients concerning their treatment. Another factor that has to be taken into account is the potential substitutability of medicines and/or therapies in day-to-day medical practice. A key feature relating to the demand side is that in their choice of medicines prescribing doctors are the main determinant of demand in pharmaceutical prescription markets (see recital (115)). Actual trends in the consumption of medicines prescribed therefore constitute a key factor in assessing competitive constraints between categories of medicines (see recital (360) above). Such trends often crystallise after a certain period of time due to inertia in doctors’ prescribing behaviour (see recital (115)). In choosing between different medicines prescribing doctors were, at the relevant period (see recital (130)), primarily guided by the therapeutic appropriateness and effectiveness of different medicines rather than by their price.
- (363) Second, since neither the key decision-makers on the demand side (the doctors) nor the ultimate consumers (the patients) bear the bulk of the cost for prescription medicines within the EEA, the public authorities have, by various mechanisms, instituted a high degree of price control (see recitals (117)-(127)). Typically the relevant authorities’ use of the different regulatory systems at their disposal follows negotiations with the pharmaceutical companies (see recital (118)). Some Member State authorities may be prepared to accept a higher price in order to reward and encourage innovation whereas other authorities place the emphasis on cost-containment. The advantages of the product in therapeutic terms as well as its cost-effectiveness will also be taken into account by those authorities (see recital (120)).

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See Notice on the definition of the relevant market, paragraph 20.

- (364) In any case, and contrary to AZ's assertions⁴⁶³, the fact that a new category of products initially receives a significantly higher price than other products used within the same therapeutic area, and maintains it over time, reflects a low degree of competitive pressure from those other products (see recitals (128) and (559)). Obtaining high initial prices from the authorities can be of particular long-term and strategic importance in the pharmaceutical sector (see recitals (298)-(301) and (532)).
- (365) A relatively higher price for a particular category of medicines may also to some extent be the result of the company's own decision in countries allowing free pricing (see recitals (117) and (129)). This also constitutes evidence of an absence of significant competitive pressure, especially if the firm is able to maintain its prices above the reimbursement level where demand tends to be more elastic. This is so as consumers generally bear this part of the costs (recital (119)). A firm's ability to obtain such high prices will be particularly strong to the extent that it can produce medical evidence suggesting that its product is necessary to adequately treat certain patient categories or medical conditions (see recitals (128) and (559)).
- (366) Third, the existence of large price differences between two classes of products strongly indicates that the public authorities have not referred to prices of one product class when setting the price or the reimbursement level of the other product class (see recitals (119)-(127)). This is especially true of countries such as Germany, the Netherlands, Denmark, Sweden and Norway applying so-called reference price systems for most of the relevant period in this case. Moreover, it appears that therapeutic substitution during the relevant period was non-existent or limited in the EEA Contracting Parties concerned (see recitals (131) and (297)). Absence of therapeutic substitution means that pharmacies were neither entitled nor encouraged to replace prescriptions for PPIs with cheaper H2 blockers. Absence of therapeutic substitution therefore strongly reduces cross price elasticity of demand between different categories of active substances used within the same therapeutic area.
- (367) More specifically, at the Oral Hearing on 17 February 2004, AZ accepted that differences in the relative therapeutic efficacy of medicines are taken into account by the relevant national authorities when determining prices, so that, for example, a class of therapeutically superior medicines could obtain a higher price than a class of therapeutically inferior medicines⁴⁶⁴ (see also recitals (120) *et seq.*)⁴⁶⁵. AZ went on to say that *"the determination of price by Member State authorities is based on value. In negotiating reimbursement levels with Member State authorities pharmaceutical companies have to provide what the industry calls a value pack or health economic justification. Whilst price is important in the reimbursement negotiations, so is the cost for the total treatment of the new product as compared to the cost of treatment by alternatives that are already available on the market. Those cost comparisons of treatment costs then form the basis of good faith negotiations with each competent national authority about price"*.

⁴⁶³ See 5.34, 5.38 AZ Reply.

⁴⁶⁴ Reply by Mr Martin Nicklasson. See AZ reply to letter of facts, pp. 38, 47.

⁴⁶⁵ This is also supported by studies of pharmaceutical pricing in Europe and the US which conclude that medicines characterised by a high degree of therapeutic innovation typically have higher launch prices, whereas medicines with less therapeutic value added – such as “me-too” products – typically enter the market at a lower price. See Z.J. Lu and W.S. Comanor: Strategic pricing in pharmaceuticals (*The Review of Economics and Statistics*, 80:1) and M. Ekelund and B. Persson: Pharmaceutical pricing in a regulated market (*The Review of Economics and Statistics*, 85:2).

- (368) At the same time it needs to be pointed out that throughout the 1990s the price factor has become an increasingly important competitive parameter in the EEA Contracting Parties in the sense that authorities by various cost-containment means put downward pressure on reimbursable (i.e. mainly prescription) medicines (see recitals (116)-(132)). Nonetheless, the degree of price correlation between different products - at least throughout the relevant period of this case – tends to be low as between different classes of active substances (such as H2 blockers and PPIs) (see recitals (75) and (347) on studies measuring the relationship between PPIs and H2 blockers in this case). The degree of price correlation tends in general to be stronger between different active substances within the same class (“me too” products such as the PPIs which entered the market after omeprazole). In general, the degree of price correlation is strongest as between products containing the same active substance (notably an original substance and its generic counterparts).
- (369) In summary, it appears from the above that different medicines’ characteristics and therapeutic uses and their relative therapeutic advantages constitute key factors in guiding the main decision makers’ (i.e. the doctors’) decisions. In turn, the same factors – as well as, in particular, cost-effectiveness – are key factors in determining the relative bargaining position of firms engaged in price negotiations with national buying organisations. These parameters of competition will be assessed under points (d) and (e) below.
- (370) It must be recalled that the relevant market is not determined on the basis that certain products competed against each other in a broad sense but on the basis of whether such products were sufficiently substitutable to significantly constrain each other’s market power, in particular as regards pricing. Moreover, a properly defined market does not need to include all functionally interchangeable products, as such interchangeability between products normally only defines the outer boundaries of a product market but may not be a decisive criterion. When products such as pharmaceutical products can be broadly used for the same purpose but differ in terms of price, quality, consumer preferences or other significant attributes, the products are considered to be differentiated. Although differentiated products may “compete” in some dimensions, a relevant market in competition cases should only include those products that are capable of significantly constraining an undertaking’s behaviour and of preventing it from behaving independently of an effective competitive pressure⁴⁶⁶.

(c) *The ATC System*

- (371) In the Anatomical Therapeutic Chemical (ATC) classification system, medicines are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Both the World Health Organization (WHO) and the European Pharmaceutical Market Research Association (EphMRA) maintain systems that classify medicines according to their therapeutic indications. Medicines are classified into groups at five different levels. The fourth ATC level normally takes into consideration the mode of action and the narrowest classes (individual active substances) are defined at the fifth ATC level. The third ATC level allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use. This level is generally used as the starting point for enquiring about

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See paragraph 3 of the Notice on the definition of the relevant market.

market definition in competition cases. However, it is appropriate to carry out analyses at other ATC levels if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level, and that, therefore, there are indications that the third ATC level does not lead to a correct market definition.

- (372) For the purposes of this case, it may be noted that the third ATC class “A2B” comprises “*drugs for treatment of peptic ulcer*”. Thus, this ATC class includes only one of the three main disease areas within the broad acid-related gastro-intestinal field (PUD, GERD and dyspepsia). Within the A2B category, five categories of medicines are mentioned: H2 blockers, prostaglandins (a form of mucosal strengtheners), PPIs, combinations for eradication of the H pylori bacterium and other drugs for treatment of peptic ulcer⁴⁶⁷. Antacids – i.e. medicines which neutralise acid – are mentioned as a separate third level group.

(d) *Product characteristics as evidence of competitive constraints*

- (373) In its previous decisions, the Commission has attributed great weight to differences between medicines’ *modes of action* (i.e. the manner in which they produce their therapeutic effects) in defining markets⁴⁶⁸.
- (374) The revolutionary nature of PPIs resides in their *direct* blocking effect on the proton pump in the stomach’s cells. It is this pump which causes ulcers and related conditions by injecting acid into the stomach. The uniqueness of the PPIs lies in that they directly block the source of acid secretion in the stomach, whatever the underlying indirect cause (histamine receptors, gastrin, caffeine etc.). Before PPIs came on to the market, the only medicines which were capable of proactively inhibiting acid-production in the stomach were the H2 blockers. However, they did so imperfectly because they acted *indirectly*; they targeted only one of several factors stimulating the acid-producing proton pump – the histamine receptors - without any direct impact on that pump itself (see recitals (34) and (37)). The difference in terms of mode of action is reflected in a difference in the structures of the chemical formulae of, on the one hand, the PPIs and, on the other hand, the H2 blockers (recital (87)).
- (375) Nor do other medicines for the treatment of acid-related gastro-intestinal diseases or conditions directly block the source of the acid-production in the stomach which causes these diseases or conditions. They essentially strengthen the mucosal defences (cytoprotective agents), facilitate the evacuation of the stomach contents (prokinetics), neutralise acid (antacids) or form a protective layer against acid reflux (alginates) (see recitals (31)-(33)).
- (376) As a result, the PPIs have a mode of action which is fundamentally distinct from that of the H2 blockers and – even more so – from those of other categories of medicines used within the field of acid-related gastrointestinal diseases or conditions.

⁴⁶⁷ The group “combinations for eradication of the H pylori bacterium” is only listed in the Guidelines from 2000 but not in the Guidelines from 1993 and 1996 [6739d, 207, 6740d].

⁴⁶⁸ See Case No COMP/M.1397 – Sanofi/Synthelabo, point 30, Case No COMP/M.1403 – Astra/Zeneca, point 36, and Case No COMP/M.2922 – Pfizer/Pharmacia, point 29.

- (377) This direct blocking action which is unique to the PPIs is strongly linked to the therapeutic superiority of the PPIs over the H2 blockers and, whilst insufficient by itself to determine the market (see recital (360) above), supports a relevant product market comprising only PPIs. In fact, in its internal documents AZ strongly emphasises the key importance of Losec's unique mode of action in relation to the competition⁴⁶⁹.
- (378) In view of the above and contrary to AZ's submissions (see recital (330)), the Commission regards the mode of action in this case as a key product characteristic which determines the relative therapeutic effectiveness and appropriateness of PPIs and H2 blockers. In this case, the Commission does not attribute independent significance to the mode of action in the sense that this factor alone suffices to establish a separate PPI market. In line with the Notice on market definition, the Commission has conducted a classic market definition exercise basing itself on an overall assessment of in particular product characteristics, product uses, demand and price factors (recital (360)).
- (379) Based on extensive evidence (see recitals (374)-(377) above), the Commission has concluded that the PPIs' mode of action explains the perception of their therapeutic superiority vis-à-vis H2 blockers and other categories of medicines. By and large, the PPIs tend to cure more patients than the H2 blockers and they tend to cure them more rapidly (recital (382)).

(e) Therapeutic uses as evidence of competitive constraints

- (380) Another important parameter for the definition of pharmaceutical product markets is the products' therapeutic uses. The Notice on market definition, at point 36, refers to "*functional interchangeability*" among products.
- (381) In determining the functional substitutability of medicines it is not enough, for the purposes of product market definition, to state that different medicines are prescribed for the same general illness or disease. In its previous decisions, the Commission has established that varying degrees of efficiency and appropriateness of different medicines can be a factor in defining separate and thus possibly narrower product markets⁴⁷⁰. This finding does, however, not entail the consequence that new, innovative medicines are automatically defined as new and separate product markets.
- (382) The file in this case contains ample evidence showing that PPIs were considered, in particular by virtue of their singular mode of action, therapeutically superior to H2 blockers and *a fortiori* to other medicines used for the treatment of PUD, NSAID-induced ulcers, Zollinger-Ellison syndrome, GERD (and in particular RO and related complications) as well as dyspepsia. Compared to other available medicines, PPIs manifestly appear to yield superior results in terms of symptomatic relief, cost effectiveness, healing rates and long term treatment/prevention of recurrence. In a significant number of cases involving PUD, NSAID-induced ulcers, Zollinger-Ellison-syndrome, GERD/RO and dyspepsia, PPIs are deemed to provide the only effective

⁴⁶⁹ Vol 2, Annex 4.12.3, pp.18 and 19; Vol 2, Annex 4.12.4, p.10 (in section "Losec"); Vol 2, Annex 4.12.6, p.10 AZ Reply (in section "establishing the therapeutic standard in the post-H2 era").

⁴⁷⁰ Case No COMP/M.1397 – Sanofi/Synthelabo, point 31.

remedy. In these respects, reference is made to recitals (37)-(47) and the various studies or AZ documents they refer to.

- (383) As regards this body of evidence, reference is, in particular, made to a detailed AZ publication from 1998 (see recital (38)) attesting to omeprazole's – and, by extension, the PPIs' – superiority over other classes of medicines (including H2 blockers) used in respect of the three main diseases and conditions (PUD, GERD and dyspepsia) within the gastrointestinal acid-related disease area. The fact that some 80 scientific sources supporting the findings of this publication date from 1994 or much earlier strongly suggests that this therapeutic superiority was well recognised by the scientific community by 1993 (i.e. when the conduct by AZ which is relevant to this Decision started). This conclusion is supported by an internal AZ document from the early 1990s stating that clinical use of Losec has been documented for more than ten years' time in clinical studies on around 30 000 patients⁴⁷¹. In the context of GERD, it may also be noted that AZ in its marketing has relied on scientific articles from 1994 which refer to considerable clinical experience advocating the use of omeprazole against severe RO as well as demonstrating omeprazole's superiority over ranitidine (a H2 blocker) in all cases of RO, including the milder grades (see recital (37)).
- (384) Moreover, another significant difference in the use of the two product categories is the fact that while H2 blockers were available on a non-prescription basis (OTC) during the relevant period in this case, only one strength of one PPI (10 mg Losec MUPS) was sold OTC in one country (Sweden) during part of the last year of the relevant period (as of April 2000) (see recital (68))⁴⁷². Indeed, AZ's internal documents concerning the early 1990s indicate that the switch to H2 blockers sold OTC resulted at least in part from competitive pressure from Losec forcing the H2 blocker firms to focus on milder "downstream" conditions for which antacids and alginates have traditionally been used (see recital (490)).
- (385) The very fact that AZ was able to extract a much higher price than H2 blockers, taking into account that public authorities assess the value of products in terms of therapeutic innovation, is also an indication that PPIs, of which Losec constituted the pioneer medicine, were perceived as therapeutically superior.
- (386) In conclusion, the available evidence on the file indicates that there is a significant patient population for which only prescription PPIs provide a sufficiently appropriate and effective response to their PUD, GERD/RO, dyspepsia, NSAID-induced ulcer and Zollinger-Ellison syndrome conditions. This conclusion is substantiated by actual prescribing practice in all jurisdictions which demonstrates that doctors increasingly – across the entire disease spectrum – considered that PPIs constituted the most effective and appropriate remedy (see recital (393) below for a more detailed account of actual prescribing practice). This trend is also consistent with the evidence attesting to the superior cost-effectiveness of PPIs compared to H2 blockers (see recitals (37)-(38)).
- (387) AZ's arguments to the contrary based on external medical sources and prescribing practice are unconvincing.

⁴⁷¹ The document [2581] covers Astra's operations for the year 1991, for which reason it is assumed that the document dates from no later than 1992.

⁴⁷² The IMS data contained in the CD-Rom referred to at [10316] shows that AZ's OTC sales of 10 mg Losec MUPS made up at the very most around 4% of AZ's total sales of Losec MUPS in Sweden during 2000.

- (388) First, AZ relies on the medical evidence in order to show that the increase in use of PPIs over the relevant period was a gradual process. This assertion and the factors adduced by AZ in support thereof (inertia in prescribing practice, safety fears concerning Losec etc.) are not inconsistent with the conclusions that the Commission draws from the objectively verifiable trends in demand for PPIs and H2 blockers on the relevant markets (see recitals (360) and (401)). Indeed, the gradual – but regular and significant – trend in favour of PPIs is one of the key arguments supporting the conclusion that H2 blockers have not exercised a significant competitive constraint on PPIs (see recital (401)). The fact that the trend in favour of PPIs was gradual does not imply that H2 blockers exerted a significant competitive constraint on PPIs (see also section (f) below). Indeed, the Commission guidelines on the applicability of Article 81 of the Treaty to horizontal cooperation agreements state that if research and development efforts have resulted in significant change of an existing product or even a new product replacing an existing one, substitution with the existing products may be imperfect or long term⁴⁷³. Consequently, the guidelines find that the old and the potentially emerging new products are not likely to belong to the same relevant market. Subjective views of market conditions should be taken into account for the purposes of market definition only to the extent that such views are sufficiently backed by factual evidence⁴⁷⁴.
- (389) Second, AZ’s assertion that PPIs only tended to be used for the more severe conditions, diseases and symptoms is also consistent with a relevant product market comprising PPIs only. Indeed, the concept of the “step-up” or “step-down” approach implies by its very nature a hierarchy of medicines used in the treatment of acid-related gastrointestinal conditions, diseases and symptoms. Under this approach, PPIs, being the most potent of the medicines in this hierarchy by virtue of their specific and direct mode of action, constituted either the first line treatment (“step-down”) or the treatment of “last resort” (“step-up”) for GERD, non-investigated dyspepsia and – prior to the use of *H. pylori* eradication therapy – for PUD. Indeed, in internal documents dating from the start of the relevant period in this case, AZ states that Losec was increasingly prescribed following H2 blocker failure or as first-line treatment in place of H2 blockers⁴⁷⁵.
- (390) Third, the fact that most treatments of acid-related gastrointestinal conditions or symptoms were carried out on a non-investigated basis at the primary care level and the fact that several of these conditions and symptoms cannot be strictly demarcated, do not rebut the evidence on the actual developments on the markets concerned.
- (391) Fourth, the same consideration applies to AZ’s assertion that it is not possible to define with exactitude the number of patients for which PPIs are required. A key argument for determining the existence of significant constraints between classes of products is the actual demand trends, i.e. the prescribing practice in the relevant markets over time, rather than *ex ante* assessments of the number of patients for which a particular medicine may hypothetically be required.

⁴⁷³ OJ C 3, 6.1.2001, p. 2 at paragraph 45.

⁴⁷⁴ See paragraph 40 of Notice on the definition of the relevant market.

⁴⁷⁵ Vol 2, Annex 4.12.5, p. 5 (in section “Losec (omeprazole)”); Vol 2, Annex 4.12.6, p.1 (in section “Losec (omeprazole)”); Vol 2, Annex 4.12.6, p.5 AZ Reply (in section “Losec (omeprazole)”).

- (392) Fifth, AZ's claim that the fact that H2 blockers and PPIs have both been prescribed across a wide range of microdiagnoses in the relevant markets is by itself insufficient to demonstrate that H2 blockers and PPIs belong to the same relevant market. As stated it is the trend – i.e. increasing demand for PPIs and decreasing demand for H2 blockers in a growing market - which is one of the key arguments for determining the existence of competitive constraints and therefore the relevant market (recital (360)).
- (393) In any case, the IMS report confirms at a disaggregated level (by diagnosis) the trends at the aggregate level (all diagnoses) summarised at recitals (386) and (401). Over time, the same pattern is found in all relevant markets (except Denmark for which the IMS study does not provide data on prescriptions by diagnosis). Relatively speaking, the PPIs expand across virtually all diagnoses whereas H2 blockers contract across virtually all diagnoses⁴⁷⁶. For the same reasons, the gradual shift towards PPIs at the expense of H2 blockers, as evidenced in the practice-specific study for the United Kingdom for 1996-2000, is not inconsistent with a market comprising PPIs only. Rather, it confirms it.
- (394) AZ's Reply and the IMS report rely largely on volume data. Specifically, AZ asserts that volume (in particular measured in terms of the number of prescriptions) is a better reflection of competition in the pharmaceutical market than sales measured by value. AZ's contention cannot be accepted. The products at stake in this case are differentiated in nature (e.g. in terms of dosage forms, pack sizes and strength). For such products sales in value and their associated market share will – according to the Notice on market definition – usually better reflect the relative position and strength of each supplier⁴⁷⁷. This guidance is also relevant to the pharmaceutical sector. Considering the differentiated nature of the products in terms of e.g. strengths and pack sizes different prescriptions are not necessarily comparable. Sales in terms of value therefore better reflect the position on the market than the number of prescriptions written by doctors. The Lexecon study provided by AZ clearly recognises the relevance of product differentiation in the context of acid-related gastrointestinal diseases (see recitals (345) and (347) above). In addition, the fact that PPIs generally heal more quickly than H2 blockers (see recital (382)) means that measuring significant competitive constraints in terms of treatment days is a less reliable variable than the number of prescriptions and – in particular – sales in value terms.
- (395) In any case, the IMS data on sales in terms of prescriptions (especially in percentage terms) broadly reveal the same patterns – although in somewhat less acute form – as the IMS data on sales value⁴⁷⁸. In point (f) below the Commission will analyse the price and sales trends for H2 blockers and PPIs.
- (396) The Commission agrees with AZ's submission (recital (335) above) that the data on actual prescribing practice in the IMS Report provided by AZ in its Reply constitute key evidence for the purpose of defining the market in this case. Contrary to AZ's allegation, the Commission is not ignoring this evidence. The Commission simply

⁴⁷⁶ For Belgium 1991-2000 see figures 5.13-15; for Germany 1991-1998 see figures 8.13-14; for the Netherlands 1991-2000 see figures 9.13-15; for Norway 1992-1996 see figures 10.13-14; for Sweden 1992-2000 see figures 11.13-15 and for the United Kingdom 1992-1999 see figures 12.13-15.

⁴⁷⁷ See Notice on the definition of the relevant market, paragraph 55.

⁴⁷⁸ Figures 5.3-4 (Belgium); 8.3-4 (Germany); 9.3-4 (Netherlands); 10.3-4 (Norway); 11.3-4 (Sweden); 12.3-4 (United Kingdom).

draws different conclusions from the raw data than AZ (see recitals (388)-(393) and (401)). Incidentally, AZ's argument in its reply to the letter of facts that actual *ex post* evidence of prescribing practice constitutes the "most compelling" evidence for the purpose of market definition in this case (see recital (335)) contrasts with its argumentation in its Reply to the Statement of Objections to the effect that such *ex post* evidence does not prevail over evidence in the form of the contemporaneous views of competitors and the medical community at the time.

- (397) In short, whereas AZ takes a static approach to the market definition (focusing on whether there is demand for both PPIs and H2 blockers for a particular diagnosis at a given moment in time, the Commission prefers to take a dynamic view, analysing the trends in usage and demand patterns in relation to PPIs and H2 blockers as they unfold over the relevant period (see recitals (388)-(393) and (401)). A significant competitive constraint (the decisive criterion for defining markets in competition cases) is a phenomenon which can only be observed over time. This dynamic approach is supported by the Notice on market definition which attaches particular significance to evidence of substitution in the recent past (see recital (360)).
- (398) Moreover and contrary to AZ's assertion⁴⁷⁹, the Commission does not suggest that the IMS Report defines a discrete – i.e. distinct - PPI market. The IMS Report does not purport to define a relevant product market pursuant to Article 82 of the Treaty. The Commission does, however, consider that the market trends emerging from data provided in the IMS Report on prescription at a disaggregated (diagnosis-specific) level support the finding of a distinct PPI market in the EEA Contracting Parties concerned.
- (399) The Commission also takes issue with AZ's contention that as the IMS data in question are shares of PPI and H2 blocker prescriptions by micro-diagnosis, it does not support the conclusions that the Commission draws from IMS data on price or sales information⁴⁸⁰. In reality, both measurements reveal different aspects – value and volume - of the demand for PPIs and H2 blockers. The diagnosis-specific data in the IMS Report confirms the general trend of increasing demand for PPIs and decreasing demand for H2 blockers whether measured by value or volume (see e.g. recital (401)).

(f) Demand, price and non-price factors of competition as evidence of competitive constraints in the relevant market

- (400) In line with the Notice on market definition, this section examines actual demand in terms of sales, in particular in relation to prices, whilst taking account of the specificities of the pharmaceutical sector (see recitals (360) and (362)-(369)). An overall assessment is set out in recitals (401)-(408)) followed by country-by-country assessments in recitals (409)-(457).
- (401) The price and sales trends between 1991 and 2000 for the PPIs on the one hand, and for PPIs as compared to H2 blockers on the other hand, yield the following broad conclusions. First, PPI sales have grown dramatically in absolute terms during 1991-2000; over the same period, in absolute terms, H2 blockers sales have in general fallen

⁴⁷⁹ AZ reply to letter of facts, p. 15.

⁴⁸⁰ AZ reply to letter of facts, p. 16.

significantly, in some cases they have stabilised, and in exceptional situations they have increased (see tables 9-16 in the Annex as well as recital (48)). Second, in every country (except the Netherlands) sales of H2 blockers decrease for the first time in 1993 (by 8% to 26%). Third, in relative terms, PPI sales increase compared to the total sales of PPIs and H2 blockers during each and every year in the period 1991-2000, in every country relevant to this decision, without exception. Fourth, and significantly, in most markets the greatest increase of PPI sales as a percentage of overall PPI and H2 sales took place during the early years of the relevant period (especially in 1993 and 1994). Fifth, prices for PPIs have in general been significantly higher than those of H2 blockers during 1991-2000 (tables 1-7). Sixth, the price of generic versions of omeprazole has had the strongest impact on demand for AZ's omeprazole (and other PPIs)⁴⁸¹. Seventh, prices of other PPI products are apparently also capable of constraining, to some extent, demand for AZ's omeprazole (see tables 31-37). Eighth, the generally much lower prices for H2 blockers have – for most of the ten-year period 1991-2000 – not exerted a significant competitive constraint on the demand for omeprazole (or other PPIs). Tables 17-23 in the Annex which set out sales figures in volume (in terms of 28-day treatment courses) confirm the upward trend for PPI sales and the downward – or at best – stagnating trend for H2 blocker sales (see also recitals (64)-(65)).

- (402) One significant price constraint that PPIs have faced which they have in common with H2 blockers is the increased pressure on prices exerted by national public authorities (see recitals (70) and (116)-(131)).
- (403) It should be noted that supply-side substitutability (see recital (361)) is not taken into account in this case considering that, in this case, its effects are not equivalent to those of demand substitution in terms of effectiveness and immediacy. This is so considering the long period required to develop pharmaceutical products as well as the need to avoid infringing the patent protection of the incumbent company (in this case AZ) (see recitals (517) *et seq.*).
- (404) In the assessments in respect of the relevant EEA Contracting Parties below references will be made to two studies on the case file. First, AZ provided, as part of its Reply, an econometric study (“Lexecon study”) purporting to prove that the relevant market in this case in Germany and the United Kingdom comprised both PPIs and H2 blockers. The methodology and results of the Lexecon study are also addressed at a specific section below (recitals (458)-(487)).
- (405) Second, the complainant submitted a study on possible demand-side substitution between PPIs and H2 blockers (“Correlation study”). The study examines the correlations between relative prices and market shares in six markets relevant to this case purporting to show that PPIs and H2 blockers do not form part of the same relevant market (see recitals (75)-(76)).
- (406) Reference has already been made to the particular significance of absolute price differences between different product categories in pharmaceutical markets as evidence of absence of significant competitive constraints exerted by a much cheaper category of medicines (see recitals (362)-(366)). On the other hand, while the effect of

⁴⁸¹ During the period 1991-2000 only one generic PPI product (omeprazole) was marketed (in Germany as from April 1999).

relative price differences (especially between different categories of molecules such as PPIs versus H2 blockers) matters relatively speaking less as a competitive parameter in pharmaceutical prescription markets, price competition has become increasingly important during the 1990s in the EEA, chiefly as a result of cost-containment measures imposed by the public authorities (recital (368)). Therefore, despite the relatively low cross price elasticity of demand between different product categories in pharmaceutical prescription markets, the effect on demand substitution of changes in relative price differences between PPIs and H2 blockers examined by the Correlation study submitted by the complainant is not irrelevant for determining whether PPIs or H2 blockers form part of the same or distinct markets. The results of the Correlation study are therefore referred to below. It should be underlined, however, that the Correlation study suffers from a number of methodological weaknesses. Most importantly, the study does not take into account the specificities of pharmaceutical prescription markets (see section 2 (b) above). Furthermore, the study does not take into account key natural events such as the entry of generic H2 blockers or other PPIs. This could potentially lead to a bias in the estimated coefficients.

- (407) It is emphasised that both the Correlation study and the Lexecon study constitute subsidiary sources of evidence in this case, with the exception of the effects of certain actual events (“natural events”) (see recital (421)) in Germany and the United Kingdom described in the Lexecon study. The Lexecon study is more sophisticated than the Correlation study *inter alia* in that it considers several possible parameters of competition apart from the price factor. It will be shown that neither study rebuts the Commission’s finding of a distinct PPI market in the relevant EEA countries concerned.
- (408) It should also be noted that the relevant EEA markets in this case (Belgium, Denmark, Germany, the Netherlands, Norway, Sweden and the United Kingdom) are distinct geographic markets for the purposes of this case, notwithstanding the similar patterns in terms of demand and prices that can be observed in those countries (see recital (503) below). For this reason it is necessary to take market developments and other relevant factors on each respective market into account.

Belgium

- (409) Tables 1, 9 and 16 in the Annex show a clear one-way substitution pattern in the context of an overall growing market. H2 blocker sales fall by 25% in 1993 and again by 16% in 1994. During the same period, PPIs sales more than double. In fact, in relative terms, PPIs expansion compared to the overall sales of H2 blockers and PPIs reaches its highest level in the whole decade in 1993 and 1994 (see table 16, which shows that PPIs share of the total sales went up from 24% to 38% and 54% respectively in 1992, 1993 and 1994). As early as 1994, PPI sales already largely exceed those of H2 blockers. 1995 is the only year when H2 blockers sales increase in absolute terms (from USD 35.5 to USD 39.5 million). However, the level of sales of H2 blockers that year remains largely below its 1992 level. In addition, the sales increase of H2 blockers of around 10% from 1994 to 1995 appears limited compared to the 37% increase in sales of PPIs over the same period (from USD 41.8 million to 57.1 million). Furthermore, H2 blocker sales in 1995 are already significantly lower than those of PPIs. All in all, PPIs sales increased from USD 25.5 million in 1993 to

USD 83.8 million in 2000, while H2 blocker sales decreased from USD 42.2 million to USD 15.8 million.

- (410) During 1991-1995, PPI prices exceeded H2 blocker prices by 43-45%. Even at their lowest (1996 and 1998-1999), the price differences remain significant (31-33%).
- (411) For Belgium the Correlation study concludes that, on the sole basis of the correlation coefficients (+0.15), there is *prima facie* no substitution between PPIs and H2 blockers (see recital (76)).
- (412) In view of the foregoing trends, it can be established that a PPI market existed in Belgium from at least 1993 until at least 2000.

Denmark

- (413) Tables 2, 10 and 16 in the Annex illustrate a very clear trend. From 1992 to 2000, PPI sales constantly and regularly increase; they grow by more than four times (from USD 8.9 million to USD 37.8 million). During the somewhat shorter period (1992 to 1999), H2 blockers sales constantly decrease, without any exception; in 1999, the sales represent 30% of the level reached in 1992. In percentage terms, the growth of PPI sales is especially pronounced in 1992-1993 (from 30% to 39% of all PPI and H2 blocker sales), 1993-1994 (39% to 49%), 1994-1995 (49% to 61%) and 1995-1996 (61 to 74%). PPI sales equal those of H2 blockers as early as 1994.
- (414) Furthermore, PPI prices exceed H2 blocker by a very considerable amount during the entire period. During 1991-1995 the price difference is at its lowest in 1993 (but still very high at 77%) and at its highest in 1991 (109%). In the period 1996-1999 the price gap widens to 163-211%.
- (415) These clear-cut trends are in line with AZ's perception, as expressed in a strategy document dated 2 November 1998 relating to Denmark, that lansoprazole (a PPI) is the only major competitor in that country (see recital (99)).
- (416) For Denmark the Correlation study concludes that, on the sole basis of the correlation coefficients (0.88), there is *prima facie* no substitution between PPIs and H2 blockers (see recital (76)).
- (417) In view of the foregoing, it can be established that a PPI market existed in Denmark from at least 1993 until 1999, the last year for which market data is available for Denmark.

Germany

- (418) In Germany (see tables 3, 11 and 16 in the Annex), PPI sales rise each year in absolute terms (from USD 73 million in 1991 to USD 388.5 million in 2000), with the exception of 1993; during that year, sales decrease by approximately 8% (from USD 112 million to USD 103 million)⁴⁸². H2 blocker sales decrease by more than one-

⁴⁸² Germany introduced a uniform 5% reduction on the ex-manufacturer price of all prescription products in January 1993. See Lexecon study, p. 11.

quarter in 1993. They increase again in 1994; however, the level of the increase remains largely inferior to the increase in PPI sales that year. From 1995 onwards, H2 blockers sales fall significantly. In 2000, they represent less than a third of the 1994 level. All in all, over the entire period (1991-2000), PPIs capture an increasing share of overall PPI and H2 blocker sales. This increase is particularly marked in 1994-1995 (32% to 42%) and 1995-1996 (42% to 57%). By 1996, the sales of PPIs largely exceeded those of H2 blockers.

- (419) A clear price trend in three phases can be detected in Germany. During the first phase (1991-1992) the price gap remains relatively narrow ranging between 3% in 1991 and 7% in 1992. During the second phase (1993-1995), the gap increases to the range 12-15%. In a third phase (1996-2000), PPI and H2 blocker prices begin to diverge dramatically. In 1996, the price gap increases by more than five times to 67%. Thereafter – in 1997-2000 – PPI prices exceed H2 blocker prices by 137% to 219%.
- (420) As mentioned, AZ provided an econometric study (“Lexecon study”) purporting to prove that the relevant market in this case in *inter alia* Germany comprised both PPIs and H2 blockers. However, it is striking that the conclusions of the study are not in line with certain key events on the German market as evidenced in the figures contained in the report. Below a number of events – the entry of the second PPI (pantoprazole) in 1994, the introduction of generic H2 blocker ranitidine in 1995 and the introduction of generic omeprazole in 1999 – will be described.
- (421) These “natural events” constitute important evidence of the existence of significant competitive constraints on the market as they allow for testing of AZ’s hypothesis of a common relevant product market containing PPIs and H2 blockers. Indeed, paragraph 38 of the Notice on market definition states, in the section dealing with evidence to be used when defining markets in competition cases, that “[i]n certain cases, it is possible to analyse evidence relating to recent past events or shocks in the market that offer actual examples of substitution between two products. When available, this sort of information will normally be fundamental for market definition”.
- (422) First, the launch of a PPI pantoprazole in September 1994 in Germany was accompanied by a reduction in the price of Losec of 16%, without significantly affecting the slowly falling trend in the price level of H2 blockers (figures 1 and 3 of Lexecon study).
- (423) The second “natural event” concerns the market entry of generic H2 blocker ranitidine in 1995. It is clear from figure 3 of the Lexecon study that the introduction of generic ranitidine in August 1995 put strong downward pressure on H2 blocker prices; over a period starting just before entry of generic ranitidine in August 1995 and ending three months later, H2 blocker prices declined by roughly 40%. The prices of Losec and of the other PPIs however remained unaffected and total PPI sales continued to grow rapidly. The impact of generic H2 blockers on H2 blocker prices – as opposed to PPI prices - is logical considering the existence of a reference price system in Germany including generic products within the same “cluster” as the original version (see recitals (119) and (123)).
- (424) Third, at figure 5 the IMS data reveal a sharp increase in promotional activity – measured in detailing activity – in the H2 blocker segment shortly before as well as a sharp decrease in detailing shortly after the introduction of generic ranitidine.

However, the entry of generic ranitidine did not cause any effect on either promotional activities or the market shares of PPIs (see also figures 2 and 3). This is clear evidence that an increase in competition between H2 blockers – both in terms of prices and promotional activity – had no spill-over effect into the PPI market. Hence, this “natural event” corroborates the existence of a distinct PPI market in Germany, at least at that point in time.

- (425) Fourth, the launch of generic omeprazole in Germany as of April 1999 had a very significant effect on the volume of Losec sales as well as on Losec’s market share. As can be seen from figure 4 in the study, the entry of generic omeprazole resulted in a decline in Losec’s sales volume of around 60% and a drop in market share (in volume) of around 65% in approximately five months. While the effect of the entry of generic omeprazole on Losec was most pronounced, all PPI firms lost market share. This result is worth highlighting given the constant positive trend in market share for those firms before entry of generic omeprazole (see figure 3). The entry of generic omeprazole clearly put downward pressure on the volume of the other non-generic PPIs (figures 3 and 4). This “natural event” clearly demonstrates that Losec was not constrained by H2 blockers nearly as much as by the closest substitute, i.e. generic omeprazole – at least not at this point in time.
- (426) Taken together, these natural events, which reveal actual developments on the German market in response to entry of respectively cheaper H2 blockers and PPIs, constitute very strong cumulative evidence that any competition from H2 blockers did not significantly constrain PPIs in Germany. The clear-cut nature of the effects of these events strongly indicates that the absence of significant competitive pressure exerted by H2 blockers existed before September 1994 and August 1995, i.e. the points in time when those events – i.e. the entry of significantly cheaper H2 blockers and PPIs – occurred. Indeed, the nature of the underlying regulatory system for determining the reimbursement price – i.e. the reference price system – did not change from 1993-1995 (see recital (123))
- (427) As regards the first natural event, AZ argues that the effect or lack thereof of pantoprazole’s entry in Germany on Losec and H2 blockers does not necessarily imply that other products do not exercise a significant competitive constraint⁴⁸³. AZ claims that while national and regional governments have introduced price competition at the intra-molecular level (i.e. between bioequivalent products) they have usually found it extremely difficult to introduce price competition at the inter-molecular level with the exception of “me-too” products (such as pantoprazole) with a very similar therapeutic profile to the pioneer product. Consequently, according to AZ, any such price competition as there may have been between PPIs and H2 blockers in Germany has mainly taken place through more indirect routes (such as the drafting of prescribing guidelines where both therapeutic efficacy and cost were taken into account).
- (428) In the Commission’s view, AZ’s submissions effectively confirm that Member States have usually found it extremely difficult to introduce price competition at the inter-molecular level (e.g. between PPIs and H2 blockers) (see recital (366)) with the exception of products with a very similar therapeutic profile to the pioneer product. Moreover, AZ does not claim that there has been price competition between PPIs and H2 blockers in Germany (“*any such price competition as there may have been*”). AZ’s

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AZ reply to letter of facts, p. 22.

reply to the letter of facts therefore rather supports the Commission's conclusion in respect of the existence of a separate PPI market in Germany (and in other Member States).

- (429) As regards the second natural event, AZ notes that mechanisms involving incentives for doctors and pharmacists to substitute more expensive versions of an off patent product with its generic equivalents caused the price of H2 blockers to sharply decrease following the introduction of generic ranitidine⁴⁸⁴. AZ observes that competition might instead take place mostly through non-price factors.
- (430) AZ moreover asserts that the fact that the price of Losec and other PPIs in Germany did not decrease when generic ranitidine was introduced and the fact that Losec sales did not decline sharply when interpreted in the light of the evidence submitted by AZ on clinical substitution, documental evidence and prescribing patterns therefore simply indicates that German physicians at the time were not price sensitive when choosing between different molecules⁴⁸⁵. In pharmaceutical markets where price is not an important factor of competition, such price sensitivity does not support the existence of a separate PPI market in Germany⁴⁸⁶.
- (431) In the Commission's opinion, AZ's submissions confirm the Commission's conclusion that these mechanisms operate directly at the intra-molecular level (i.e. as between an original brand and generic and parallel traded versions thereof) and not at the inter-molecular level (see recital (366)). This, moreover, contradicts AZ's interpretation that a cross-price elasticity coefficient of 0.22 between Losec and H2 blockers in Germany signifies a significant competitive constraint (see recitals (474)-(475)).
- (432) In respect of the third natural event, AZ notes that competition in promotion mainly takes place at the inter-molecular level⁴⁸⁷. According to AZ there was no increase in PPI promotion in Germany when generic ranitidine was introduced as this was not a "new" product, but simply the launch of a cheaper version of an existing product. While generic products mostly compete on prices with bio-equivalent products, innovative products (such as Zantac and Losec) mostly compete among themselves through marketing activity and the funding of clinical trials.
- (433) AZ's submissions show that lower H2 blocker prices did not put pressure on PPIs in the sense that there was no need to lower prices or increase promotional activities for PPIs. To this extent, the natural event in question supports the existence of a PPI market in Germany.
- (434) In AZ's view, the fourth natural event is not relevant to the market definition issue⁴⁸⁸. The effect of the entry of generic omeprazole is to be expected given an institutional framework set up to encourage generic substitution. According to AZ the institutional framework was such that doctors in Germany at the time had an incentive to consider both therapeutic effectiveness and cost when selecting across different PPIs⁴⁸⁹.

⁴⁸⁴ AZ reply to letter of facts, p. 22.

⁴⁸⁵ AZ reply to letter of facts, p. 23.

⁴⁸⁶ AZ reply to letter of facts, p. 23.

⁴⁸⁷ AZ reply to letter of facts, p. 23.

⁴⁸⁸ AZ reply to letter of facts, p. 23.

⁴⁸⁹ AZ reply to letter of facts, pp. 23-24.

- (435) The Commission notes AZ's admission that the event shows that doctors in Germany at the time had an incentive to consider e.g. cost when selecting across different PPIs but not H2 blockers (see recitals (362) and (369) as well as AZ's argument at recital (430) above concerning low price sensitivity between different molecules at the point of prescription. To this extent, the event underpins the finding of a PPI market in Germany. Moreover, as the Commission has pointed out, there is a clear ranking in the cross-price elasticities in the Lexecon study between Losec and generic omeprazole (strongest impact), other PPIs (intermediate impact) and H2 blockers (weakest impact). This is in line with the Commission's overall findings as well as its findings of market developments in Germany (see recital (401)).
- (436) To conclude the assessment in respect of Germany, reference is made to the Correlation study which finds that, on the sole basis of the correlation coefficients (+0.92), there is *prima facie* no substitution between PPIs and H2 blockers (see recital (76)).
- (437) In view of the above, it can be established that a PPI market existed in Germany from at least 1993 until the end of 2000, the last year for which market data is available.

The Netherlands

- (438) In the Netherlands (see tables 4, 12 and 16 in the Annex), PPI sales rose regularly and significantly each year during the reference period (1991-2000) (from USD 27 million in 1991 to USD 205 million in 2000), without any exception. This is true both in absolute terms and in relative terms (i.e. comparing the sales of PPIs to the overall sales of PPIs and H2 blockers). In percentage terms, the PPI expansion was especially marked in 1994-1995 (from 41% to 51% of overall PPI and H2 blocker sales) and 1995-1996 (from 51% to 59%). The trend in H2 blocker sales can be broken into two periods. From 1992 until 1995, the sales of H2 blockers marginally increase (ranging from 0.6% to 3% depending on the year). At the same time, however, PPI sales more than double. PPI sales exceed those of H2 blockers as of 1995. In the second period, from 1996 to 2000, H2 blocker sales fell steadily each year. In 2000, they reach one third of the level of 1995 (USD 31 million compared to USD 103 million); at the same time, PPI sales double (from USD 107 million to 204 million).
- (439) In the Netherlands, the pattern of prices is more erratic than the countries dealt with so far. Nevertheless, PPI prices remained significantly higher than H2 blocker prices over the entire period, the smallest price gap occurring in 1994 and 1995 (respectively 23% and 21%). Before these years, in 1991-1993, the divergence was considerably greater (respectively 53%, 53% and 40%). The same applies to the period 1996-2000 with the gap widening to a range of 46-96%.
- (440) For the Netherlands the Correlation study concludes that, on the sole basis of the correlation coefficients (+0.54), there is *prima facie* no substitution between PPIs and H2 blockers (see recital (76)).
- (441) In view of the above, it can be established that a PPI market existed in the Netherlands from at least 1993 until 2000, the last year for which data is available.

Norway

- (442) In Norway (see tables 5, 13 and 16 in the Annex), PPI sales increase each year constantly and significantly during 1992 to 1999 from USD 8 million to USD 36.9 million, after which sales fall to USD 35 million in 2000. The PPI expansion (as a percentage of all PPI and H2 blocker sales) is particularly marked in 1992-1993 (31% to 40%), 1993-1994 (40% to 49%) and 1995-1996 (53% to 64%). H2 blocker sales fall by more than 17% from 1992 to 1993; they then stabilise in 1994 and increase by 12% in 1995. However, despite this increase, H2 blocker sales remain below the level of 1992. Furthermore, at the same time, PPI sales rise by 45% in 1994 and by 34% in 1995. Moreover, PPIs capture the entire growth of the overall sales of PPIs and H2 blockers in 1994 and more than two-thirds of it in 1995. It should also be borne in mind that PPI sales almost equal those of H2 blockers in 1994; since then, the gap between PPI sales and H2 blockers sales widens dramatically. Indeed, as of 1996, H2 blocker sales drop by a third and continue to decrease up to 2000, where they reach half of the sales level of 1992. At the same time, PPIs sales grow constantly.
- (443) Throughout the reference period, PPI prices exceeded H2 blockers by a very significant amount, in particular during the first three years 1992-1994 (92%-99%) and the last three years 1998-2000 (93%-136%). In the middle of the period (1995-1997), the gap remained very significant (48%-68%).
- (444) In view of these developments, it can be established that a PPI market existed in Norway during the entire period for which data is available (1992 until the end of 2000).

Sweden

- (445) Tables 6, 14 and 16 at in the Annex show that PPI sales expand quickly each year from 1991 to 1996 (from USD 23 million to USD 130 million), after which they drop to USD 95.6 million in 1997. Over the next years PPI sales again rise to USD 130 million in 1999, after which they fall to USD 121 million in 2000. In percentage terms, the constant increase in the PPIs share of all PPI and H2 blocker was the strongest in the early years: 41% to 51% in 1991-1992, 51% to 63% in 1992-1993 and 63% to 73% in 1993-1994. H2 blocker sales decrease significantly in 1993 (26% decrease compared to 1992). They then stabilise in 1994 and grow again in 1995 and 1996. However, despite these increases, H2 blockers sales only reach their 1992 level. Furthermore, in 1995, H2 blockers represent only one quarter of the overall sales of PPIs and H2 blockers, compared to one half in 1992. In Sweden, Astra's home country, the sales of omeprazole already exceed those of H2 blockers as of 1992. The gap between the two then widens very quickly. In fact, after 1996, H2 blocker sales decrease each year to USD 17 million in 2000. One can add that the 1997 decrease of PPI sales does not lead to an increase of H2 blocker sales; in fact, H2 blocker sales also decrease by more than 25% that year.
- (446) During 1991-1997, PPIs were considerably more expensive than H2 blocker prices, with a price gap varying between 72% (in 1997) and 94% (in 1991). In 1998 the price gap increased significantly to 129%. In 1999 and 2000 the difference further increased to respectively 138% and 131%.
- (447) For Sweden, the Correlation study finds that, on the sole basis of the correlation coefficients, there is *prima facie* substitution between PPIs and H2 blockers (see

recital (76)). However, the strength of this conclusion is weakened by the fact that the negative coefficient in respect of Sweden is small (-0.26). In any case, the Correlation study's finding in respect of Sweden is not sufficient to rebut the overwhelming evidence in terms of demand and prices (see two previous recitals) supporting the finding of a PPI market in Sweden.

- (448) In view of the above, it can be established that a PPI market existed in Sweden from at least 1993 until the end of 2000, the last year for which data is available.

The United Kingdom

- (449) In the United Kingdom (see tables 7 and 15-16 in the Annex), PPI sales rise markedly each year from USD 44 million in 1991 to USD 569 million in 1999, after which sales fall to USD 546 million in 2000. The increases in PPI sales as a percentage of PPI and H2 blocker sales are most pronounced in 1991-1992 (11% to 21%), 1992-1993 (21% to 33%) and 1993-1994 (33% to 43%). H2 blocker sales decrease in 1993 compared to 1992 by more than 15% (from USD 392.2 million to USD 331.5 million). In 1993-1996, H2 blocker sales remain relatively stable within a spectrum of USD 331-339 million. At the same time, PPI sales increase by more than 160%; by 1995 PPI sales exceed those of H2 blockers, while they represent only one quarter of H2 blocker sales three years earlier. After 1996, H2 blocker sales drop more and more rapidly. In 2000, they represent less than one quarter of the overall sales of PPIs and H2 blockers.
- (450) From 1991 to 2000, PPI prices considerably exceed H2 blocker prices by 49% to 84%.
- (451) For the United Kingdom the Correlation study concludes that, on the sole basis of the correlation coefficients (+0.82), there is *prima facie* no substitution between PPIs and H2 blockers (see recital (76)).
- (452) Moreover, table 16 shows that PPI sales in absolute terms as well as their share of overall PPI and H2 blocker sales in the United Kingdom continue to increase from 1997 onwards despite the fact that cheaper generic H2 blockers enter the market in 1997. This natural event supports the conclusion that H2 blockers did not, at least at that time, exercise a significant competitive constraint on PPIs in the United Kingdom.
- (453) AZ - in relation to the first part of this natural event (i.e. Losec sales remaining unaffected despite the entry of cheaper H2 blockers) - admits that the result appears anomalous contrasting, in AZ's view, with other evidence submitted by AZ⁴⁹⁰. According to AZ it is possible that the growth of sales in OTC ranitidine had won sales from (among others) prescription H2 blockers. It is also possible that the element is explained by low price elasticity due to institutional features of the demand side. In AZ's view this would also be consistent with the finding that changes in the relative price of competing PPIs had no effect on Losec's market share in the United Kingdom⁴⁹¹.
- (454) According to the Commission the event shows that, in any case, a considerable fall in H2 blocker prices did not affect PPI sales. This is also in line with the results in Germany (see recital (423)). To this extent, the event supports the existence of a PPI

⁴⁹⁰ AZ reply to letter of facts, p. 26.

⁴⁹¹ AZ reply to letter of facts, p. 27.

market in the United Kingdom, in particular as of the entry of generic ranitidine. AZ's alternative explanations for the lack of impact on Losec's sales are speculative.

- (455) In relation to the second part of the natural event (i.e. Losec's price increasing despite the entry of cheaper H2 blockers), AZ refers to the Lexecon study which says that the weighted average price of Losec increased because of a composition effect arising from an increase over time in prescriptions of the more expensive (per day of treatment) 10 mg presentation form⁴⁹². However, the prices of the individual presentation forms did not change.
- (456) In any case, in the Commission's view, the event shows that a considerable fall in H2 blocker prices at least did not put downward pressure on Losec prices. To this extent, the event supports the existence of a PPI market in the United Kingdom, in particular as of the entry of generic ranitidine.
- (457) In view of the foregoing, it can be established that a PPI market existed in the United Kingdom from at least 1993 until the end of 2000, the last year for which data is available.

(g) The Lexecon study

- (458) AZ criticises the Statement of Objections for relying excessively on the price factor in defining the relevant market (see recital (343)). This criticism is misguided.
- (459) First, the relevant market definition flows from a combination of factors relied on (the characteristics, therapeutic uses, sales, prices and non-price factors). One of those factors is the very significant price differences that have existed between PPIs and H2 blockers during most of the period 1991-2000 in the markets concerned.
- (460) Second, large absolute price differences between two categories of medicines used within the same therapeutic area reflect an absence of significant competitive pressure exercised by the lower priced product category (see recitals (364)-(365)). Moreover, wide price differences between two classes of products strongly indicate that the public authorities have not based their pricing and reimbursement decisions on comparisons between the two product classes (see recital (366)).
- (461) While it is not denied that other variables than price – such as the variables used in the Lexecon study (see recital (343) *et seq.*) – are relevant to competition in the pharmaceutical sector, it is submitted that the results of the Lexecon study do not confirm the existence of a relevant market comprising PPIs and H2 blockers in Germany and the United Kingdom. The inconclusive nature of the study for competition law purposes relate both to the methodology of the study as well as the specific results for the two Member States concerned.

The methodology underlying the Lexecon study

- (462) First, the methodology underlying the Lexecon study is to measure the effect of various factors (such as prices, promotion or incremental product innovation) on the

⁴⁹² AZ reply to letter of facts, p. 27.

market share of Losec in an assumed common market for H2 blocker and PPIs. The reliance on market shares of a market comprising H2 blockers as well as PPIs results in a potentially artificial relationship between the variables and Losec's market share, overestimating the actual competitive constraint exerted by H2 blockers on Losec.

- (463) More specifically, additional H2 blocker sales (caused by lower H2 blocker prices, increased promotion or incremental product innovation) in market segments uncontested by PPIs will, under the chosen methodology, inevitably adversely affect Losec's market share without reflecting any factual competitive constraints exerted by H2 blockers on Losec. In fact, even a product strategy of gradual market exit of H2 blockers by expanding in low price and/or market segments towards the milder end of the acid-related disease spectrum (a trend relied on by the Commission: see recital (490)) would, under the chosen methodology, result in a positive cross-price relationship⁴⁹³ between the two product classes.
- (464) By the same token, any expansion by the PPI class (resulting from e.g. increases in promotion) into market segments demanding more potent and effective therapies, which thereby expands the market (at the expense of outside goods or into segments hitherto not served at all) will inevitably result in a significant relationship between the variables and Losec's market share. Again, any relationship detected by the proposed methodology would not reflect a process of real rivalry between the two product classes, but an autonomous effort by the PPI firms to expand the market, independently of H2 blockers. This factor acquires particular significance considering that the size of the overall sales of PPIs and H2 blockers trebled in Germany and doubled in the United Kingdom during the relevant period. By not controlling for these market expansion effects, the methodology underlying the study potentially overestimates any possible constraints exerted by H2 blockers on PPIs⁴⁹⁴.
- (465) In this connection, it should be noted that AZ does not contest the existence of this bias but accepts that "*the magnitude of the cross price elasticity is lower*" if the Commission's concerns are taken into account⁴⁹⁵. In arguing that the size of this bias is rather small, AZ does not provide any substantive arguments why this may be the case. In addition, AZ only provides one specification check⁴⁹⁶ (based on volume) which does not rely on the market share of Losec in an assumed common H2 blocker and PPI market⁴⁹⁷. That specification check produces results which are inconsistent with those in the baseline models. AZ has not provided explanations as to why the

⁴⁹³ By the term "cross-price relationship", the Lexecon study refers to the relationship between price and market share.

⁴⁹⁴ It is worth pointing out that it is standard practice to control for such type of effects. For instance, a multi-stage budgeting approach was used by Hausman, Leonard and Zona (*Annales D'Économie et de Statistique* (1994), pp. 34, 159-180) to construct a multi-level demand system for differentiated products. At the bottom level, the demand for each brand as measured by market shares is a function of its own price, its rivals' prices and a measure of real consumer expenditures divided by a price index. The last factor controls for market expansion effects. Such controls do not, however, form part of the estimates in the Lexecon study.

⁴⁹⁵ Lexecon memorandum dated 11 February 2004, p. 6

⁴⁹⁶ See tables 7 (Germany) and 13 (United Kingdom) of the Lexecon study, pp. 45, 51. The purpose of specification checks is to investigate whether the model which has been chosen to depict the interdependence between the explanatory ("independent") variables and the to-be-explained ("dependent") variable in the analysis correctly models the phenomenon under investigation.

⁴⁹⁷ In the specification check, the volume of Losec sales in absolute terms is used as the dependent variable.

results differ from those derived from the models using Losec's market share as the dependent variable⁴⁹⁸.

- (466) Second, the Lexecon study does not take due account of the so called "cellophane fallacy"⁴⁹⁹ by failing to analyse the cross-price relationship at the competitive price level. As the cross-price relationship tends to be lower at the competitive price level such an approach results in too broad a definition of the relevant market. This shortcoming is of particular significance in this case given the high price differentials between PPIs and H2 blockers as well as evidence for at least one of the countries analysed in the Lexecon study – Germany - that the price level of Losec fell after entry of other PPIs and that this price level was further reduced following entry of generic omeprazole. Hence, there is ample evidence that the price level for Losec was above the competitive price level. Given that the methodology underlying the Lexecon study does not take due account of the cellophane fallacy, the results of the study tends to overestimate the cross-price relationship at the competitive price level, i.e. the relationship which is of relevance for market definition.
- (467) Third, even if the Lexecon study's approach to use Losec's share of an assumed PPI plus H2 blocker market as the dependent variable is considered to be valid, the statistically significant effect on Losec's market share of the "time trend" variable (purporting to capture the delayed positive effect on Losec's market share resulting from the publication of studies, the "word-of-mouth" factor and promotional activity) is, in any case, not inconsistent with the Commission's finding of a relevant market comprising PPIs only. AZ has failed to produce any evidence suggesting that the statistically significant effect resulting from the "time trend" variable is attributable to any competitive constraint exercised by H2 blockers. Rather, the time trend indicates that the displacement by PPIs of H2 blockers took place over time due to inertia in the dissemination of knowledge about PPIs to the wider medical community and, therefore, inertia in prescribing practice. However, such inertia which is inherent in pharmaceutical prescription markets is an exogenous factor and, as such, does not imply any significant competitive constraint exerted by H2 blockers.
- (468) Therefore, the existence of a gradual time trend towards PPIs is perfectly consistent with the Commission's finding of inertia in doctors' prescription pattern independent from the firms' efforts in promoting their products (see recital (115)). In fact, other empirical work by the authors of the study on the phenomenon of inertia in pharmaceutical prescription markets suggests that "*most of the observed gradual growth in omeprazole's market share is predominantly explained by doctors' accumulation of first-hand experience of the drug via actual prescription*" and thereby only partially susceptible to being influenced by the firm's promotion strategies.⁵⁰⁰

⁴⁹⁸ For Germany see tables 1 and 7 at pp. 39, 45 of the Lexecon study; for the United Kingdom see tables 9 and 13 at pp. 47, 51 of the Lexecon study.

⁴⁹⁹ Simply speaking, the cellophane fallacy implies that due account must be taken of the fact that the prices charged by a dominant undertaking often are above the competitive level. Unless this fact is appropriately taken into account, the relevant market may be defined too widely. The cellophane fallacy derives from the US Supreme Court case *E.I Du Pont de Nemours and Co.* 351 U.S. 377 (1956).

⁵⁰⁰ See Andrea Coscelli, Matthew Shum (2004): An empirical model of learning and patient spillover in new drug entry. *Journal of Econometrics*, 122, 213-246. Citation from p. 234. The paper analyses the diffusion process of the newly introduced omeprazole into the anti-ulcer drug market in Italy during the early nineties. While based on a detailed prescription sample, the sample is restricted to a small sample of doctors in the region of Rome.

- (469) Fourth, despite analysing time series data⁵⁰¹ AZ does not provide any statistical test for the problem of autocorrelation⁵⁰², a general problem inherent in respect of time series data. In particular, the existence of autocorrelation poses serious problems for the statistical inferences, thereby making it more or less impossible to derive any robust conclusions as to the statistical significance of the estimated coefficients.
- (470) In summary, the methodology on which the Lexecon study is based tends to overestimate actual cross-price relationships of relevance for market definition. This is so as it relies on market shares in an assumed common market for H2 blockers and PPIs without controlling for outside goods or expansion into new market segments. The same methodological weakness attaches to the Correlation study submitted by the complainant (see recital (406)). Furthermore, in not controlling for the cellophane fallacy, the study introduces an additional bias leading to overestimated cross-price relationships. In addition, the identified gradual time trend cannot be associated with any competitive constraint exercised by H2 blocker firms vis-à-vis AZ or other PPI firms. Finally, as AZ has not provided relevant and standard statistical tests the reliability of the results is further diminished.
- (471) In addition, the Lexecon study fails to take due account of the superiority of PPIs over H2 blockers in terms of fundamental innovation (as opposed to purely incremental innovation in the form of different strengths, dosages, presentation forms etc.). More specifically, the Lexecon study (and AZ's Reply in general) largely disregard the outcome of the competition on fundamental innovation between PPI and H2 blocker producers reflected in the results of price negotiations with national authorities. The PPI firms have, in general, been able to obtain considerably higher prices from the authorities. This demonstrates an absence of significant competitive constraint on the part of the H2 blocker firms. Ultimately, the market share of pharmaceutical companies is a function of the price they negotiate with the authorities and the prescriptions written for their products. Securing and maintaining a high price in bargaining with the authorities is also significant in the context of transition between an older and newer version of the same type of medicine as evidenced by AZ's strategy documents concerning the conversion from Losec/Losec MUPS to Nexium (see recitals (298)-(301)). Therefore, AZ is fundamentally mistaken to claim that significant price differences between two categories of medicines are totally irrelevant for market definition purposes unless a hypothetical "competitive price" can be established for the products concerned⁵⁰³.
- (472) The Lexecon study thus fails to take due account of differences in fundamental innovation (i.e. the invention of a new chemical entity (PPIs) entailing significant therapeutic value-added over the active substances in the H2 blockers). The Lexecon

⁵⁰¹ Time series data are chronologically ordered observations made at regular intervals (daily, monthly etc.) over a period of time. The Lexecon study is based on such time series data. On the basis of these observations in respect of a particular explanatory variable, so-called estimates (or coefficients) are calculated to assess the size of the interaction between the explanatory variables and to-be-explained variable.

⁵⁰² Autocorrelation refers to a situation where the observations over time of the individual explanatory ("independent") variables (such as price) are correlated due simply to the time period of observation and not randomly distributed. Autocorrelation implies that it is not possible to draw robust conclusions as to the validity of the estimates (or coefficients) for the explanatory variables or as to the explanatory power of the model as such. Standard statistical tests have been developed to check for autocorrelation.

⁵⁰³ See AZ reply to letter of facts, pp. 22-23, 37.

study only incorporates variables taking account of incremental innovation such as different presentational forms and strengths. AZ's reply and the Lexecon study ignore the significance of the value added in terms of innovation embodied in the Losec/PPIs compared with H2 blockers.

The results for Germany

- (473) The specific results arrived at by the Lexecon study for Germany are not inconsistent with a finding of a distinct PPI market. The first three main results demonstrate that there is a clear ranking both in the baseline model and the specification checks in terms of the relative effects on Losec's market share of PPI entry and prices, generic omeprazole entry and prices and H2 blocker prices⁵⁰⁴. The effect of generic omeprazole entry and prices on Losec's market share is almost four times stronger than the effect of H2 blocker prices in the baseline model⁵⁰⁵. This is consistent with the Commission's findings on the impact of generic omeprazole in Germany (see recitals (73)-(74) and (401)).
- (474) AZ claims that the degree of the cross-price elasticity (0.22) that the Lexecon study has found between Losec and competing H2 blockers constitutes a significant competitive constraint and that this degree of cross-price elasticity between the product classes is more than sufficient in economic terms to establish substantial competition⁵⁰⁶.
- (475) However, AZ does not in any way substantiate why a cross-price elasticity of 0.22 in this case or in general is sufficient to establish a significant competitive constraint. In any case, it is clear that the cross-price elasticity between Losec and H2 blockers is considerably lower than the corresponding cross-price elasticities arrived at by the Lexecon study in respect of the relationship between Losec and other PPIs and – even more so – the relationship between Losec and generic omeprazole.
- (476) Furthermore, the fourth and fifth results for Germany (recital (349)) do not support the hypothesis put forward by AZ that marketing effort as measured by the Lexecon study (number of presentational forms and detailing activity) is a significant strategic variable. The number of presentational forms for Losec and for the other PPIs had no statistically significant effect on Losec's market share. Nor did detailing activities by H2 blocker producers have any statistically significant effect on Losec's market share. On the other hand, detailing of generic omeprazole had a statistically significant negative impact on Losec's market share. This result is also consistent with the Commission's market definition.
- (477) Moreover, the specification check using the volume of Losec sales as the dependent variable did not find a statistically significant cross-price elasticity between H2 blocker prices and the sales volume of Losec⁵⁰⁷.

⁵⁰⁴ See Lexecon study, table 2, first column, at p. 40.

⁵⁰⁵ Taking the slightly different method to calculate the elasticities in Lexecon memorandum dated 27 January 2004, the relationship increases even further to more than seven times (see table 1, at p. 4 of the memorandum).

⁵⁰⁶ AZ reply to letter of facts, p. 21.

⁵⁰⁷ Lexecon study, p. 35.

- (478) As regards a number of “natural events” derived from the Lexecon study see the Commission’s assessment of the German market above (recitals (420)-(426)).

The results for the United Kingdom

- (479) The specific results for the United Kingdom arrived at by the Lexecon study must be treated with a considerable degree of caution considering that the estimates in the baseline model are partially counterintuitive and non-robust.
- (480) Indeed, as regards the first result, the impact of H2 blocker prices on Losec’s market share in the baseline model cannot be considered as being “broadly consistent” with the alternative estimates provided by AZ, considering that the minor adjustments to the baseline model in all the specification checks (e.g. replacing detailing with advertising as an independent variable)⁵⁰⁸, resulted in H2 blocker prices having either contradictory or statistically insignificant effects on Losec’s market share.
- (481) Moreover, in respect of the first result, AZ’s explanation that after the entry of generic ranitidine in January 1997, H2 blocker prices did not restrict Losec’s market share due to lower promotional efforts in the H2 blocker segment is not consistent with the result in the baseline model which shows a positive relationship between detailing of H2 blockers and Losec’s market share even after entry of generic ranitidine.
- (482) Furthermore, the study’s findings are counterintuitive in so far that the study finds a positive cross-price relationship between PPIs and H2 blockers but does not find that PPI entry and prices (as well as Losec’s own prices) had a statistically significant effect on Losec’s market share, even though other PPIs are clearly more substitutable with Losec than H2 blockers.
- (483) Moreover, the point made by AZ as part of its presentation of the first result, namely that Losec prices had a statistically significant impact on the market share of H2 blockers, is not inconsistent with a PPI market; indeed, it is the Commission’s case that PPIs significantly constrained H2 blockers whereas the reverse was not the case. In respect of the second result reference is also made to the “natural event” relating to the lack of impact of the entry of generic H2 blockers in January 1997 on demand for and prices of PPIs in the assessment of the United Kingdom market (see recital (452) above). The Lexecon study itself admits that this lack of impact is “anomalous”⁵⁰⁹.
- (484) As regards the third result it should also be noted that the fact that detailing in favour of Losec showed a statistically significant competitive effect on Losec’s market share does not imply that Losec or the PPI category as a whole were constrained by H2 blockers.
- (485) The findings that the increase in presentation forms of competing PPIs had a negative impact on Losec’s market share, that the entry of competing PPIs had a negative impact on the market share of H2 blockers and that the decrease in the relative price between competing PPIs and H2 blockers had a negative impact on the market share of H2 blockers (see the fourth result presented by AZ), do not imply that Losec or the PPI category as a whole were significantly constrained by H2 blockers.

⁵⁰⁸ See table 4 of the memorandum dated 27 January 2004 submitted by AZ
⁵⁰⁹ Lexecon study, p. 36. 4.144(ii) AZ Reply.

- (486) As regards the fifth result, it is clear that the statistically significant effect of the “time trend” variable on Losec’s market share is in any case not inconsistent with a market comprising PPIs only. The fact that there was a delayed positive effect on Losec’s market share through “word-of-mouth” among doctors and patients, publication of clinical results and promotion does not prove that H2 blockers exercised a significant competitive constraint on PPIs (see also recital (468)).
- (487) Table IV of a Lexecon memorandum dated 27 January 2004 sets out the elasticities of the main robustness checks undertaken by AZ in respect of the results of the Lexecon study for the United Kingdom. The table reveals that the model chosen to reveal the interaction is not robust if changes in the specification of the model are introduced. This indicates that the study is not able to confirm a robust and statistically significant interaction between H2 blockers and Losec in terms of prices and detailing in the United Kingdom.

(h) Contemporaneous business documents

- (488) Actual evidence of substitution in the past, where available, is normally fundamental for defining the relevant market. Comprehensive and aggregated evidence – which by definition is of an *ex post* nature – is available in this case in respect of each relevant market.
- (489) In any event, the content of contemporaneous documents submitted by AZ are at least equally consistent with the conclusion that the H2 blockers did not constitute a significant competitive constraint on PPIs. In fact, AZ’s documents rather show that PPIs exercised a significant competitive constraint on H2 blockers, a factor which in no way is inconsistent with a market definition comprising PPIs.
- (490) First, AZ’s internal documents⁵¹⁰ reveal that already at the start of the relevant period Losec placed the H2 blockers under such significant competitive constraints that the H2 blockers were forced to “downstream” towards milder acid-related conditions and even to launch OTC products, thereby putting competitive pressure on products such as antacids and alginates at the lower end of the hierarchy of medicines used for acid-related gastrointestinal treatment. Indeed, a planning document for 1990-1992 notes that OTC H2 blockers had already been launched in Denmark by this time. In later documents, AZ refers to the start of promotion of H2 blockers sold OTC in the United Kingdom (planning document for period 1994-1996) as well as to “the OTC wave” (planning document for period 1996-2000).
- (491) Second, AZ’s documents often state that the H2 blockers showed “*resilience*”. Such resilience is, however, not evidence of the existence of a significant competitive constraint on PPIs. To the contrary, it reflects the gradual trend in favour of PPIs, which supports the finding that the market in this case comprises PPIs only⁵¹¹.

⁵¹⁰ Vol 2, Annex 4.12.1, p. 22 (in first section); Vol 2, Annex 4.12.4, p. 6 (in section “Market Trends and Sales Performance”); Vol 2, Annex 4.12.5, p. 9 (in section “Market Trends”); Vol 2, Annex 4.12.5, p. 17 (in section “Losec (omeprazole)"); Vol 2, Annex 4.12.6, p. 12 (in section “Market Trends”) AZ Reply; Vol 2, Annex 4.12.7, p. 8 and p. 2 (in section “Gastrointestinal Portfolio 1996-2000”).

⁵¹¹ Vol 2, Annex 4.12.4, p. 2 (in section “Cardiovascular/Gastrointestinal”); Vol 2, Annex 4.12.4, p. 19 (in section “Losec (omeprazole)"); Vol 2, Annex 4.12.5, p. 2 (in section “Losec (omeprazole)”) AZ Reply.

- (492) Third, while it is clear that AZ's internal documents often state that AZ's "*primary competitive focus for Losec® has and continues to be the [H2 blockers]*"⁵¹², this does not imply that the H2 blockers were in fact able to exert significant competitive constraints on Losec and other PPIs. Rather, it appears from AZ's documents that H2 blockers were a "*competitor*" to AZ in their capacity as incumbents with large sales volumes that AZ continually "*eroded*"⁵¹³ and "*displaced*"⁵¹⁴, thereby taking "*patient management into the post-H2 era*"⁵¹⁵.
- (493) In this context reference is also made to the Notice on market definition which states that "*the concept of 'relevant market' is different from other definitions of market often used in other contexts*" and that "*companies often use the term 'market' to refer to the area where it sells its products or to refer broadly to the industry or sector where it belongs*". It is in this light that AZ's use of the terms competitive "*focus*" and competitive "*target*" in respect of H2 blockers or AZ's reference to an acid-related gastro-intestinal disease "*market*" should be seen (see recitals (49) to (51) and (53)).
- (494) As regards AZ's claim (see recital (337)) concerning the Commission's alleged acceptance of the probative value of AZ internal documents, the Commission would like to point out that the contemporaneous AZ documents in question, while not irrelevant for market definition purposes in this case, are of secondary probative value in relation to hard evidence relating to the actual use of and demand for the products concerned. As market definition is essentially an objective exercise, established objective facts (e.g. on actual substitution between products) will normally prevail over the operators' or third parties' subjective perceptions of developments (see e.g. recitals (388) and (421)).
- (495) Second, in its Reply to the Statement of Objections, AZ presented in a one-sided manner the said internal documents as evidence that PPIs and H2 blockers form part of the same market. The Commission takes the view that numerous elements in the documents suggest otherwise. Reference can be made to AZ documents on the general market trends (recital (51)) and on the situation in specific countries (see recital (99) in respect of Denmark and recital ((57) in respect of Sweden).
- (496) Moreover, AZ disputes that three internal AZ documents cited by the Commission support the conclusion that AZ in its internal documents "*strongly emphasises the key importance of Losec's unique mode of action in relation to the competition*"⁵¹⁶.
- (497) More specifically, in respect of the first of these documents, AZ claims that the two pages in AZ's "Business Planning Commentary" for the period 1992-1994⁵¹⁷ referred to by the Commission do not support the Commission's allegation that the different mode of action between PPIs and H2 blockers puts them in separate markets⁵¹⁸. AZ

⁵¹² Vol 2, Annex 4.12.5, p. 19 (in section "Losec (omeprazole)"); Vol 2, Annex 4.12.6, p. 16 (in section "Losec (omeprazole)") AZ Reply.

⁵¹³ Vol 2, Annex 4.12.5, p. 20 (in section "Losec (omeprazole)"); Vol 2, Annex 4.12.6, p. 17 (in section "Losec (omeprazole)"); Vol 2, Annex 4.12.7, p. 20 (in section "Gastrointestinal Portfolio"); Vol 2, Annex 4.12.7, p. 2 (in section "Gastrointestinal Portfolio") AZ Reply.

⁵¹⁴ Vol 2, Annex 4.12.6, p. 11 (in first section); Vol 2, Annex 4.12.7, p. 8 (in first section) AZ Reply.

⁵¹⁵ Vol 2, Annex 4.12.7, p. 14 (in section "Gastrointestinal Portfolio"); Vol 2, Annex 4.12.8, p. 17 (in section "Gastrointestinal Portfolio") AZ Reply.

⁵¹⁶ AZ reply to letter of facts, p. 10.

⁵¹⁷ Vol 2, Annex 4.12.3, pp. 18-19 AZ Reply.

⁵¹⁸ AZ reply to letter of facts, p. 10.

also cites pages 20-23 of the said document which refer to “*considerable competitive pressure from H2 blockers*” as proof of the difficulties that AZ will face in moving Losec into routine use in acid-related diseases. According to AZ, its attempts at the time to differentiate Losec on the basis of its mode of action to gain market share from H2 blockers highlights the fact that the clinicians were not influenced by the different mode of action of Losec in their prescribing practice. According to AZ, the fact that Losec was struggling to gain market penetration in the light of the established market position of the H2 blockers is evidence that PPIs and H2 blockers were in the same market.

- (498) In respect of the second internal document, AZ similarly claims that the two pages in AZ’s Business Planning Overview 1993-1995 (section “Market Trends and Sales Performance”)⁵¹⁹ referred to by the Commission do not support the Commission’s allegation that the different mode of action of PPIs and H2 blockers puts them in separate markets. According to AZ, page 10 refers to competition from H2 blockers. AZ notes that the statement quoted by the Commission follows an explanation by AZ that “*Continued competitive pressure*” is slowing the market penetration of Losec⁵²⁰. In AZ’s view, that page shows that it is apparent that clinicians were either unaware of the different mode of action of Losec or, if they were aware of it, they did not regard it as important.
- (499) In respect of the third document, AZ maintains that there is no basis on which the page in AZ’s Business Planning Overview 1995-1997⁵²¹ can support the relevant conclusion⁵²². According to AZ the internal document in question deals with the difficulties in getting prescribing physicians to consider Losec as their drug of first choice⁵²³.
- (500) In reply to those statements by AZ, the Commission repeats that it does not claim that the differences in the modes of action in this case by themselves entail a separate PPI market (see recitals (360) and (378)). As regards AZ’s interpretation of the relevant pages in the three documents, the Commission refers to its explanation that objectively verifiable events on the market prevail over subjective assessments (see e.g. recitals (388) and (421)) as well as the conclusions it has drawn from the actual market trends aggregated at the level of each relevant geographic market in this case (see recitals (388)-(393) and (401) as well as recitals (409) *et seq.*). Moreover, even on AZ’s interpretation of the documents concerned, it simply shows that AZ faced some inertia (from prescribers) and resilience (from H2 blockers) in displacing (in the context of overall market growth) the latter product category (see recitals (488)-(493)).
- (501) AZ also disputes that two of the three internal AZ documents cited by the Commission support the conclusion that AZ in its internal documents “*states that Losec was*

⁵¹⁹ Vol 2, Annex 4.12.4, p. 10 (in section “Losec (omeprazole”) AZ Reply.

⁵²⁰ AZ reply to letter of facts, p. 11.

⁵²¹ Vol 2, Annex 4.12.6, p. 10 AZ Reply.

⁵²² See AZ reply to letter of facts, p. 11.

⁵²³ AZ refers to the following passage on the page cited by the Commission: “*The full potential of the product [Losec] will only be realized through establishing broad routine use in both peptic ulcer disease and gastro-oesophageal reflux disease. This in turn requires that the tradition of H2RA prescribing be disturbed, and ‘Losec’ selected for first line intervention*”. AZ also observes that page 11 of the same document refers to the intensified competitive situation in the market for H2 blockers and PPIs. AZ reply to letter of facts, p. 11.

*increasingly prescribed following H2 blocker failure or as first-line treatment in place of H2 blockers*⁵²⁴.

- (502) Contrary to AZ's contentions the Commission's conclusions are supported by the following three elements on the pages concerned in AZ's Business Planning Commentaries for 1994-1996 and 1995-1997: (a) "*Losec® is largely prescribed following H2RA failure, or first line in severe forms of GERD*"⁵²⁵; (b) "*[t]he achievement of a 21% share in PUD/GERD indicates that Losec® is being increasingly prescribed as first-line treatment in place of H2RA's, in patients with less severe disease. The Losec® share of 1.6% in Dyspepsia likely reflects its use in patients with severe acid-related dyspeptic symptoms, following failure of H2RA's*"⁵²⁶ and (c) "*Losec® is still largely prescribed following H2RA failure, or first line in severe forms of GERD*"⁵²⁷.

3. THE RELEVANT GEOGRAPHIC MARKET

- (503) The national nature of pharmaceutical markets derives from a number of factors. These include in particular different price and reimbursement rules (see e.g. the wide differences between national rules on incentives for cheaper generic and parallel imported products at recitals (112)-(142)), as well as different brand and packing strategies, different distribution and different prescribing habits of physicians. As an illustration, reference can be made to the varying prices for PPI products in the different EEA Contracting Parties in question (see tables 8 and 35-42 in the Annex). At this stage, Community harmonisation is mainly limited to rules relating to the authorisation of medicinal products (either nationally or through a centralised Community system), in particular rules aimed at ensuring that the products concerned fulfil requirements in terms of safety, quality and efficacy. In all Commission decisions regarding pharmaceutical products, the relevant geographic market has been defined as national. AZ does not dispute that the relevant geographic markets are national in this case (see recital (329)).

4. CONCLUSION ON THE RELEVANT MARKET

- (504) In view of the preceding analysis, it is concluded that prescription PPIs faced no significant competitive constraints from H2 blockers or other products used for the treatment of acid-related gastro-intestinal diseases or conditions in Belgium, Germany, the Netherlands, Norway, Sweden and the United Kingdom from at least 1993 to the end of 2000 and in Denmark from at least 1993 to the end of 1999. Due to the absence of data, a PPI market cannot be established beyond the end of 2000 and – in the case of Denmark – 1999. Therefore, it is concluded in respect of those markets and years that prescription PPIs constituted a separate product market. This conclusion thus corresponds to the fourth ATC level (see recital (372)). It should be specified that for the purposes of this case the relevant product market includes oral formulations of PPIs and that it does not include sales to hospitals, considering that hospital markets

⁵²⁴ AZ reply to letter of facts, pp. 12-13.

⁵²⁵ Vol 2, Annex 4.12.5, p. 5 in section "Losec (omeprazole)" AZ Reply.

⁵²⁶ Vol 2, Annex 4.12.6, p. 1 in section "Losec (omeprazole)" AZ Reply.

⁵²⁷ Vol 2, Annex 4.12.6, p. 5 in section "Losec (omeprazole)" AZ Reply.

present significant differences as compared to pharmacy markets (see recitals (18) and (68)).

C. DOMINANT POSITION

1. SUMMARY OF AZ'S ARGUMENTS

- (505) AZ argues that application of the Commission's market share test (in volume as opposed to value terms) to the market definition which is correct in its view (i.e. PPIs and H2 blockers) shows that AZ was not dominant in the relevant period, with the exception of one Member State (Sweden) for a short period of time⁵²⁸.
- (506) AZ then argues that, in any event, market shares and price differences should not be given great weight in assessing dominance in the pharmaceutical sector. The presence of a monopsony buyer and price regulation (in various forms) in the pharmaceutical markets deprive pharmaceutical companies of the ability to either determine their prices or exercise market power in respect of price. Further, the separation between the principal decision maker (the prescribing doctor) and the payer (national health authorities or private insurance) results in limited price sensitivity on the part of the decision maker, whose prescription decisions will be primarily based on therapeutic appropriateness. Because of the unusual features of pharmaceutical markets, companies will compete principally by reference to non-price factors, such as product innovation, marketing and promotion.
- (507) AZ argues that it is not possible to infer much from the lower initial prices for other PPIs (i.e. other than Losec) since regulatory factors will have had a strong influence on the setting of that price and it cannot be assumed that any price difference reflects the competitiveness of the market. In a similar vein, AZ claims in its reply to the letter of facts that price differentials are not useful evidence of dominance where price is not a major factor of competition. Competition in product innovation and marketing and promotion is far more important⁵²⁹.
- (508) In any event, AZ claims that based on the figures produced by the Commission, there is no evidence that Losec was able to consistently maintain significantly higher prices than other PPIs and to the extent that there is any pattern in terms of prices, it is one of downwards price convergence between Losec and other PPIs⁵³⁰.
- (509) Moreover, AZ argues that it did not enjoy any special advantage with regard to the main relevant factors of competition. As to product characteristics, Losec was not regarded by doctors as a materially superior product. As to innovation, there is no evidence that AZ was able to refrain from R&D. In fact, the market has been characterised by a high degree of innovation by AZ and its competitors over the relevant period. As regards marketing and promotion, evidence shows that other PPIs were more heavily promoted in the United Kingdom and in Germany; AZ's competitors had considerable financial resources and were perfectly able to undertake marketing or promotion so as to compete effectively on the market.

⁵²⁸ See also AZ reply to letter of facts, p. 34.

⁵²⁹ AZ reply to letter of facts, p. 37.

⁵³⁰ See also AZ reply to letter of facts, pp. 37-38, 47-48.

- (510) As a result, there is no evidence that AZ was able to act independently of its competitors, customers or consumers to any appreciable extent during the relevant period. AZ was in fact significantly constrained by its competitors (H2 blockers and other PPI producers) and customers (due to national price regulations and to the role of national health authorities as effective monopsony purchasers).
- (511) Finally, AZ observes that the existence of barriers to entry is not evidence of dominance. In fact, market entry did take place. There is no suggestion that AZ's patent litigation against Takeda and Byk Gulden was not legitimate. It is in any event irrelevant for the purpose of dominance.

2. DOMINANCE - THE COMMISSION'S ASSESSMENT

(a) The concept of dominance – the caselaw of the Court of Justice

- (512) As appears from the definition of the relevant market, AZ's dominance must be assessed on national markets for oral formulations of prescription PPIs.
- (513) The Court of Justice defines a dominant position as “*a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers*”⁵³¹.
- (514) Such a position does not preclude some competition but enables the undertaking which profits by it, if not to determine, at least to have an appreciable influence on the conditions under which competition will develop, and in any case to act largely in disregard of it so long as such conduct does not operate to its detriment⁵³². Such power may involve the ability to eliminate or seriously weaken existing competition or to prevent potential competitors from entering the market. As the Court stated, the existence of a dominant position does not however require the producer enjoying it to have eliminated all possibility of competition⁵³³. Similarly, dominance does not imply the absence of any competitive constraint. In particular, in dynamic markets, such as the pharmaceutical sector, where innovation plays an important role, dominance cannot be limited to situations where the dominant company would simply refrain from investing in R&D. In such markets, a dominant company has to invest regularly if it wants to preserve its market position. Thus, contrary to AZ's contention in its Reply, the mere fact that a company invests in promotion and R & D does not by itself rule out dominance.

(b) Relevance of market shares – the caselaw of the Court of Justice

⁵³¹ Case 27/76 *United Brands v Commission*. See also Case 85/76 *Hoffman-La Roche v Commission* and Case 322/81 *Michelin v Commission*.

⁵³² See Case 85/76 *Hoffmann-La Roche v. Commission*, paragraphs 38 and 39.

⁵³³ See Case 27/76 *United Brands v Commission*, paragraph 113.

- (515) A dominant position may be the outcome of a number of factors which, considered separately, would not necessarily be determinative⁵³⁴. According to constant case law market shares of the allegedly dominant undertaking in absolute terms as well as in relative terms (i.e. in comparison with the market shares of its main competitors) are an important parameter⁵³⁵. In *Hoffmann-La Roche* the Court of Justice ruled that “*very large market shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position*”⁵³⁶. Market shares ranging from 75% to 87% were deemed to prove dominance without any further analysis⁵³⁷. The Court of Justice has attached considerable importance to market shares, especially when the undertaking concerned manages to maintain its high market share over a long period of time and when the market share gap in relation to its competitors is considerable. In *AKZO* a market share of 50% over at least three years was considered strong evidence of the existence of a dominant position⁵³⁸.
- (516) The country-by-country analysis (section 3 below) will show that AZ maintained at least high market shares over the entire relevant period in the countries concerned.

(c) AZ’s technology and regulatory rights as barriers to entry and constraints on its competitors

- (517) A factor of considerable importance in determining dominance in this case relates to AZ’s technology in the form of intellectual property and other rights derived from pharmaceutical law.
- (518) Indeed, an OECD report cites some evidence to the effect that, generally speaking, “*intellectual property rights, in the form of patents and trademarks are relatively more important in the pharmaceutical industry than in other sectors*” and refers, in this connection, to “*one survey of several industries which ranks the pharmaceutical industry the highest in its reliance on patent protection*”⁵³⁹. Similar rights derived from pharmaceutical law also effectively result in barriers to entry into the pharmaceutical sector. In particular, until the expiry of data exclusivity applications for market authorisation need to rely on costly and lengthy preclinical and clinical trials. In addition, one study of pharmaceutical firms’ decisions to launch new pharmaceutical products in a large number of OECD countries identifies national market authorisation and price approval rules and bodies as barriers to entry⁵⁴⁰. Such rules, many of which remain national, entail costs and often long delays before a pharmaceutical product can be actually marketed (see recitals (145) and (258)).
- (519) In this case, AZ itself considers the patent protection around Losec to be exceptionally strong: “[t]o the best of Astra’s knowledge, no other major pharmaceutical product

⁵³⁴ See, inter alia, Joint Cases T-24/93 to T-26/93, T-28/93 *Compagnie maritime belge v. Commission* [1996] ECR II-1201, paragraph 76.

⁵³⁵ See inter alia C-85/76 *Hoffmann-La Roche v Commission*, notably para 39, *United Brands v Commission*, paragraphs 105-111, and Case 322/81 *Michelin v Commission*, paragraphs 52 and 60.

⁵³⁶ *Hoffmann-La Roche v Commission*, paras 39 and 41. See also Case T-30/89 *Hilti v Commission* [1991] ECR II-1439, paragraphs 91-94.

⁵³⁷ *Hoffmann-La Roche*, paragraphs 53-56.

⁵³⁸ Case C-62/86 *AKZO v Commission* [1991] ECR I-3359, paragraph 60.

⁵³⁹ See at [8967]. See also [9096-9097].

⁵⁴⁰ [9038-9039]. See also Commission Decision of 17 July 1996 in Case No IV/M.737 *Ciba-Geigy/Sandoz*, point 59.

has been subjected to so many innovations relating to it. The patent position throughout the world is unique ... [t]he patent situation concerning ... Losec is remarkable and far better than those that have ever covered other major pharmaceutical products ... no leading substance in the history of [the] pharmaceutical industry has had such a strong, overall protection as omeprazole” (see recital (23)). In addition reference may be made to AZ’s trademarks as well as copyright protection and design protection relating to Losec (recital (98) on Sweden).

- (520) As the pioneer inventor of PPIs, and, therefore, as the holder of the key technology protecting omeprazole, AZ has been able to act as a “gatekeeper”, i.e. independently of its competitors, in relation to three categories of competitive threats: latecomer producers of PPIs, producers of generic omeprazole and parallel importers of Losec. Indeed, through its abuses in this case, AZ sought to extend, legally or *de facto*, the period of protection of its technology, thereby strengthening or at least maintaining its position on the market.
- (521) Whilst it is true that AZ’s patent and SPC protection did not prevent market entry of the other PPI producers (Takeda, Byk Gulden and Eisai in order of entry), AZ was able to use both its substance and other patents (notably a formulation patent specially designed to provide protection against other PPIs than the substances covered by its own substance patent) (see recital (22)) to put pressure on its research based competitors Takeda, Byk Gulden and Eisai through patent litigation in numerous countries (see recitals (87)-(95)). These actions resulted in overall settlements between AZ and the three companies.
- (522) In particular, AZ was in a position to exert considerable competitive pressure on Takeda which in fact admitted infringement of AZ’s patent. In other words, AZ was in a position to determine the conditions for Takeda’s access to the market in the negotiations leading to the settlement of 16 May 1994 (see recitals (89)-(90)). The balance of rights and obligations of the parties under the settlement agreement clearly reflects AZ’s ability to dictate its terms. **[confidential]**
- (523) **[confidential]** it was in effect able – through its patents – to put pressure on and raise the costs of its much smaller competitor (see recitals (78), (86) and (93)-(95)). As will be seen in the country-by-country analysis (section 3 below), Byk Gulden remained a minor – and often marginal – actor on the market, with the exception of Germany.
- (524) Eisai was also forced to pay compensation and grant other product-related rights to AZ under the settlement in 1996 (recital (95)). It may be noted that Eisai only achieved marginal market shares in the markets concerned during the period relevant to this case.
- (525) Considering that Takeda’s possibility to market its lansoprazole products is dependent on the license agreed with AZ, AZ’s market shares do not sufficiently reflect its actual power on the markets concerned whereas Takeda’s market shares, for the same reason, overstate its position as an independent competitive force on these markets. In its market-by-market assessment (see section 3 below), the Commission has nevertheless adopted a conservative approach and has not included Takeda’s sales in the calculation of AZ’s shares of the markets concerned.

- (526) In relation to generic omeprazole, the primary competitive threat to AZ in this case, AZ enjoys an exceptionally strong patent protection in the form of e.g. substance patents (recital (19)) and SPCs (recitals (186)-(245)) as well as formulation patents (see recital (22)). By their very nature, substance patents and SPCs keep generic producers out of the market. Moreover, since generic firms do not normally possess patents, they are at a disadvantage to negotiate any settlement with AZ. It must be recalled that settlements (typically involving cross-licensing) are the standard way to reduce the uncertainty relating to patent litigation, which is especially acute in the pharmaceutical sector, and that the technological base of the parties (normally absent in the case of generic producers as opposed to research based undertakings) will determine their bargaining position.
- (527) AZ also enjoyed so-called data exclusivity, a form of regulatory protection that during its term prevents the issuing of market authorisations in respect of generic products (see recital (261)). Moreover, as generic manufacturers of omeprazole needed to refer to AZ's reference market authorisation to obtain their own authorisations under the generic procedure, AZ was in a position – by deregistering or varying its marketing authorisations – to hinder or attempt to hinder generic authorisations (recitals (259)-(261), (271) b), (287)-(295)).
- (528) Moreover, in relation to the two abuses in this case, AZ was in practice the sole undertaking in a position to act as it did. As the inventor of the first PPI, AZ's basic patent protection was the first to expire, paving the way for generic firms. Entry of generic versions of omeprazole would result in a significant and immediate decrease in the sales and prices of PPIs. Entry of generic PPIs (other than omeprazole) was not possible until Takeda's and Byk Gulden's patent protection and data exclusivity expired several years later in 2004-2005 and would not have the dramatic effect on prices resulting from entry of generic omeprazole. Only AZ was in a position at the relevant point in time to implement an exclusionary strategy aimed at excluding such generic competitors and artificially maintain prices for the whole range of PPIs. In addition, the presence of Takeda, Byk Gulden and Eisai was not sufficient to prevent an exclusionary strategy, or its effects, a fact which testifies to AZ's ability to behave independently vis-à-vis the main potential competitive threat in the market, namely generic versions of omeprazole.
- (529) Finally, in relation to parallel importers of Losec, it should be borne in mind that, by their very nature, parallel traders are not engaged in the marketing of products differing from the original reference product. After repackaging and relabelling as the case may be, parallel traders in fact sell AZ's product which they have obtained, directly or indirectly, from AZ in another EEA country. Parallel traders do not consequently detract from the relative strength of the position of AZ's technology on the market in the import countries. From the perspective of prescribers, patients and pharmacists the technology remains essentially the same. The total sales of Losec therefore better reflect the strength of AZ's product, brand and technology at the point of prescription. Furthermore, only AZ – as opposed to Takeda and Byk Gulden – was in a position to independently prevent or attempt to prevent access to the market of parallel traders whose import licenses depended on AZ's market authorisations for the products concerned (see e.g. recitals (263)-(264) and (283)). Moreover, these parallel traders were entirely dependent on whether and to what extent AZ decided to supply markets in low-price countries. For example, as part of its MUPS Strategy, AZ specifically decided not to launch Losec MUPS in certain low-price countries (see

recitals (282)-(306)). The fact that parallel trade in Losec constituted the least potent threat on the PPI market is confirmed by the inability of the parallel traders to maintain their sales and related market shares over time (see the country-by-country analyses in section 3 below). For these reasons, the market shares held by parallel importers at any given time in the markets concerned overstate their actual market power. Similarly, AZ's market shares understate the strength of AZ's technology on the market. In any case, purchases of Losec by parallel traders in countries of exportation intended for parallel trade have generated revenues for AZ.

- (530) The dependence of parallel traders on successful patented products is also borne out by the fact that parallel trade of reference products tends to decrease – generally dramatically – once generic versions of the reference products enter the market.
- (531) It follows from the foregoing that, broadly speaking, for most of the relevant years and in most of the relevant countries, AZ has in reality been deriving revenues from the bulk of all sales on the relevant PPI markets. Apart from its own sales (mostly from a position as market leader) **[confidential]** Moreover, revenues from Losec sales intended for parallel trade have also accrued to AZ via its marketing companies in the countries of exportation. Pantoprazole sales by Byk Gulden only reached, relatively speaking, sizeable levels in Germany.
- (532) These additional revenues from sales on the relevant PPI markets flowing into AZ's coffers constitute one explanation why AZ may have been willing to consent to a declining market share on the PPI markets. A further reason for AZ's possible willingness to forego some market share is related to the fact that in the pharmaceutical industry, which is characterised by the replacement over time of different generations of medicines within the same therapeutic area, the ability to maintain high prices in connection with a switch to a new generation product is strategically valuable in a European context where the ability to obtain a high reimbursement price is a key competitive parameter. Indeed, the primary aim of AZ's Losec Post Patent Strategy is to facilitate the switch from its omeprazole based products to its esomeprazole based products at as high a reimbursement price as possible, in particular through exclusion of generic omeprazole prior to the launch of the new generation product. This emerges clearly from AZ's national strategy documents for Denmark, Norway and Sweden (see recitals (298)-(301)).
- (533) AZ disputes that its belief that its patent protection was exceptionally strong acted as a barrier to entry⁵⁴¹. AZ also claims that its patent protection is not relevant to dominance⁵⁴².
- (534) The Commission does not share this view. Apart from AZ's own internal assessment of the exceptional strength of its patent protection around Losec (see recital (519)), it is a fact that **[confidential]**, a factor which affects the competitive relationship between those companies. In certain cases, AZ was also able to use its formulation patents to prevent generic market entry (see recitals (271) (e), (309) and (320)). Manifestly, AZ's patent protection is relevant to its position on the market vis-à-vis its competitors and therefore also to the assessment of dominance.

⁵⁴¹ AZ reply to letter of facts, p. 42.

⁵⁴² AZ reply to letter of facts, p. 43.

- (535) In addition, AZ maintains that there is no basis for claiming that AZ's legal actions were not legitimate⁵⁴³. However, the Commission does not suggest that the legal actions were not legitimate. For the reasons explained in the previous recitals the legal actions instituted by AZ are nevertheless highly relevant for assessing its dominance in this case.
- (536) **[confidential]**⁵⁴⁴
- (537) The Commission takes the view that evidence suggests otherwise. **[confidential]** AZ's argument that Takeda was already active on certain markets when AZ brought its infringement proceedings⁵⁴⁵, is immaterial. The relevant point is that AZ - by virtue of its patent portfolio relating to Losec and omeprazole - could to a large extent dictate the terms of Takeda's continued existence on certain markets and its right to enter other markets on a worldwide scale.
- (538) AZ claims that in respect of Byk Gulden there was no pressure and refers to claims for patent invalidity brought by Byk Gulden in connection with the litigation leading to the settlement⁵⁴⁶.
- (539) In the Commission's opinion AZ was in a "striking position" as the holder of the original PPI patent vis-à-vis *inter alia* its much smaller competitor Byk Gulden (see recital (87)). A worldwide campaign of patent litigation against Byk Gulden was carefully planned by AZ at the highest level of the company (as emerges from internal documents) (see recital (93)). The same documents indicate that patent litigation is lengthy and, therefore, costly. The proportionate burden on the smaller competitor Byk Gulden will therefore have been greater (see recitals (78)-(86)). The bringing of counterclaims is a standard defensive reaction of a company subjected to patent infringement proceedings in the pharmaceutical sector. It does not put the company sued on an equal footing vis-à-vis the litigant.
- (540) As regards AZ's technology it may finally be mentioned that during the period 1991-2000, AZ was the only producer able to introduce a second generation PPI substance, namely esomeprazole (see recitals (107) and (108)).

(d) Advantages related to incumbency in the pharmaceutical sector

- (541) Beyond the rights related to its pioneer technology, AZ enjoyed significant competitive advantages as incumbent on the PPI market. An OECD study (see recital (518)) concludes *inter alia* that expected profits decline as a function of the number of competitors and products already on the market. An increase of only one new competitor reduces the probability of another's entry by almost 30% and one additional older incumbent reduces the probability of entry by almost 40%. The study also finds that experience of the market and domestic status constitute very significant advantages. In this, AZ's Losec was marketed for five years within the EEA before the first competing PPI (lansoprazole) was launched in 1993. The market shares obtained by lansoprazole, pantoprazole and rabeprazole confirm the clear advantage of the

⁵⁴³ AZ reply to letter of facts, p. 43.

⁵⁴⁴ **[confidential]**

⁵⁴⁵ AZ reply to letter of facts, p. 44.

⁵⁴⁶ AZ reply to letter of facts, pp. 44-45.

incumbent compared to the latecomers. Although the second entrant (lansoprazole) was able to gain appreciable market shares in some EEA Contracting Parties, the third entrant (pantoprazole) remained a minor and often even marginal competitor, with the exception of Germany. Except for Germany, pantoprazole's market share generally did not exceed 3% and at most amounted to 7%. The market shares achieved by the fourth entrant (rabeprazole) mostly remained below 2%.

- (542) An often strong component of inertia in doctors' prescribing behaviour (see recital (115)) as well as brand loyalty⁵⁴⁷ confers an additional advantage on the first mover into a relevant market (such as AZ in the PPI market). Several AZ documents confirm that the strength and reputation of the Losec trademark and image as well as Losec's first-mover advantage constitute competitive strengths (recital (99) on Denmark, recital (101) on the Netherlands and recital (104) on Sweden). A Swedish strategy document describes the Losec trademark as well as the fact that Losec was the "*first product on the market*" as "*major strengths*" (recital (106)). A strategy document for the Netherlands AZ also refers to Losec as the most "*experienced PPI*" (recital (101)). The well-known brand image of Losec also derives from the fact that by 1998 (as well as during at least 1999 and 2000), it becomes the world's best selling prescription medicine ever (see recital (9)). AZ also emphasises the importance of being the "market leader" when launching a successor product (see recital (299)).
- (543) The advantages associated with incumbency in the pharmaceutical sector referred to above shed light on the fact that only a handful of competing PPIs entered a market characterised by double-digit growth for most of the relevant period in the countries concerned. The PPI producers, with the exception of Takeda, by and large remained minor competitors. By contrast, in 1998, a few years after the launch of competing PPIs, Losec became the best selling prescription medicine ever and remained so in 1999 and 2000.

(e) The relevance of price as a competition parameter in the pharmaceutical sector

- (544) In this case AZ has – generally speaking – been able to maintain higher prices than its PPI competitors (see tables 8 and 31-37 in the Annex as well as the market-by-market assessments in section 3 below and recitals (99), (101), (104), (106), (111) and footnote at the end of recital (69)).
- (545) In 1997 AZ observes that "*price as a competitive factor has received a more prominent role – partly at the expense of purely medical criteria*" (see recital (70)). Moreover, in several of its internal strategy documents covering three of the markets relevant to this case (Denmark, the Netherlands and Sweden) AZ indirectly admits that price is a relevant factor of competition. More specifically, the documents claim that AZ's higher prices constitute a competitive disadvantage compared to other PPIs (see recitals (99), (99), (101), (104) and (106)). See also recital (368) on the increasing importance of price as a competitive parameter during the 1990s in the EEA.

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- (546) More fundamentally, and contrary to AZ's claims⁵⁴⁸, AZ's higher prices constitute evidence of its market power in relation to its competitors on the PPI market (see recitals (363)-(366) and (460)).
- (547) First, in so far that AZ's higher prices reflects its greater – compared to Takeda and Byk Gulden - bargaining power vis-à-vis the national authorities to extract higher prices for Losec and Losec MUPS, this is evidence of AZ's market power.
- (548) Second, to the extent that the price differences between AZ's products and those of its PPI competitors result from AZ's ability to charge a price premium above the reimbursement level for Losec and Losec MUPS, it also reflects AZ's relatively greater competitive strength on the PPI market. The second scenario is possible in several of the countries relevant to this case (such as Denmark, Germany, the Netherlands, Sweden and the United Kingdom) which in principle allow free pricing (e.g. above the reimbursement level) (see recital (117)). Above the reimbursement level demand is normally elastic, considering that consumers will typically – in the form of copayment – have to pay for the amount exceeding that level (see recitals (119) and (133) *et seq.*). AZ accepts that that it is common in pharmaceutical markets for the first entrant in a specific category to maintain a “price premium” over later entrants⁵⁴⁹. Thus, such a pricing power is a further advantage related to incumbency in the pharmaceutical sector.
- (549) AZ contends that in the Statement of Objections the Commission did not identify the competitive price of Losec in each market or isolate any distorting effects of the role of national health authorities⁵⁵⁰. In AZ's view, in order to make any assessment of the significance of price differences the Commission would have to indicate what they considered the competitive price to be. The competitive price for Losec in each country would be the price that allows AZ on average to recover globally all of the R&D costs associated with Losec (including a return for shareholders) and some of the costs associated with R&D programmes that are unsuccessful, taking into account factors such as patent expiry. The Commission has, in AZ's view, advanced no evidence as to what the competitive price was in each market over the relevant period and whether the actual price was above or below that level.
- (550) In criticising the Commission for relying on price differences between Losec and other PPIs as evidence of a first mover advantage for the purpose of the dominance assessment, AZ explains that when assessing applications for reimbursement, most national authorities take into account pharmacoeconomic evaluations, particularly in cases where a price premium is requested for innovative products (e.g. Sweden, Denmark). Those evaluations weigh the therapeutic benefits vis-à-vis those of comparable products. The results of those evaluations are used to determine whether there is any therapeutic value added to the new products⁵⁵¹. Reimbursement bodies across Europe tend to view submissions for “me-too” products, line extensions and new formulations of existing drugs sceptically on the grounds that such products add only limited value.

⁵⁴⁸ 5.34, 5.38 AZ Reply.

⁵⁴⁹ 5.38 AZ Reply.

⁵⁵⁰ AZ reply to letter of facts, p. 37.

⁵⁵¹ AZ reply to letter of facts, p. 47.

- (551) The Commission takes the view that price differences between different products and categories of products resulting from bargaining with authorities are relevant for determining market power (see recitals (364)-(365) and (471)). The Commission's view is, moreover, that first-mover status is a phenomenon relevant for assessing dominance in the pharmaceutical sector. As admitted by AZ, first entrants are commonly able to maintain a price premium over new entrants. The available data in this case also shows that AZ – the first mover – spent less (in proportion to sales) on promotional activities than its two main competitors on the PPI market (Takeda and Byk Gulden) (see recitals (563)-(564)). Obtaining and maintaining as high a price as possible is also strategically important in the pharmaceutical sector in the context of transferring business to a new generation of medicines at a higher reimbursable price (see AZ's internal strategy documents: recitals (298)-(301)).
- (552) In the Commission's view, AZ's explanation of the practice of European reimbursement bodies evaluating "me-too" products (such as lansoprazole and pantoprazole) confirms the Commission's assessment that being the first mover entails competitive advantages in relation to later entrants. In addition, AZ's explanation confirms the Commission's view that relative therapeutic innovation as evidenced in the outcome of bargaining with national authorities is a crucial factor for assessing competitive constraints in the pharmaceutical sector.

(f) The relevance of monopsony buyers and price regulation in pharmaceutical prescription markets

- (553) AZ argues that the presence of monopsony buyers and price regulation (in various forms) in pharmaceutical markets deprive pharmaceutical companies of the ability to either determine their prices or exercise market power in respect of price.
- (554) AZ's general argument must be rejected. In fact, the influence on pricing exercised by the health systems which characterises pharmaceutical markets confers more market power on pharmaceutical companies compared to a situation where the final consumer would bear the full cost of the medicines. This is so due to the very inelastic demand which normally exists in pharmaceutical markets within the EEA (see recital (366)). The inelasticity of demand mainly derives from two factors. First, the consumer is fully insured or insured to a large extent against the costs of his or her medicines by the health system. Second, the key decision-maker in most cases – the prescribing doctor - does not bear the cost for the medicines.
- (555) For these reasons, the authorities in the EEA Contracting Parties have by and large introduced mechanisms aimed at reducing the quantity and price as well as improving the cost-effectiveness of the medicines consumed (see recitals (117)-(142) and (363)). One category of such cost-containment mechanisms aims to increase price sensitivity.
- (556) However, under a scenario where individual consumers bore the costs of medicines consumed, such government-imposed mechanisms designed to make demand more elastic would not exist. Therefore, price regulation whereby increased price sensitivity is introduced into pharmaceutical markets characterised by a high degree of market power, is simply a means of curtailing to some extent such excessive market power. Nevertheless, the residual market power is – for the reasons explained above – often considerable (see also recitals (363)-(366), (369) and (550)-(552)).

- (557) Indeed, in most EEA Contracting Parties prices are regulated only if the product is reimbursed (see recitals (117) and (121) - (127)). In such a case prices are not imposed, but the result of a rational choice by the undertaking, which is offered a potentially huge demand through the reimbursement by the health system. The undertaking can choose not to market a product in a particular country, a choice that AZ made use of when deciding not to launch Losec MUPS in several EEA Contracting Parties (see recitals (304) - (306)).
- (558) In view of the above, arguments about “buyer power” constituting an element conducive to lack of dominance are exaggerated. The health system may negotiate a price for a medicine, but it cannot normally determine the quantity of the medicine that will be bought, as the decision is mainly taken by a third party (normally the prescribing doctors and, to a limited extent, the final consumer). Within the EEA measures are often taken to encourage doctors to prescribe more cost-effective medicines but their effects are often limited. See for example the unsuccessful attempt by the authorities in the United Kingdom to discourage prescription of PPIs to treat dyspepsia (recital (29)).
- (559) In addition, since the national health system is also entrusted with the responsibility of ensuring the availability of the best medicines in order to protect public health, its bargaining power differs radically between a situation where it negotiates the price of genuinely innovative medicine from a situation where it negotiates the price of line extensions or other products in the same class of medicines. In general the health system cannot simply prevent or unduly delay the marketing of an innovative product through demands which can be perceived to be excessive. Indeed, there are many strong indications that Losec was in fact such an innovative product (see recitals (374), (382), (383) and (401) . On the other hand, the availability of medicines in the same class (such as “me-too” products) will tend to diminish the pressure on the health system, thereby increasing its bargaining power.
- (560) The relative bargaining power of the two parties - such as the therapeutic value added in relation to existing products the undertaking will bring to the negotiating table - will determine the outcome (see recitals (363)-(366) and (369)). Submissions by AZ at the Oral Hearing and the reply to the letter of facts reveal that AZ accepts that two-party bargaining – as opposed to unilateral imposition – influence and determine price and reimbursement levels (see recitals (367) and (550)).
- (561) In any event, the fact that a dominant undertaking may make more limited use of price as a parameter of competition does not mean that it may not behave to some extent independently of its competitors. For example, as evidenced by this case, a dominant company may still engage in exclusionary practices and put pressure on its competitors. Such practices are clearly liable to influence prices. The existence of health systems, which were clearly interested in generic entry as such entry was likely to put strong downward pressure on prices for the whole PPI class, was not sufficient to prevent AZ’s exclusionary strategies or their effects. This is an indication of AZ’s ability to behave independently vis-à-vis the health systems to a significant extent. While the health systems are in a position to negotiate a price level corresponding to the respective bargaining positions of the parties to the negotiation, they can neither determine nor influence the entry of competitors, including generic firms. Indeed, by virtue of its technology and first mover status, the dominant company may be the only undertaking in a position to do so (see recitals (520)-(531)).

(g) The relevance of research and development, promotion as well as financial strength and resources

Research and development as a factor of competition

- (562) AZ contends that dominance in pharmaceutical markets can be reflected in reduced research and development efforts. The Commission does not share this position. It should first be noted that the simple fact of having a dominant position on a given market is not as such contrary to the Community competition rules. Continuing investment in research and development is necessary for dominant companies as well, considering that dominance in pharmaceutical markets is generally short-lived due to the entry – sooner or later – of generic products. Such entry is particularly likely in the case of blockbuster products like Losec. The maintenance of dominance is therefore necessarily linked to the development of new generations of medicines (or improved versions of existing medicines) which enable the dominant company to maintain its lead. AZ's Losec Post Patent Strategy illustrates this phenomenon (see recitals (268)-(273)).

Promotion and marketing as a factor of competition

- (563) As to AZ's argument that a dominant pharmaceutical company needs to invest less in promotion and marketing, the Commission finds that this proposition is borne out by the evidence in this case. AZ's level of detailing activities for Losec (which AZ argues is a significant non-price factor of competition in pharmaceutical markets), compared to its sales, always remained far below the detailing of its competitors in the two markets (Germany and the United Kingdom) where such data is available⁵⁵². The fact that the incumbent – in this case AZ – had to invest less in promotion activities relative to its sales than later entrants to the PPI market – constitutes further evidence of AZ's dominance in this case as well as of the advantages linked to incumbency in the pharmaceutical sector.
- (564) In view of fact that AZ invested relatively less in promotion than Takeda and Byk Gulden in the markets where such data exists (Germany and the United Kingdom), AZ's continuing position as market leader must be attributable to other factors such as a perception of Losec as a better known product with an established reputation (i.e. advantages linked to AZ's position as incumbent) (see recital (542) above).

The need for financial strength and resources

- (565) The pharmaceutical industry is characterised by very high R & D and marketing costs which constitute further barriers to entry⁵⁵³. It is therefore also relevant to the assessment of AZ's dominance to compare AZ's financial strength, resources and specialisation in the pharmaceutical sector with those of the other two main research companies on the PPI: AZ's licensee Takeda and Byk Gulden.

⁵⁵² See Lexecon study, pp. 12-14, 17-19 (figures 1-3, 5-6) in respect of Germany and pp. 20, 22-23, 25-26 (figures 7-9, 11-12) in respect of the United Kingdom.

⁵⁵³ [8952, 8961-8963]; see also [8807].

(566) A comparison between AZ's, Takeda's and Byk Gulden's annual reports covering the period 1993-2000 reveals AZ's superiority on the PPI market in terms of a number of parameters (recitals (78)-(86)). First, the size of AZ's annual turnover (including its rate of increase) dwarfed that of Byk Gulden and considerably exceeded that of Takeda (recital (79)). Of particular importance for competition on the PPI market in this case is the sheer size of AZ's Losec sales which accounted for more than 50% of AZ's turnover in 1993 and more than one third of the said turnover in 2000 (ibidem). Moreover, whilst AZ's turnover almost exclusively related to pharmaceutical products, around one-third of Takeda's and Byk Gulden's respectively was attributable to non-pharmaceutical sales (recital (78)). AZ's total assets significantly exceeded those of Byk Gulden over the relevant period (recital (80)). From being inferior to Takeda's total assets in 1994, AZ's total assets exceeded Takeda's total assets in 2000 (ibidem). Third, AZ's earnings after tax exceed those of Takeda and – in particular – those of Byk Gulden (recital (81)). Fourth, reference can also be made to AZ's relative superiority in terms of return on equity and its generally strong financial position (recitals (82)-(83)). Fifth, AZ's R & D resources are superior to those of both Takeda and in particular Byk Gulden (recital (84)). Sixth, AZ's marketing resources are clearly superior to those of Byk Gulden (recital (85)). For example, in its annual report for 1994, AZ attributes its competitive strength on the German market to its "*highly competent sales force*" which AZ considers to be "*clearly decisive*" (recital (99)). Finally, unlike Takeda and Byk Gulden, AZ has not been obliged to rely on licensees in the relevant markets in this case (recital (86)).

3. AZ'S DOMINANCE ON THE RELEVANT GEOGRAPHIC MARKETS

(567) AZ's dominance on each of the seven AZ relevant markets will now be assessed with reference to country-specific factors. The reference periods are limited respectively to 1993-2000 (Belgium, Germany, the Netherlands, Norway, Sweden and the United Kingdom) and 1993-1999 (Denmark). Logically, dominance can only be established for the year as of which a PPI market has been established in each respective market (see recital (504)). Obviously, from 1988 to 1993, Losec – the only PPI available – accounts for all PPI sales. The figures below are based on sales in terms of value. AZ's argument that volume is a better measure than value in the context of assessing markets and dominance in the pharmaceutical sector has been addressed at recital (394).

(568) The country-by-country assessments below should be considered against the background of the Commission's general observations on dominance including the Court's general caselaw (e.g. on the relevance of market shares) (recitals (512)-(516)), AZ's technology and regulatory rights as barriers to entry and constraints on its competitors in this case (recitals (517)-(539)), the advantages relating to incumbency in the pharmaceutical sector (recitals (541)-(543)), the relevance of price as a competition parameter in the pharmaceutical sector (recitals (544)-(552)), the relevance of monopsony buyers and price regulation in the pharmaceutical sector (recitals (553)-(561)) as well as certain non-price factors as competition parameters in the pharmaceutical sector (recitals (562)-(566)).

(a) Belgium (tables 24 and 31)

- (569) During the reference period for Belgium (1993-2000), AZ sold its products both through its own marketing company and a licensee (Bio-Therabel). In view of the nature of the contractual arrangements between AZ and Bio-Therabel the latter company cannot be deemed to be a competitor of AZ (see recital (110)). Therefore, Bio-Therabel's sales have – for the purposes of this assessment – been attributed to AZ (see also recitals (572) - (576) below).
- (570) In Belgium AZ increases its sales and holds at least very large shares of an expanding PPI market. From 1991 to 2000, AZ's sales of Losec rise from USD 13 million to USD 57 million. It holds 100% of the PPI market in 1993. After the entry of Takeda, as a licensee of AZ under the settlement agreement of May 1994 (see recital (90)), AZ's market share remains above 90% from 1994 to 1996 and falls slightly below 90% in 1997, the first year when AZ faces two competing PPIs. In a growing overall PPI market, AZ's sales remain stable from 1998 to 2000 in absolute terms, while its market share decreases from 81% in 1998 to 68% in 2000. Over the same years, Takeda captures the bulk of the growth on the PPI market which takes its market share to 27% in 2000. Byk Gulden's market share never exceeds 5%. Until the end of the reference period (2000), AZ thus remains overwhelmingly the largest player on the PPI market in Belgium.
- (571) In 1994 (which is not representative, since lansoprazole sales represent only USD 70 000), 1996 and 1997, Takeda's prices somewhat exceed AZ's prices. In 1995 and from 1998 to 2000 the two companies' respective prices largely converge. However, it should be borne in mind that the competitive threat posed by Takeda is reduced due to its status as licensee of the incumbent's technology in respect of omeprazole (see recitals (90) *et seq.* and recital (525)).
- (572) AZ asserts that the existence of a licensed version of omeprazole on the Belgian market under a different brand name (i.e. Logastric) and marketed by a third party must necessarily represent a competitive restraint on Losec⁵⁵⁴. The material difference in the evolution of the market shares of Losec and Logastric over what the Commission maintains is the relevant period is, in AZ's opinion, testament to the competition between Astra and Bio-Therabel. AZ maintains that the convergence of prices between Logastric and Losec is symptomatic of the regulatory regime in Belgium as opposed to direct evidence that the licensor and the licensee are acting as one.
- (573) [confidential]⁵⁵⁵
- (574) [confidential]
- (575) [confidential]
- (576) [confidential]

(b) Denmark (tables 25 and 32)

⁵⁵⁴ AZ reply to letter of facts, p. 34.

⁵⁵⁵ [confidential]

- (577) Over the period 1993-1999, in an expanding PPI market, AZ's sales increase from USD 12 million to USD 27 million. Takeda's and Byk Gulden's sales rise to respectively USD 4.6 million and USD 2.4 million in 1999. From 1993 to 1999, omeprazole sales represented at least three quarters of all PPI sales (and sometimes much more). The years 1995 to 1997, however, display a specific feature in that a significant, albeit volatile, share of omeprazole sales is accounted for by parallel importers of Losec. Nevertheless, as explained above (see recital (529)), the parallel traders' – sometimes significant – market shares overstate their real competitive position on the Danish PPI market. Indeed, the fact remains that from 1995 to 1997, 85% to 75% of PPI sales were attributable to AZ's Losec. In other words, from the point of view of the prescribers, Losec overwhelmingly remained the leading technology. Furthermore, the parallel traders' possibilities to engage in trade in Losec were largely dictated by AZ's decisions to continue to supply Losec in low-price jurisdictions. It is thus not surprising that the size of the parallel traders' sales was highly erratic. Paranova's share of the market decreased from 22.8% in 1995 to no more than 8% the following year. By the end of 1997, parallel traders of Losec had virtually disappeared from the Danish market. In 1998, the parallel traders were completely excluded from the Danish market as a result of AZ's abusive strategy (see recitals (302) and (311)).
- (578) As of 1995, AZ faces competition from two other PPI producers. Of these, Byk Gulden poses only an insignificant competitive threat, attaining at most a market share of 6.7% in 1999. Takeda enters the market following its settlement with AZ in May 1994 as a licensee of AZ's technology and attains at most one fifth of the Danish PPI market in 1997 (including the parallel traded versions of lansoprazole). In 1995 to 1997, Takeda captures a greater part of the market growth than AZ.
- (579) However, in 1998, when it introduces Losec MUPS, AZ, whose prices are by then significantly higher than those of Takeda and Byk Gulden, increases its market share. Not only does it recover the sales of Losec by parallel importers, it also captures the entire market growth and even appropriates some of Takeda's and Byk Gulden's market shares. AZ's market share then decreases in 1999 but remains at a very high level approaching 75%, despite the fact that Losec MUPS prices exceed those of lansoprazole and pantoprazole by approximately 13%.
- (580) Numerous competitive advantages enjoyed by AZ as the incumbent on the Danish PPI market are set out in an AZ strategy document dating from 1998 (see recital (99)). The document observes that Takeda is AZ's only major competitor on the Danish market (confirming the lack of seriousness of the threat posed by parallel traders) and lists a number of parameters where AZ considers itself to be superior to its licensee: market share (confirming the relevance of market shares in the pharmaceutical sector), indications and documentation of its products, number of prescriptions, size and experience of its sales force, promotion and detailing, company image, trade marks, R & D image, management and experience. AZ considers that its higher prices compared to Takeda constitute its only competitive disadvantage. However, as already mentioned (see section 2 (e)), AZ's ability to maintain higher prices than Takeda and the other later PPI entrants, attests to its dominance.

(c) Germany (tables 26 and 33)

- (581) In an overall market which grows from 1993 onwards, AZ's sales rise every year to USD 179 million in 1998 save for 1996-1997 when there is a small dip in AZ's sales (from USD 144 million to USD 142). In 1999 and 2000 – following the entry into the German PPI market of numerous generic omeprazole products – AZ's sales, market share and prices fall. Byk Gulden's sales increase from its launch year 1994 to USD 94 million in 1999, after which they fall to USD 85 million in 2000. Likewise, sales by AZ's licensee Takeda rise from its launch year 1993 to USD 47 million in 1999, after which they decline to USD 36 million in 2000.
- (582) In terms of market shares, AZ holds 96% in 1993. In 1994, its share falls to 83% while Takeda's and Byk Gulden's market shares are respectively 12% (from 4% in 1993) and 5% (year of launch). In 1994, AZ's price is 12% higher than Byk Gulden's price and similar to Takeda's prices. Germany is the only relevant EEA Contracting Party where Byk Gulden attains rather significant market shares. Its sales between 1995 and 2000 account for between one fifth and one quarter of the market depending on the year. However, AZ's market share remains at least twice as high as Byk Gulden's market share from 1995 to 1997. In its annual report for 1996, AZ notes that in 1995 Losec is the best selling pharmaceutical product in Germany, despite competition from Byk Gulden (recital (99)).
- (583) Meanwhile, Takeda's market share develops as follows: 12% (1994), 13% (1995), 16% (1996), 17% (1997) and 16% (1998). The market shares of AZ, Byk Gulden and Takeda all fall considerably during 1999 and 2000 following market entry of generic omeprazole during 1999.
- (584) During 1995-1998 the price of Losec capsules is more or less identical to the prices of Byk Gulden and Takeda prices. In 1998, AZ succeeds in raising the price of Losec MUPS to a level of more than 5% above those of Byk Gulden's and Takeda. In this context, it can be noted that AZ was the first PPI manufacturer to introduce a new formulation of its active substance (Losec MUPS). AZ considered this to be a competitive strength (See recitals (101) and (104)).
- (585) The Lexecon study provided by AZ as part of its Reply contains data on non-price competition (in particular promotion in the form of detailing to doctors) in Germany (see recital (348)). The study shows that, relatively speaking, Takeda and Byk Gulden promote their product more heavily than AZ in Germany. In particular, from the end of 1994 (when pantoprazole is launched on the German market) to the end of 2000, there is greater detailing for pantoprazole than for Losec with the difference significantly widening after 1997 (often by two to three times). Detailing activities for lansoprazole remain equivalent to those for Losec over the relevant period in Germany. It should be borne in mind, however, that at the same time Losec's sales remain significantly higher than those of its competitors (see table 33 in the Annex). In other words, the ratio between detailing activities and sales for Losec was always far narrower than that of the other PPI producers. Moreover, this ratio even decreases for Losec over the years, since the number of detailing activities stay generally stable, while Losec sales continue to increase. This confirms the high level of entry barriers for and competitive constraints on new entrants on pharmaceutical markets, as new entrants in general need to invest relatively more in promotion than the incumbent (see recital (563)).

(d) The Netherlands (tables 27 and 34)

- (586) During 1993-2000 AZ's sales increase from USD 40.4 million to USD 171.6 million. Over the same period Takeda's and Byk Gulden's sales never exceed USD 12.5 million (1996) and USD 16 million (2000) respectively. From 1993 to 2000, omeprazole sales range from 100% to at least 86% of the sales of PPIs. Until 1998, parallel traders of Losec represent a significant part of these sales. However, for the reasons stated above (recital (529)), the existence of parallel trade in Losec entails that AZ's market share understates its real competitive position. Indeed, during this period (1993-1998), the vast majority of PPIs prescribed is made up of AZ's Losec. A drastic reduction in parallel imports of Losec occurs after 1998 and by the end of 2000 parallel traders of Losec virtually vanish.
- (587) In any case, no single parallel trader is able to challenge AZ's dominance in terms of market shares. In 1996, AZ's sales fall to their lowest level (below 59%). At that time, the two main parallel importers of Losec accounts for around 25% of PPI sales. During the entire period (1993-2000), AZ's price is the highest with one exception. In 1996 Stephar's price is 21% higher than the price of AZ's Losec. However, the market share of that importer is no more than 1%.
- (588) The market shares of the other two PPI producers remain at rather low levels, despite the fact that their prices are generally lower than those of AZ. Lansoprazole sales peak at just above 10% in 1996 and those of pantoprazole reach their maximum at slightly less than 8% in 2000.
- (589) In addition, reference is made to an internal AZ strategy document dating from October 1998 which reveals that overall AZ enjoyed considerable competitive advantages in relation, in particular, to its PPI competitors (recitals (101)-(102)). For example, AZ refers to its "*strong relationship with our opinion leaders*" (recital (102)) and states – in the context of the introduction of Losec MUPS – that "*Being the market leader, Losec can benefit more from increased penetration than other PPI's do*" (recital (101)).

(e) Norway (tables 28 and 35)

- (590) Between 1993 and 2000 AZ's sales rise from USD 9 million to USD 22.5 million. During the same period, Takeda's sales peak at USD 7.8 million in 1999, while Byk Gulden remains a marginal actor. From 1993 to 2000, omeprazole sales range from 100% to 74% of total PPI sales (and even more than 76% if AZ's sales of its new PPI – esomeprazole – are included). The years 1997 and 1998 exhibit a specific feature in that a significant – albeit changing – part of Losec sales is attributable to parallel importers. In 1998, AZ's share falls significantly to 45% of total PPI sales, with two parallel importers jointly accounting for 32% of the market. For the reasons explained (recital (529)), these market shares understate AZ's real market power, since it is AZ which possesses the key technology during the period in question. At that time (1997-1998), AZ is the holder of the market authorisation of Losec capsules in Norway, i.e. the reference market authorisation which serves as the basis for parallel traders' licenses until its deregistration at AZ's request on 1 December 1998 (see recitals (320)-(321)). AZ's success is such that the parallel traders of Losec almost completely disappear from the market the next year (1999), which again attests to the inability of

parallel traders to pose a serious and sustainable threat to AZ (see recital (529)). That same year, AZ's market share climbs back to its previous level of around 75%, with its sales more than doubling from 1998 to 1999.

- (591) Byk Gulden never reaches more than 1.8% of the market. Takeda, a licensee of AZ's technology by virtue of the settlement agreement of May 1994, gains market shares over the years. Its sales – including parallel traded lansoprazole - peak at 21.1% and 22.2% in 1999 and 2000 respectively. In these years AZ's market shares approach 75% and 67% respectively (including esomeprazole sales).
- (592) Throughout the period (1992-2000) AZ's prices are the highest on the PPI market. In 2000, the price gap between Losec and lansoprazole even widens, without resulting in a significant increase in Takeda's market share.

(f) Sweden (tables 29 and 40)

- (593) Between 1993 and 2000, AZ's sales increase from USD 45 million to USD 77.5 million (reaching a maximum of USD 122 million in 1996). Takeda's sales during the period 1993-2000 never exceed USD 7.4 million, with the exception of 2000, when its sales suddenly rise to USD 14 million. Byk Gulden's maximum sales are USD 2.9 million (in 2000).
- (594) Over the entire period, omeprazole sales represent more than nine tenths of PPI sales, with the exception of 2000 when they decrease to more than eight tenths of the total market. Until 1996, all Losec sales are attributable to AZ. A specific feature of the period from 1997 onwards is that a significant, albeit changing, proportion of omeprazole sales is accounted for by parallel importers. This is particularly true of 1998 when AZ's market share falls below 44%, while omeprazole sales still account for more than 92% of PPI sales. As explained (see recital (529)), sales of Losec by parallel traders means that AZ's market share understates its real strength on the PPI market. AZ's technology remains by far the leading technology throughout the period. Furthermore, the erratic pattern of parallel trade in Losec illustrates the inability of parallel traders to mount a sustainable competitive threat to AZ.
- (595) Finally, the very presence of the parallel traders on the market depends to a high degree on AZ. On 20 August 1998, by requesting the deregistration of the market authorisation for Losec capsules, AZ implements the tablet/capsule switch and capsule deregistration which it has planned since 1997, a key purpose of which is to prevent parallel trade of Losec capsules (see recitals (105), (283) and (314)). AZ's strategy is based on the fact that the continuing validity of the parallel import licences depends on the existence of AZ's market authorisation for Losec capsules (recitals (263), (264) and (315)). It is clear that the Swedish authority interprets the relevant Community and national provisions in the way hoped for by AZ at the relevant point in time, i.e. that the parallel trade licenses for Losec will be automatically revoked if AZ's reference authorisation is deregistered (recital (315)).
- (596) The market shares of the parallel traders rapidly erode to the sole benefit of AZ. Indeed, from 1998 to 1999, AZ's direct sales leap from 44% to almost 65%, while total omeprazole sales remain roughly unchanged at around 92%. In 2000, the parallel

traders' market share continues to decrease significantly with the two main parallel importers losing half their market share from 1999 to 2000.

- (597) The other PPI producers Byk Gulden and *a fortiori* the latecomer Eisai are no more than marginal players on the Swedish PPI market. Their market shares do not exceed 2.4% and 0.8% respectively, despite being much cheaper than AZ's products. Takeda's lansoprazole, which enters the market after the settlement arrangement with AZ in May 1994, never exceeds 7% of the PPI market (including parallel traded lansoprazole). The only exception concerns the year 2000 when lansoprazole's market share suddenly rises to more than 15%. However, between 1999 and 2000 Takeda cuts its price level by 30% taking it lower than AZ's prices by more than one third. Nevertheless, it appears that it is the parallel traders in Losec, rather than AZ, which suffer the most from Takeda's increase in market share, as AZ's market share decreases only marginally from 65% to 63.9%.
- (598) In addition, it is clear from AZ's internal documents that it possesses numerous competitive advantages on its home market Sweden, including its well-known and reputable trademark with a strong position and its first mover advantage (see recitals (98) and (104)-(106)).

(g) The United Kingdom (tables 30 and 37)

- (599) In the United Kingdom AZ's sales almost double from 1993 to 2000 (USD 163.9 million to USD 312.5 million), with a peak in 1997 when it reaches sales of more than USD 385 million. AZ's market share remains monopolistic or very high between 1993 (100%) and 1996 (88%). After 1997, AZ's market share decreases but remains more than twice as high as those of its first competitor, Takeda, whose access to the market is based on the terms of the 1994 settlement agreement with AZ under which it operates as a licensee of AZ: 78% as against 20% (1997); 68% as against 29% (1998) and 63% as against 31% (1999). In 2000, Takeda's market share rises to more than 33%, more than half of AZ's market share for that year (57%). From 1994 (Takeda's launch year) to 2000, AZ's prices are higher than Takeda's by the following percentages: 6% (1994); 6% (1995); 6% (1996); 14% (1997); 3% (1998); 2% (1999) and 14% (2000). Byk Gulden's market share never exceeds 3.6% (2000) and Eisai's market share never reaches 5%.
- (600) The Lexecon study also shows that all competing PPIs were promoted at least as heavily as Losec throughout the relevant period (see figure 12 of the study), while their sales volumes were significantly lower. As was the case in Germany (see above recital (585)), this confirms the existence of barriers to entry on that market, since entry requires a high level of promotion activities. It also shows that AZ did not have to significantly increase its detailing activities to match the entry of competing PPIs.

4. CONCLUSION ON DOMINANCE

- (601) In view of the foregoing, it is concluded that AZ held a dominant position within the meaning of Article 82 of the Treaty on the PPI market in the following countries and in the following years which are relevant to the present case: Belgium from 1993 until the end of 2000; Denmark from 1993 until the end of 1999; Germany from 1993 until

the end of 1997; the Netherlands from 1993 until the end of 2000; Sweden from 1993 until the end of 2000 and the United Kingdom from 1993 until the end of 1999. For the purposes of Article 54 of the EEA Agreement, dominance in Norway occurred with the entry into force of that Agreement (1 January 1994) and lasted until the end of 2000.

D. THE FIRST ABUSE – AZ’S MISLEADING REPRESENTATIONS AS PART OF ITS SPC STRATEGY FOR OMEPRAZOLE

1. SUMMARY OF AZ’S ARGUMENTS

- (602) AZ argues that Article 82 of the Treaty does not apply to a case relating to the ownership (as opposed to the exercise) of an intellectual property right.
- (603) Absent express provisions in the SPC Regulation, national patent offices and courts should have exclusive competence to deal with cases where an applicant has sought, or obtained, an SPC by making misrepresentations, and to determine the available remedies.
- (604) If the sanctions available under particular national laws are insufficient to protect the public interest and to deter the making of such misrepresentations, the only possible remedies would be for the Commission to take infringement proceedings against the Member States in question or for the Community institutions to amend the SPC Regulation to require Member States to amend their law.
- (605) AZ claims that it based its applications for SPCs on a bona fide and reasonable interpretation of Article 19 of the SPC Regulation which is consistent with the history, purpose and text of that Regulation and supported by the opinion of external counsel. The judgment of the ECJ of 11 December 2003 reflects the lack of clarity of Article 19 of the SPC Regulation.
- (606) AZ denies that there was any exclusionary SPC strategy involving deliberate misrepresentations and concealment in relation to patent agents and patent offices.
- (607) Its instructions were prepared under strong time pressure and resource constraints and their content reflected the best information in AZ’s possession at the time. Some errors were made. But they constitute no evidence of intent to mislead.
- (608) AZ claims that the dates indicated in the instructions reflect the additional information which AZ had obtained by the time it drafted the instructions, namely the effective authorisation dates in France and Luxembourg. The patent agents required details of the first authorisation date in the Community as well as the technical authorisation date in their home country. Once it was established that the “effective authorisation” date was Luxembourg, the details of effective authorisation dates in other countries were not relevant to the patent agents.
- (609) AZ argues that the technical authorisation numbers which appear in Part C of the instructions were an unintended leftover of a previous draft of 29 March 1993. AZ was not aware that the numbers were incorrect. With specific reference to the numbers cited by AZ in the instruction for Luxembourg and France, AZ argues that the patent

department had not considered whether it was appropriate or not to cite these reference numbers while making the argument as to effective authorisation. Viewed in retrospect, this created an apparent inconsistency in the information given with the instructions to the national patent attorneys, but one which was not relevant.

- (610) AZ contends that it inserted the required legal basis relating to the technical authorisation in Luxembourg in the instructions on advice from its Luxembourg lawyers and that the patent department did not at this stage know all the pricing regulations in Luxembourg.
- (611) As regards its use of the Luxembourg List in the instructions, AZ contends that it believed, prior to instructing its patent attorneys, that it had sufficient information to make applications for SPCs on the basis that the first effective authorisation date was after 1 January 1988 namely on 21 March 1988 in Luxembourg. It was clearly relying on the information provided by the Belgian marketing company in this regard.
- (612) AZ argues that its behaviour was “normal” competition. Its centralised approach to applications for and defence of SPCs was normal and legitimate. The instructions were contained in the same standard form for administrative convenience. The instructions to the patent agents reflected the practice at the time. It would have been unusual to include information explaining the underlying basis for the instructions. Legal issues were the domain of patent lawyers not the patent agents which drew up the instructions. The expectation of the national patent attorneys is that they will apply the information given by the client or its “home attorney” to the application forms used in their own national offices. AZ was under no enhanced obligations in its dealings with patent agents, patent offices and courts. AZ claims that Article 82 does not apply to any conduct but a dominant undertaking, only to conduct which is not normal, that is conduct that differs from normal competition.
- (613) AZ moreover asserts that the patent offices published details on applications and grants and that this was closely monitored by competitors.
- (614) AZ claims that the basis of its SPC applications was discussed with most patent attorneys. It admits that in later dealings with patent offices an error was made and patent agents acted without instructions but AZ denies that it deliberately misled patent offices. In this respect, AZ has made a large number of specific arguments. Considering their detailed nature and the large number of jurisdictions concerned, these arguments will be set out and replied to below in respect of each relevant jurisdiction (see section 4 below).
- (615) As regards its second round of SPC applications for omeprazole in December 1994, AZ argues that it was satisfied in the light of further investigations as to the first effective authorisation date in Luxembourg that there was no need to change the basis of its SPC applications.
- (616) AZ claims that it cannot be criticised for failing to use the Swedish date during the second round of applications and that this was due to an “oversight”. First there was (and still is) uncertainty as to whether this would in fact be the relevant date given the complexities of the amendments to the SPC Regulation in applying it to the EEA, and later to the accession countries. Second, if this was in fact the correct date it would

simply mean that the duration of the SPC in Austria, Finland and Norway would be marginally (by a matter of weeks) shorter than the SPCs that were ultimately granted.

- (617) AZ denies that there were any deliberate misrepresentations to national courts in Germany, Norway and Finland. Conduct as defendant in legal proceedings is incapable of amounting to an abuse in any case. In respect of those proceedings, AZ has provided specific arguments. These will be addressed in the Commission's assessment dealing with those proceedings (see section 4 (i), (j), (k) and (l) below).
- (618) AZ further defends its changing presentation of its "effective marketing" theory as constituting normal behaviour involving adjustments and refinement over time (e.g. taking account of the litigation context). In essence, AZ claims that it has consistently relied on the "effective marketing" theory.
- (619) AZ contends that the Commission's proceedings in this case subvert the pending national SPC litigation in Finland, German and Norway where the courts may have to engage in further fact-finding. These courts have according to AZ not accepted the plaintiffs' fraud allegations against AZ and the allegations have in any case been peripheral or irrelevant in the proceedings.
- (620) AZ finally argues that an infringement of Article 82 requires that the conduct produce or be likely to produce an appreciable effect on competition. In that context, a "misrepresentation" requires that it was in fact acted upon.
- (621) AZ claims that there were in any case no appreciable effects on competition for the following reasons.
- (622) First in some countries the SPC was granted for a term which was no longer than – even on the Commission's case – the term to which AZ was entitled (the United Kingdom) or no SPC was granted at all.
- (623) Second, in some countries the SPC was set aside well before expiry of the substance patent (Germany) or shortly after (Norway).
- (624) Third, in some countries, generics suppliers have ignored the SPC and launched products following the date on which the Commission contends the SPC should have expired (in the 1988 countries on the expiry of the substance patent) and before expiry of the SPC (Austria, Belgium, the Netherlands and Finland).
- (625) Fourth, there were other reasons why generic competitors did not enter or were excluded from the market, for example, valid formulation patents (in particular in Belgium, Denmark, Finland and Norway) and a variety of commercial factors which operated as a disincentive to entry (for example, in Belgium and Finland).

2. THE FIRST ABUSE – THE COMMISSION'S ASSESSMENT

- (626) In essence, the abuse consists of a pattern of misleading representations knowingly engaged in by AZ – as part of its overall SPC Strategy – to patent agents, patent offices and national courts in order to acquire (or preserve) SPCs for omeprazole in the so-called 1988 countries as well as in certain 1982 and 1985 countries. Through these misleading representations AZ aimed to keep generic manufacturers away from the

market. It should be emphasised that the abusive character of the said behaviour – involving misleading representations within the framework of a highly centralised and coordinated strategy – follows from the specific facts set out in this decision. The assessment takes account of the fact that AZ’s behaviour did not constitute normal business behaviour and that the patent offices instrumentalised by AZ in this case in practice exercised a limited degree of discretion when assessing the information submitted by the SPC applicants.

- (627) AZ’s misleading representations as part of its SPC Strategy for omeprazole concern the information which AZ provided to patent agents and patent offices pursuant to the transitional provisions of the SPC Regulation (Article 19).
- (628) AZ’s single and continuous abuse unfolds in stages. AZ’s decision of 6 May 1993 not to reveal certain crucial data on the final form of the instructions for omeprazole to be filed to the patent offices via the patent agents constitutes a key piece of evidence revealing AZ’s exclusionary intent. More precisely, AZ conceals two technical authorisation dates which it knows are pre-1 January 1988. It replaces them with two later dates, which are post 1 January 1988, and which AZ will refer to – at a later stage – as “effective marketing” dates⁵⁵⁶. In line with that decision, AZ makes misleading representations in connection with its SPC instructions of 7 June 1993 for the SPC applications in seven Member States in June 1993 (Belgium, Denmark, Germany, Ireland, Luxembourg, the Netherlands and the United Kingdom). The transmission of those instructions is considered to be the starting point of the abuse.
- (629) In a second stage, during 1993 and 1994 AZ makes misleading representations to patent offices when they raise questions about AZ’s applications. AZ also makes misleading representations during its second round of SPC applications in three EEA Contracting Parties (Austria, Finland and Norway) in December 1994. Thereafter, AZ continues to make misleading representations before other patent offices and in the context of proceedings brought before certain national courts by generic manufacturers with a view to invalidating AZ’s SPCs in those countries.
- (630) AZ’s strategy to obtain and maintain SPCs through its misleading representations is highly successful resulting in SPC protection in three countries (Finland, Germany and Norway) and SPC protection of considerably longer duration than would otherwise have been the case in four other countries (Austria, Belgium, the Netherlands and Luxembourg).
- (631) It has been noted that the misleading representations formed part of a centralised and coordinated strategy covering numerous EEA Contracting Parties. In order to grasp that strategy and the interlinked nature of the misleading representations it is appropriate to describe AZ’s behaviour in all the countries concerned by the strategy, regardless of whether the Commission concludes that AZ was dominant in those markets.

3. THE FIRST STAGE OF THE ABUSE

⁵⁵⁶ Under this “effective marketing” theory, which AZ will only formulate at a later stage, the relevant date under Article 19 of the SPC Regulation is the point in time when all legal and administrative formalities (such as pricing and/or reimbursement decisions) have been completed to enable effective marketing of the product (see recital (213)).

(a) AZ's strategy for omeprazole and other products for which first technical market authorisation date in the Community is situated before 1 January 1988

- (632) A key piece of evidence of AZ's exclusionary intent dates from 6 May 1993 when AZ decides not to reveal certain crucial data in its final instructions, sent on 7 June 1993, for the SPC applications for omeprazole.
- (633) Indeed, by mid-March 1993 at the latest, AZ has identified a problem with regard to omeprazole in the sense that the first technical authorisation date in the Community for omeprazole is situated before 1 January 1988 (i.e. disqualifying AZ from SPCs in the 1988 countries Denmark and Germany where the applicable cut-off date is 1 January 1988).
- (634) This emerges most clearly from one memorandum by an employee at AZ's patent department to Hässle dated 16 March 1993. That memorandum, which contains draft instructions to the patent agents for the omeprazole SPC applications, cites "*France... april 1987*" as the "*first market registration in an EC country*" and states that AZ's patent department therefore considers that for Denmark and Germany (i.e. the 1988 countries) "*an [SPC] application is not possible as the first market registration in the EC was before 1988*" (see recital (164)). The patent department's belief that no SPC can be obtained for omeprazole in the 1988 countries recurs in two other memoranda to Hässle (dated 16 March 1993 and 5 May 1993) containing draft instructions for omeprazole sodium (respectively recitals (165) and (178)).
- (635) Apart from omeprazole, Hässle was also to sign the instructions for SPC applications for two of its other products (omeprazole sodium and felodipine) (recital (162))⁵⁵⁷. By mid-March 1993, AZ's patent department has identified the same problem in respect of those two products as for omeprazole: the first technical authorisation date in the Community for omeprazole sodium and felodipine is before 1 January 1988 (i.e. disqualifying AZ from SPCs in Denmark and Germany where the applicable cut-off date is 1 January 1988) (see recitals (163) and (166))⁵⁵⁸.
- (636) As of mid-March 1993, AZ's patent department collects information from the local marketing companies, via Hässle, to support its SPC applications. However, the collection of data is highly selective in that it only concerns the "problem products" omeprazole, omeprazole sodium and felodipine. Moreover, the collection of data takes the selectivity even further in the sense that it only focuses on the "problematic" dates, i.e. only those authorisation procedures where the technical authorisations were issued prior to 1 January 1988.
- (637) On 22 March 1993, as part of the collection process, AZ's Belgian subsidiary (which was responsible for AZ's Luxembourg business at the time) provides Hässle with copies of the technical authorisation of omeprazole in Luxembourg dated 16 November 1987, as well as a copy of the Luxembourg price approval for omeprazole dated 17 December 1987 (stamped by Astra Belgium on 31 December 1987 during the Christmas closure) (recital (170))⁵⁵⁹.

⁵⁵⁷ 6.66 AZ Reply.

⁵⁵⁸ 6.67 AZ Reply.

⁵⁵⁹ See also 6.70 AZ Reply.

- (638) One week later, in a memorandum dated 29 March 1993 from the patent department to Hässle containing updated draft instructions for omeprazole, the patent department cites France as “*the first market registration in an EC country*”. At the same time, the patent department takes the position that for the 1988 countries – and only for these countries – a post-1 January 1988 date will be used (“*for the applications in DE and DK the patent department will argue before the respective patent offices that the first valid registration in the EC took place only after 1 January 1988*”) (recital (167)). No indication is given of the nature of this post-1 January 1988 date. The authorisation date given for Luxembourg is October 1987 (*ibidem*). It is important to note that those draft instructions dated 29 March 1993 form the template on the basis of which AZ on 6 May 1993 takes its final decision on the instructions. It will be shown that – at that crucial stage – AZ decides to conceal the French and Luxembourg technical authorisation dates from the patent agents, the only technical authorisations predating the decisive cut-off date for the 1988 countries.
- (639) Meanwhile, AZ’s patent department continues to receive strategic information from Hässle and the local marketing companies. In a memorandum of 30 March 1993 from Hässle to the patent department⁵⁶⁰, Hässle confirms the results of its inquiries raised with national marketing companies to Astra’s patent department. Hässle’s memorandum contains data on the authorisation procedure for omeprazole in Luxembourg and France as well as for felodipine in Denmark (recitals (169)-(171)).
- (640) The information on omeprazole in Luxembourg reflects the information sent by Astra Belgium to Hässle on 22 March 1993 (see recital (637) above) whilst adding that “[t]he price must be officially published before the product can be sold in the Pharmacies [in Luxembourg], but I do not know the date ... yet” (*ibidem*)⁵⁶¹. The information on France states that the technical authorisation was granted in April 1987, that the price negotiations were concluded in the spring of 1989 and that the price approval was published on 22 November 1989.
- (641) Moreover, in the same memorandum dated 30 March 1993 Hässle identifies six types of dates that it will investigate. None one of those dates are later than the date of publication of the price. In fact Hässle states that it considers this date of publication of the price as decisive. It proposes to the patent department to obtain the same type of data for other countries. This emerges from the following passage in the memorandum: “[w]e will obtain the same information from the other countries in order to determine dates according to the same criteria in the various countries” (recital (168))⁵⁶².
- (642) However, Hässle’s proposal to obtain the same data for other countries on the instructions is not followed up by Astra’s patent department.

⁵⁶⁰ The memorandum of 30 March 1993 is a reply to a memorandum of advice from the patent department dated 29 March 1993 which, according to AZ, appears to have been lost (see recital (168)). See also footnote 385 at 6.72 AZ Reply.

⁵⁶¹ 6.73 AZ Reply.

⁵⁶² By “other countries”, Hässle can only refer to the ten other countries on the draft instructions prepared by the patent department (including the draft instructions for omeprazole dated 29 March 1993) or to countries relevant for the omeprazole sodium and felodipine applications. The term cannot refer to countries relating to AZ’s SPC applications for products other than those for which Hässle is the relevant product company (omeprazole, omeprazole sodium and felodipine).

- (643) In the end, Astra’s patent department uses the collected data very deceptively and selectively in its final instructions. In fact, Astra uses alleged “effective marketing” dates, as it will describe them later, only for the “problem products” omeprazole and omeprazole sodium (recitals (246)-(253))⁵⁶³. This is necessary to take the crucial first authorisation date in the Community across the decisive cut-off date for the 1988 countries (i.e. 1 January 1988).
- (644) However, for felodipine, AZ uses a second type of date – the first date of the publication of the technical market authorisation (*in casu* in Denmark on 21 January 1988) (recital (249))⁵⁶⁴. AZ does so even though it knows from Hässle’s memorandum of 30 March 1993 that Denmark is an “effective marketing” country where no pharmacy would sell felodipine without knowledge of publication in the *Specialitetstaksten* (see footnote at recital (169)). From that document AZ even knows the exact date of “effective marketing” for felodipine in Denmark (29 February 1988) (*ibidem*). This is not consistent with the statement at the Oral Hearing by the then head of AZ’s patent department that he would have liked to have filed “effective marketing” dates for all of AZ’s products but that there was not enough energy, resources, cooperation and time to collect the relevant data. It is clear from the foregoing that AZ, at least for felodipine, knew that it had obtained the “first effective marketing” date more than two months before it filed its SPC applications for felodipine. It is noteworthy that AZ, in its submissions, does not address its awareness of the effective marketing date for felodipine in Denmark⁵⁶⁵.
- (645) As regards the five other products for which AZ was to file SPC applications under the transitional provisions (recital (162)), AZ uses a third type of date – the technical authorisation date – all of which are later than 1 January 1988 (recital (254)).
- (646) Thus AZ uses three different types of authorisation dates when filing its SPC applications pursuant to Article 19 of the SPC Regulation at around the same time (recitals (246) *et seq.*).
- (647) Moreover, AZ’s final instructions for the omeprazole applications are drafted in a highly misleading form. It is in this sense that the term “misleading representation” should be understood in the context of the first abuse. More specifically, AZ’s instructions create a false impression that they are entirely based on technical authorisation data. AZ does not even reveal this anomaly to its patent agents and the patent offices. The origin and nature of this crucial misleading representation is described below (point (b)).

(b) AZ’s decision to conceal and its instructions of 7 June 1993 for the omeprazole SPC applications

- (648) The origin of AZ’s misleading instructions for omeprazole – and a key piece of evidence of AZ’s exclusionary intent – is Hässle’s decision of 6 May 1993 (in

⁵⁶³ In its French and Swedish applications for omeprazole sodium, AZ cited the technical authorisation date. For France, AZ claims that the patent agent disobeyed AZ’s instruction and for Sweden, AZ claims that this was “an error” resulting from the unclear situation arising out of Sweden’s EU accession (see the relevant footnotes at recital (247)).

⁵⁶⁴ With the exception of Ireland, where AZ used the technical authorisation date.

⁵⁶⁵ AZ reply to letter of facts, p. 54.

Swedish) on the final form of the instructions to be filed to the patent offices via the patent agents (recital (175)). As mentioned the basis for that decision is the patent department's draft instructions of 29 March 1993 (to be signed by Hässle) which set out the technical authorisation in France as the first Community authorisation (see recital (638) above). It also states that the Luxembourg authorisation was granted in 1987. These are the only two pre-1 January 1988 authorisation dates for omeprazole on the draft instructions, which also contain authorisation data for the ten other Member States. Crucially, AZ adds a number of handwritten annotations (in Swedish) to the draft instructions. These annotations, which appear on the decision of 6 May 1993, overrule the original draft in a number of decisive respects. Through the handwritten annotations AZ decides not to reveal the only two pre-1 January 1988 dates on the draft instruction form.

- (649) Specifically, a handwritten annotation instructs that “*Luxembourg March 1988 to be cited as first in EC*” replace both “*France*” and “*April 15 1987*”. Another handwritten annotation orders that the French date be changed to 22 November 1989 (“*FR: 22 November 1989 to be cited!*”). Moreover, a further handwritten annotation instructs in respect of Luxembourg, that “*October 1987*” be removed and replaced by “*March 1988*” (see recitals (176)-(177)).
- (650) It is not clear whether these handwritten annotations emanate from Astra's patent department or Hässle. In either case, they prove first of all that AZ decides not to reveal the Luxembourg technical authorisation date (16 November 1987) and tries to create the impression that the date instead given for Luxembourg – “*March 1988*” – is the technical authorisation in Luxembourg as well as the “*first authorisation ... within the Community*” as referred to in Article 19 of the SPC Regulation (recitals (151), (156)). This strategy would however not work if the French technical authorisation date is revealed. Accordingly, on the final decision of 6 May 1993, AZ decides to strike out the reference to the French technical authorisation date in the draft instructions.
- (651) As a result, the final instructions for the SPC applications for omeprazole dated 7 June 1993 to all seven first round patent agents – which constitute the starting point of the abuse - are highly misleading (recital (179)-(182)). They contain two sets of data – technical authorisation data and data purporting to relate to effective marketing. This distinction is neither revealed nor explained. Furthermore, in its instructions AZ only submits “effective marketing” dates to the extent that it is really necessary not to reveal to its patent agents (and thereby the patent offices) the only two pre-1 January 1988 technical authorisation dates on the instruction form: 15 April 1987 for France and 16 November 1987 for Luxembourg. Since all the data, except the dates for France and Luxembourg, relate to the technical authorisation, the reader is necessarily led to believe that those two dates also relate to the technical authorisation.
- (652) This conclusion emerges from an analysis of the dates, numbers and legal basis cited on the instruction form (*ibidem*), which includes data relating not only to France and Luxembourg but also to the ten other Member States at the time (recital (182)).
- (653) First as regards the dates it is clear that AZ cites the technical market authorisation dates for seven of the Member States on the form (*ibidem*). The date cited for Portugal in fact even precedes the technical authorisation date, whilst no dates are cited for

Spain and Italy (*ibidem*). The dates for France and Luxembourg bear no relation to the technical authorisation.

- (654) Second, as regards the number of the first Community authorisation (Article 8 (1) (a) (iv) of the SPC Regulation – see recital (151)), AZ misleadingly cites the number printed on the Luxembourg technical authorisation dated 16 November 1987 (“445/87/11/0446”) (recitals (170), (179)). The same misleading and unexplained discrepancy is applied by AZ to France: the technical market authorisation number is inserted but the date given – 27 November 1989 – bears no relation to the technical market authorisation of 15 April 1987 (recital (163), (164), (169) and (171)). For seven of the other Member States appearing on the instruction form, AZ also inserts the technical market authorisation numbers (recital (182)). No numbers are cited for Spain and Italy. In respect of Portugal two numbers are cited. AZ does not claim that those numbers do not relate to the technical authorisation for Portugal.
- (655) Third, as regards the legal provision under which the first Community authorisation was granted (Article 8 (1) (c) of the SPC Regulation; see recital (152)). In its instructions AZ mentions a Luxembourg law which does not relate to the date “March 1988” cited as the first Community authorisation but to the technical authorisation dated 16 November 1987, of which AZ obtained a copy already on 22 March 1993 and which clearly cites the legal provision relevant to the technical authorisation (recital (170))⁵⁶⁶.
- (656) Finally, as regards the copy of the notice publishing the first Community authorisation in the “*appropriate official publication*” (Article 8 (1) (c) of the SPC Regulation – see recitals (151)-(152)), AZ supplies a copy of the cover page and page 246 of the Luxembourg List, which – even on AZ’s effective marketing theory – is misleading.
- (657) In order to explain why AZ, even on its “*effective marketing*” theory, could not reasonably rely on the Luxembourg List and in order to address AZ’s claim that it believed that it had sufficient information to make applications for SPCs on the basis that the first effective authorisation date was on 21 March 1988 in Luxembourg (see recital (611)), it is appropriate to recall a few facts, especially in respect of the information received from Astra Belgium in March and April 1993, which, according to AZ, formed the basis for its reliance on the List in its SPC applications for omeprazole.
- (658) On 22 March 1993, AZ had received copies from Astra Belgium of the technical authorisation in Luxembourg dated 16 December 1987 and the price approval dated 17 December 1987 (recital (170)). Nearly two weeks later, on 5 April 1993, Hässle also received the cover page and page 246 of the Luxembourg List from Astra Belgium (recitals (172)-(173)). On 7 April 1993 Hässle forwarded the two pages of the List to Astra’s patent department (recital (172)). Specifically, the cover page of Astra Belgium’s letter simply refers with respect to the cover page and page 246 of the Luxembourg List to a “*copy of an official paper, dated March [1988] listing the authorized products in Great-Duchy of Luxembourg*” (recital (173)). Nothing in this

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In 1998 before the Belgian patent office, AZ continues to rely (in support of its omeprazole sodium application) on the date “21 March 1988” supported by the List (see recital (248)); in order to make the misleading information more consistent AZ this time decides not to refer to the legal basis for the technical authorisation but the legal basis for the pricing decision from December 1987.

characterisation suggests that the List has the general effect that AZ will later attribute to it, i.e. that of enabling effective marketing in Luxembourg.

- (659) Nor does Astra Belgium’s letter in any way state that it was possible to effectively market Losec in Luxembourg only after “March 1988” or – as AZ later will specify – on “21 March 1988”.
- (660) Moreover, the List contains no number on which AZ could rely to comply with Article 8 (1) (a) (iv) of the SPC Regulation. To overcome that problem, AZ cited the number of the technical authorisation of 16 November 1987, without providing any explanation therefor.
- (661) By 7 April 1993 it is also clear to AZ that it does not have the complete List and that the List does not contain a price for omeprazole capsules (see recital (173)). Indeed, in subsequent legal proceedings in Norway in May 1999, AZ admits that “*it does not have the complete Liste ... or any part thereof comprising the price of Losec*” and that “*lengthy efforts have been made to procure this document ...*” (recital (241)). The same conclusion can be drawn from AZ’s submission in the parallel SPC proceedings in Finland (recital (245)). That the Luxembourg situation was “unclear” is also admitted in internal deliberations after the AZ merger in April 1999 (see recital (230)). Moreover, an AZ document dated 14 February 1994 (recital (211)) shows that AZ did not know whether omeprazole had in fact been marketed before 21 March 1988 in Luxembourg. Yet, AZ still decides to use the List as the “notice” required by the SPC Regulation.
- (662) Although AZ initially uses “March 1988” in its first round of instructions on 7 June 1993, it afterwards – when asked by patent agents and patent offices – specifies the first Community authorisation date to be “21 March 1988” in Luxembourg (recitals (185), (186), (187), (192)-(193), (203)-(204), (207)-(208), (209), (218), (221), (233), (234) and (243)). There is no basis for AZ’s reliance on that specific date. First, AZ’s Belgian marketing company attached no specific importance to the date “21 March 1988” when it transmitted the two pages of the Luxembourg List to AZ (recital (170)).
- (663) Second, as the Belgian marketing company did not specifically refer to “21 March 1988”, there was no reasonable basis for AZ to assume that the date “21/03/88” printed on the top-left corner at page 246 referred to the date on which Losec was authorised for effective marketing (recital (173)). Moreover, considering that the list of the 23 products on page 246 starts with “Lo” and ends with “Lu”, it does not appear credible that all these products would have been authorised for effective marketing on 21 March 1988. In any case, there is no explanation why of all those 23 products only Losec capsules (omeprazole) and the injectable version of Losec (omeprazole sodium) should be deemed to have been effectively authorised for marketing on 21 March 1988.
- (664) In the account of the second stage of the abuse in section 3 below it will be shown that AZ’s obtains additional information which further undermines its reliance on the List and the “21 March 1988” date.

(c) AZ’s arguments and the Commission’s responses

- (665) First, the elaboration of AZ's overall SPC Strategy for omeprazole (see AZ's arguments at recital (606)) emerges from the nature and content of as well as the links between a large number of documents and actions by AZ (in particular the patent department's memoranda of 16 and 29 March 1993, Hässle's memorandum of 30 March 1993, AZ's handwritten amendments to the patent department's draft instruction on Hässle's decision of 6 May 1993 and the patent department's final instructions of 7 June 1993). The strategy emerges most clearly from the active concealment of the French and Luxembourg technical authorisation dates on the decision of 6 May 1993, in particular when viewed in the context of AZ's applications for its other products. Finally, on 21 October 1999, the then head of AZ's department admits to having elaborated an SPC Strategy for omeprazole in 1993 (recital (230)).
- (666) Second, this Decision raises no objections against AZ for having incorrectly interpreted the relevant law (*in casu* the SPC Regulation) (see recital (605)) but concerns AZ's pattern of misleading representations to patent agents, patent offices and national courts as part of its overall SPC Strategy for omeprazole. Against this background, the proceedings and the outcome in Case C-127/00 *Hässle AB v. ratiopharm GmbH* (i.e. the case referred to the Court of Justice of the European Communities on 1 February 2000 by the Federal Court of Justice) are not decisive for this Decision (see recitals (222) *et seq.*)⁵⁶⁷. Any lack of clarity in the SPC Regulation and in particular Article 19 thereof cannot therefore justify AZ's misleading representations and concealment as part of its SPC Strategy.
- (667) Moreover, the Commission notes that although AZ's reliance on the Luxembourg List was supposedly based on a certain interpretation of the law, AZ's misleading representations do not appear to have been instrumental to that interpretation. Indeed, no patent office ever accepts that interpretation, when AZ subsequently divulges it to certain patent offices. AZ does not - on the basis of that interpretation - challenge any of the decisions not to grant an SPC or to grant an SPC for a shorter term. In fact, AZ's use of the interpretation is limited to justifying *a posteriori* its use of the "March 1988" date before national patent offices and courts, in the context of the litigation ensuing after the granting of the SPCs. AZ's aim is in fact to hide the theory which is purported to support its SPC applications. In other words, AZ's objective is not to submit an alternative interpretation to the authorities. The fact that AZ persisted in its pattern of misleading representations and that its additional misleading representations did not relate to any particular interpretative theory (see recital (749) below), confirms that the pattern of misleading representations was not instrumental in relation to any such interpretative theory.
- (668) Third, as regards AZ's claim that its instructions were prepared under strong time pressure and resource constraints (see recital (607) above), reference should be made to the fact that Hässle already proposed to AZ's patent department on 30 March 1993 that "effective marketing" dates should be obtained for all countries appearing on the instruction forms to be used in respect of the three products for which Hässle was responsible (omeprazole, omeprazole sodium and felodipine) (see recital (641)). This was more than one month before AZ adopted its decision on the omeprazole instructions on 6 May 1993. Moreover, it does not appear from the evidence that AZ even attempted to investigate the "effective marketing" dates for any other products than the three "problem products" omeprazole, omeprazole sodium and felodipine. In

⁵⁶⁷Case C-127/00 *Hässle*, in particular paragraph 79.

addition, it appears from the evidence that, for those products, AZ selectively focused its research on the authorisation procedures in those countries where the technical authorisations were issued prior to 1 January 1988 (see recital (636)). For felodipine, AZ knew the “effective marketing” date but, nevertheless, did not use it in its felodipine SPC applications (see recital (644)). Since the number of non-problematic products was rather limited (five, to be precise), it appears difficult to believe that AZ was not able to gather the necessary information concerning these products before the instructions were sent, or at the very least soon afterwards.

- (669) Fourth, as regards AZ’s argument that the content of the instructions reflected the best information in AZ’s possession at the time, that there was no need to compile effective marketing dates for all products or for all countries on the instructions for the omeprazole applications and that most of the information in the instructions was irrelevant (see recital (608) above), the response must specifically address the key parameters in the instructions: dates, numbers and legal basis.
- (670) As regards AZ’s argument on its use of two divergent types of dates in the instructions, it should first be noted that AZ argues that the technical authorisation dates for Member States other than France and Luxembourg on the instruction form were in fact an extra “service” provided by Astra’s patent department for the purpose of Article 3 (b) of the SPC Regulation, which requires the filing of the technical authorisation in the country of application (see recitals (150) and (608)-(609)).
- (671) However, on its “service” argument logic (i.e. AZ’s assertion that it provided a service to the patent offices by including information which was not legally required), AZ should also have supplied the technical authorisation date for Luxembourg as it applied for an SPC in Luxembourg. Moreover, AZ did not apply in Greece, yet it provided the technical authorisation date for Greece (recital (182)). Nor did it apply in Portugal, yet, AZ provided a date for Portugal which even appears to precede the technical authorisation (*ibidem*). Nor was there, on AZ’s “service” argument logic, any reason to provide the date for France as AZ did not apply for an SPC for omeprazole there. In fact, AZ had ample time between 6 May 1993 and 7 June 1993 to remove irrelevant Member States – such as Greece and Portugal – from the instruction form. The inclusion of this unnecessary information could only reinforce the impression that the dates for France and Luxembourg did relate to the technical authorisations.
- (672) As regards AZ’s argument concerning the fact that the numbers in the instructions related to the technical authorisations (see recital (609)), it should first be stated that the number of the first authorisation in the Community is clearly required under the SPC Regulation (see recitals (151)-(152)). AZ knew what the technical authorisation numbers for Luxembourg and France were (see recitals (170), (174)) and must have realised that the List did not bear any number (recital (660)).
- (673) AZ’s claim that the “numbers column” was left in place by mistake is unsubstantiated (see recital (609)). Regarding AZ’s claims on “errors” see the general response in section 6 below.
- (674) Moreover, AZ offers no proof in support of its contention that it inserted the required legal basis relating to the technical authorisation in Luxembourg based on advice from its Luxembourg lawyers (see recital (610)). The SPC Regulation clearly requires a

legal basis relating to the first Community authorisation (see recital (152)). In fact, the legal basis relating to the technical authorisation in Luxembourg appears on the technical authorisation itself (received by AZ on 22 March 1993) (recital (170)). AZ, as a well-established major pharmaceutical company well aware of the applicable rules in this area, must have known that that legal basis did not relate to the List dated “March 1988”. In any event, AZ’s argument that its patent department did not at that stage know all the pricing regulations in Luxembourg is one further reason why AZ should have been more transparent.

- (675) As to AZ’s claim that some “errors” were made in the instructions (see recital (607) above) see section 6 below.
- (676) As regards AZ’s argument that its behaviour was “normal” competition (see recital (612) above), reference must first be made to the case law of the Court as regards the special responsibility of dominant companies (see section A above).
- (677) The Commission considers that the purpose underlying AZ’s SPC strategy for omeprazole was to strengthen its position on the market by delaying the entry of generic versions of omeprazole and to create extra hurdles for generic firms. Moreover, as to the alleged “normality” of AZ’s behaviour, knowingly making misleading representations to patent agents, patent offices and courts can not be deemed as normal competition or reasonable steps to protect the dominant undertaking’s own commercial interests.
- (678) First, AZ’s strategy for omeprazole was clearly not “normal” compared with its strategies for most other products which were filed to unsuspecting patent agents and offices at the time (see recitals (643)-(646) above). AZ has admitted in its Reply that it was probably aware that the likely practice among pharmaceutical companies would be to use the technical authorisation date⁵⁶⁸.
- (679) Second, AZ’s undisclosed use of alleged “effecting marketing” dates in the instructions and applications was highly misleading. AZ neither revealed nor explained that both technical authorisation and “effective marketing” data were used in its instructions, especially for the two key Member States appearing on the instruction, Luxembourg and France (see recitals (228) and (651)). Against this background, there was no reason why the patent agents and offices would have believed that the instructions were based on anything other than the first technical authorisation in the Community. Moreover, AZ did not explain its “effective marketing” theory to several patent agents (the French, Belgian and Dutch agents) even when they raised questions and doubts about AZ’s instructions (see section 4 (a)-(c) below). In view of all these factors, the instructions for omeprazole can clearly not be qualified as normal. In that context, one should note that most patent agents and patent offices reacted to AZ’s instructions or applications simply because the date initially mentioned (“March 1988”) was not precise enough.
- (680) In this case it also needs to be borne in mind that the national patent offices to which the misleading representations were made were under no obligation to verify the veracity of the information supplied by the SPC applicants (see recital (153)). Indeed, three of the 1988 countries accepted AZ’s applications without further ado and granted

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6.220 AZ Reply.

the SPC without being told about the “effective marketing” theory (until AZ’s belated explanatory memorandum sent to the Finnish patent office on 8 May 1998 (see section 4 (l)). The Belgian, Dutch and Luxembourg patent offices also granted SPCs without being made aware of AZ’s theory (until AZ’s submission of the said memorandum to the Belgian, Dutch and Luxembourg patent offices on 8 May 1998) (see section 4 (a)-(c), (j)).

4. THE SECOND STAGE OF THE ABUSE

(681) During the second stage of AZ’s single and continuous abuse which extends to the end of 2000, AZ makes a succession of misleading representations before patent offices. In addition, when AZ’s initial misleading conduct vis-à-vis the patent offices result in litigation in certain countries, AZ continues to make misleading representations before the national courts concerned. These second stage misleading representations originate in those made during the first stage of the abuse, notably AZ’s misleading use of two separate sets of date in its SPC applications and its misleading reliance on the so-called Luxembourg Liste as the factual underpinning of those applications. The misleading representations which form part of the second stage will be described in detail below in rough chronological order. Generally speaking, AZ’s strategy at this stage of the abuse consisted in three elements. First, before some patent offices AZ reveals the technical market authorisation in Luxembourg of 16 November 1987, while concealing the earlier (and first) technical market authorisation in France on 15 April 1987 (of which it is perfectly aware), thereby gaining around seven extra months of SPC protection in the Member States concerned. Second, AZ does not explain the “effective marketing” theory underlying its applications, even when some patent agents and offices raise questions and doubts (mainly about the “March 1988” date and the List), thereby leaving those patent agents and offices in the dark as to AZ’s strategy. Third, before several patent offices (and before courts where the initial misleading representations have resulted in litigation), AZ tenaciously continues to defend its reliance on the Luxembourg List as the factual basis for its SPC applications, despite its awareness of a mounting body of evidence which strongly indicates that Losec was effectively marketed in Luxembourg before the date “21 March 1988” printed on the List.

(a) Misleading representations before the Luxembourg patent office (June 1993)

(682) In Luxembourg, the Luxembourg patent agent involved files the number of the technical authorisation in that Member State (“445/87/11/0446”), as instructed by AZ. However, he disobeys AZ’s instructions in that he neither files “March 1988” nor the “Luxembourg List” (recital (207)-(208)). Eventually AZ submits the technical authorisation for Luxembourg to the patent office (*ibidem*). However, neither the patent agent nor the Luxembourg patent office is made aware of the earlier French technical market authorisation (15 April 1987).

(683) AZ claims that, when requested by its French patent agents, it explained the basis of its interpretation of the SPC Regulation and that this explanation was passed on to the Luxembourg agent⁵⁶⁹. Specifically, AZ claims it did so by its letter of 11 June 1993⁵⁷⁰.

⁵⁶⁹ 6.88-90, 6.215, 6.227, 6.243-245 AZ Reply. See also AZ reply to letter of facts, pp. 62-63.

AZ also claims that the instructions dated 17 June 1993 sent by the French agents to the Luxembourg patent agents have only recently been copied to AZ⁵⁷¹.

- (684) AZ's explanations are not consistent with the evidence. In its letter of 11 June 1993, AZ does not explain its "effective marketing" theory to the patent agent. When the French agents request the Luxembourg technical authorisation on 10 June 1993, AZ simply instructs the French agent to file "21 March 1988" even though 16 November 1987 appears on the technical authorisation and simply states that "[AZ] *is of the view that no argumentation is needed at this stage*" (recital (203)). There is thus no reason for the French agent to believe – when forwarding the List and the date "21 March 1988" to the Luxembourg agent – that he is not sending the publication of the technical authorisation in Luxembourg.
- (685) Indeed, on 17 June 1993, the French agent instructs the Luxembourg patent agent to file not the date on the technical authorisation but "*the date of publication in the Luxembourg Official Journal "Spécialités Pharmaceutiques", i.e. 21 March 1988*" (recital (204)). The reference to the "official journal" as well as subsequent correspondence with the French patent agent (see recital (205)) illustrate perfectly how an experienced person could be led to believe that the date in question related to the technical authorisation. As to AZ's claim that the letter of 17 June 1993 has only recently been copied to AZ, see general response regarding AZ's claims concerning "errors". in section 6 below. In any event, the letter addressed by the patent agent to AZ on the very same day (recital (205)), which was undoubtedly in AZ's possession, already made clear the French agent's understanding of the instructions.
- (686) All in all, the French agent's letter to AZ on 17 June 1993 shows that the agent believes he has been instructed by AZ to file the date of the official publication of the technical authorisation (recital (205)). There is no reason for him to believe that the date is an "effective marketing" date. In fact, the French agent questions whether the instruction to apply the publication date should apply also to other products for which the French agent had already filed SPC applications on AZ's behalf based on the technical authorisation date (*ibidem*). To this AZ simply replies on 21 June 1993 that the publication date should only be applied to omeprazole and omeprazole sodium (see recital (206)). This again shows that the French agent must have believed that he had been asked to instruct the Luxembourg agent to file the official publication of the technical authorisation (i.e. the theory used by AZ for felodipine). AZ does not give any explanation of its "effective marketing" theory to the French patent agent. In view of the above, AZ must have realised that the French patent agent was proceeding on false premises. The fact that the French agent may have been aware of the technical authorisation date for omeprazole in France does therefore not detract from AZ's misleading representations⁵⁷².

(b) Misleading representations before the Belgian patent office (September-November 1993)

- (687) AZ misleads the Belgian patent office when it eventually decides no longer to defend the "March 1988" date and instead – successfully – advances the technical

⁵⁷⁰ 6.89 AZ Reply.

⁵⁷¹ 6.90 AZ Reply.

⁵⁷² AZ reply to letter of facts, p. 63.

authorisation date in Luxembourg: 16 November 1987. As repeatedly pointed out, this is not the first technical authorisation in the Community, a fact of which AZ is well aware. In the end, the Belgian patent office accepts 16 November 1987 as the relevant date (see recitals (189)).

- (688) In its Reply to the Statement of Objections, AZ claims that the Luxembourg technical authorisation date 16 November 1987 was submitted to the Belgian patent office by the Belgian patent agent acting without instructions⁵⁷³. However, AZ did not react to the Belgian agent's letters of 29 September 1993 (where he explains that he will file the Luxembourg technical authorisation date of 16 November 1987 unless instructed to the contrary), 4 October 1993 (where he informs AZ that he has filed the 16 November 1987 date) and 25 November 1993 (where he informs AZ that the patent office has granted the SPC on the basis of the 16 November 1987 date) (see recitals (188)-(189)). AZ never informed the patent agent of the earlier technical authorisation date in France. As to AZ's claims in its Reply that none of these letters came to the attention of the patent department, see the general response regarding AZ's claims concerning "errors" in section 6 below. In any event, the idea that the Belgian agent acted on its own motion is difficult to believe considering that the Belgian agent was simply following the same line of instructions that AZ had given to its Belgian and Dutch patent agents (see recital (193)).
- (689) Moreover, contrary to AZ's claim⁵⁷⁴, AZ did not explain its "effective marketing" theory to the patent agent in its letter of 10 September 1993 (recital (187)). The letter does not describe AZ's "effective marketing" theory. The patent office could not have been expected to infer the nature of AZ's elaborate "effective marketing" theory from AZ's mere reference in the letter to the publication in "*Spécialités Pharmaceutiques*", in particular taking into account that that theory was not used by AZ for its other products.
- (690) AZ furthermore asserts that once it became aware that the Belgian SPC had been granted by reference to the 16 November 1987 date, AZ took legal advice and then did what it could in the light of that legal advice to correct the duration of the SPC. AZ claims that it sought to correct the duration of the SPC concurrently with its SPC application for omeprazole sodium⁵⁷⁵.
- (691) However, in its account of the sequence of events relating to the first abuse in its Reply to the Statement of Objections, AZ observes that in connection with its preparations for the German SPC proceedings during the summer of 1996 the "*anomalous position in the Benelux countries came to light*"⁵⁷⁶. Yet AZ documents dated 11 December 1996 and 28 January 1997 indicate that, at this stage, AZ had only decided to contact external counsel in Brussels to discuss the SPC situation in Belgium in general⁵⁷⁷. Incidentally, AZ's decision – as set out in an internal document of 28 January 1997 - in respect of Luxembourg is "*to do nothing for the time being*"⁵⁷⁸.

⁵⁷³ 1.31, 6.16, 6.91, 6.93, 6.242 AZ Reply.

⁵⁷⁴ 6.91, 6.215, 6.227 AZ Reply. See also AZ reply to letter of facts, p. 57

⁵⁷⁵ AZ reply to letter of facts, p. 57.

⁵⁷⁶ 6.144 AZ Reply.

⁵⁷⁷ [4492, 4493].

⁵⁷⁸ [4493].

(692) Thus nearly two years elapsed from the moment AZ, according to its own claim, became aware of the “anomalous” situation with regard to the duration of the Benelux SPCs until AZ informed the Benelux patent offices (by letter of 8 May 1998) of the “effective marketing” theory underlying its applications in June 1993 (see recital (227)). In Belgium more than two years passed until AZ, in October 1998, filed a request to the Belgian patent office to amend the duration of its Belgian SPC in line with its “effective marketing” theory. AZ’s internal documents suggest that this was only done as a result of AZ’s decision to apply for an SPC for omeprazole sodium in Belgium in 1998 (see recital (248)).

(c) Misleading representations before the Dutch patent office (November-December 1993)

(693) AZ misleads the Dutch patent office when it decides no longer to defend the “March 1988” date and instead – successfully – advances the technical authorisation date in Luxembourg: 16 November 1987. AZ is aware that that is not the first technical authorisation in the Community and that that date is incorrect both on the “technical authorisation” and the “effective marketing” theory. In the end, the Dutch patent office accepts 16 November 1987 as the relevant date (see recital (194)). AZ does not explain its “effective marketing” theory to the Dutch patent agent.

(694) In this respect, AZ asserts in its Reply to the Statement of Objections that its submission of the date “16 November 1987” to the Dutch patent office was an inadvertent and genuine error due to the fact that AZ was pursuing SPC applications for omeprazole and omeprazole sodium concurrently in the Netherlands⁵⁷⁹. AZ also claims that the fact that the Dutch SPC had been granted by reference to the wrong date did not attract the attention of AZ’s patent department at the time or indeed until 1996⁵⁸⁰. In these respects, reference is made to the general response regarding AZ’s claims concerning “errors” in section 6 below.

(695) Moreover, it appears that on 26 November 1993 the Dutch agent transmits requests from the patent office to AZ expressing doubts about the List as the basis for the applications (recital (192)). The patent office also objects to the “*imprecise date indication*” (ibidem). On 16 December 1993 AZ – whilst admitting that 16 November 1987 is the technical authorisation in Luxembourg – simply explains that the relevant date is “21.3.1988”, again without explaining the underlying theory (recital (193)).

(696) As appears from recitals (195)-(199) there is no evidence that AZ was given legal advice that nothing could be done to correct the duration of AZ’s Dutch SPC. Quite to the contrary, the opinion of AZ’s Dutch patent agent was that AZ should approach the Dutch patent office with a view to correcting the duration of AZ’s SPC. AZ made no approach to the Dutch patent office until its submission of 8 May 1998 (more than two years after – as AZ itself claims – the “anomalous” situation with regard to the Benelux SPCs had come to light).

(d) Misleading representations before the United Kingdom patent office (January-June 1994)

⁵⁷⁹ 1.31, 6.257 AZ Reply.
⁵⁸⁰ 6.258 AZ Reply.

- (697) In the United Kingdom, AZ decides to fight openly for the first time for its “effective marketing” theory. On 7 September 1993, the patent office requests a precise date (recital (209)). In its reply of 7 January 1994, AZ simply states that the technical authorisation was granted on 16 November 1987 and that “21 March 1988” may be used instead of “March 1988” (ibidem). The patent office replies that 16 November 1987 is the correct date (ibidem). On 16 June 1994, AZ specifies that the technical authorisation was published in the Luxembourg official journal (“Mémorial”) on 4 December 1987 (recital (213)). AZ then – for the first time before a public authority – sets out its “effective marketing” theory for the purposes of interpreting Article 19 of the SPC Regulation. In an annex to that submission to the United Kingdom patent office on 16 June 1994, AZ also submits a comprehensive list of dates, including a reference to the French technical market authorisation of 15 April 1987 (ibidem).
- (698) As part of compiling that list of dates, AZ’s patent department had – via Hässle – collected further information from its local marketing companies on the authorisation procedures for omeprazole in a number of countries, including Luxembourg.
- (699) That information gathering was the result of the following request to Hässle by the head of Astra’s patent department dated 14 February 1994: “*Specifically inform me if we sold Losec in any EU state prior to having the price negotiations concluded in that country*” (see recital (211)). The request confirms that AZ, at the time of its instructions and filings in June 1993 and several months thereafter, did not even know whether Losec had been sold in Luxembourg (or any other Member States) before the conclusion of the price negotiations.
- (700) By fax of 3 March 1994, Astra Luxembourg replies *inter alia* that Losec was first sold (“*the first sales (official launch)*”) in Luxembourg on “11 March 1988”, i.e. before 21 March 1988 (see recital (211)). The fax also states that the Luxembourg price approval of 17 December 1987 had not been published at all (a piece of information repeated by Astra Luxembourg in a further fax of 8 June 1994) (see recitals (211)-(212)).
- (701) Despite this crucial information from Luxembourg, AZ assures the United Kingdom patent office that “[f]irst sales in Luxembourg took place at the end of March 1988” and that “21 March 1988” is the earliest date at which the omeprazole capsules could effectively be marketed within the Community because “*as a practical matter*” doctors will not prescribe (and pharmacies will not dispense) medicines until they have received the Ministry of Health’s List of authorised products and that this system is “[i]n practice” applied generally in Luxembourg (recital (213)).
- (702) AZ eventually gives up its attempts to convince the patent office in the United Kingdom of the validity of the “effective marketing” date and accepts that the patent office bases its decision on the first technical authorisation date (15 April 1987 in France) on a “without prejudice” basis (recitals (215)-(216)).
- (703) In its Reply, AZ claims that its citation of the specific date “21 March 1988” in its submission to the United Kingdom patent office dated 16 June 1994 had been chosen by AZ “presumably” because of the significance that Astra Belgium and Astra Luxembourg had attached to this date⁵⁸¹.

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6.114, 6.147, 6.149 AZ Reply.

- (704) AZ's claim has no basis. Astra Belgium attached no specific importance to the date "21 March 1988" (see recitals (170), (173) and (658) above) in its submissions in March and April 1993. The same is true of the submissions in 1994 by Astra Luxembourg (see recitals (211), (212) and (700) above). The List is simply dated "March 1988". It is therefore clear that AZ itself derived the date "21 March 1988" from the top of page 246 of the List (see recital (173)). AZ admitted that this was so at the Oral Hearing⁵⁸². It has been explained above why AZ must have known that this could not have been a valid "effective marketing" date (see section 3 (c) above).
- (705) AZ provides no proof that – as it claims – it was advised by legal counsel on the nature of the List. In fact, the advice given by its external counsel (obtained by the complainants from the public file at the United Kingdom patent office) in respect of Luxembourg did not take any position on the actual nature of the Luxembourg List⁵⁸³.
- (706) AZ moreover argues that it was not satisfied that the information from Luxembourg was reliable and in the light of other information received from the Luxembourg marketing company regarding the relevance of 21 March 1988 as the date of effective authorisation, its statement to the United Kingdom patent office was justified by the information which it had at that time⁵⁸⁴.
- (707) It should however be recalled that the then head of AZ's patent department had "*specifically*" asked Hässle (see memo of 14 February 1994 at recital (211)) to inform him "*if we sold Losec in any EU state prior to having the price negotiations concluded in that country*". In its reply of 3 March 1994, Astra Luxembourg clearly indicated "11 March 1988" as the date of first sales (fax sent by Hässle to the patent department on 4 March 1994) (recital (211)). Hässle then asked Astra Luxembourg to confirm certain dates (but not the first sales date 11 March 1988). Astra Luxembourg replied to Hässle on 18 May 1994 (forwarded to the patent department on 20 May 1994) by resending its fax from 3 March 1994 (recital (211)). Hässle writes to Astra Luxembourg a third time asking for confirmation of certain dates (although not the date of first sales) (*ibidem*).
- (708) The information received from Astra Luxembourg is critical. It undermines AZ's use of the List as the factual basis for its applications, even on an "effective marketing" theory. If AZ considered that the information from Astra Luxembourg was unreliable, and therefore twice asked for confirmations on the authorisation process in Luxembourg it should also have asked for confirmation of the launch date. AZ's awareness of the critical importance of the timing of the actual launch of Losec is apparent from the original request dated 14 February 1994 by the head of AZ's patent department to Hässle where he asked to be "*specifically*" informed "*if [AZ had] sold Losec in any EU state prior to having the price negotiations concluded in that country*" (recital (211)).

⁵⁸² Statement by Mats Pårup (head of Astra AB's patent department at the time) at the Oral Hearing on 16 February 2004

⁵⁸³ Vol 8, Annex 6.3.38 AZ Reply. See also the external legal advice contained in the complaint [631-638].

⁵⁸⁴ 6.13, 6.106-117, 6.226, 6.247 AZ Reply.

- (709) In its Reply, AZ argues that, in any event, even if 11 March 1988 were the correct date, the difference (10 days) would not be material to the duration or relevant to the grant of the SPC⁵⁸⁵.
- (710) AZ's argument misses the key point. The information from Astra Luxembourg clearly indicates that the factual basis for the SPC applications (the List) could not have the function that AZ made it out to have throughout the abuse. More specifically, the misleading representations to the United Kingdom patent office concerns the launch date of Losec in Luxembourg. If AZ had conceded that these sales had begun before 21 March 1988, its position vis-à-vis other Member States would have been severely weakened, if not even wholly undermined.
- (711) Incidentally, even on an "effective marketing" theory, the exact date mattered as it defined the exact duration of the SPC in each market. AZ itself admits that every day counts considering the huge sales volume at patent expiry ("*As the sales volume of Losec® is so large, every day, week and month of delay in the introduction of generic omeprazole represents further, very large sales revenue*") (see also recital (271) relating to LPPS Strategy document dated 29 April 1997)⁵⁸⁶. It must be noted that Losec worldwide sales in 1993 amounted to USD 1.7 billion (see recital (9)) and that AZ used its "theory" in ten different geographic markets
- (712) In its reply to the letter of facts, AZ gives two reasons for its reliance on "21 March 1988" and not "11 March 1988" (the date of first Losec sales specified by the AZ Luxembourg's manager Mr Sulbout in his fax of 3 March 1994). First, AZ refers to alleged inaccuracies in Mr Sulbout's fax. Second, AZ claims that it relied on information provided by its Belgian marketing company (which was responsible for AZ's business in Luxemburg in 1987-1988)⁵⁸⁷.
- (713) As to the first reason, the Commission takes the view that Mr Sulbout's fax constituted the best and in fact only information in AZ's possession at the time as to the date of Losec's launch in Luxembourg. Having received the fax dated 3 March 1994, AZ made several written and oral enquiries to Mr Sulbout regarding various dates in Luxembourg (see requests for information and clarification by Astra Hässle to Mr Sulbout dated 17 and 30 May 1994)⁵⁸⁸. Yet these documents do not corroborate that AZ challenged or sought confirmation of the issue of first sales in Luxembourg (despite the fact that Sulbout's information on 3 March 1994 wholly undermines AZ's reliance on the date "21 March 1988").
- (714) AZ furthermore grossly exaggerates the inaccuracies in Mr Sulbout's fax of 3 March as far as Losec is concerned. Mr Sulbout's fax contains five points. The first point correctly refers to Losec's "registration" in Luxembourg on 16 November 1987. AZ's documents at the time (e.g. its SPC application forms) often refer to "registration" or "market registration" as synonymous with the technical market authorisation. The second point reports that first sales of Losec took place on 11 March 1988. The third point correctly observes that price agreement occurred on 17 December 1987 which is not disputed by AZ. This point also observes that the price agreement was not published (implying that the List did not have the function of incorporating the price

⁵⁸⁵ 6.247 AZ Reply.

⁵⁸⁶ Vol 2, Annex 4.12.9, p.12 (in section "Protecting the brand") AZ Reply.

⁵⁸⁷ AZ reply to letter of facts, pp. 66-67.

⁵⁸⁸ Vol 8, Annex 6.3 37G at [14204] and 37 J AZ Reply.

agreement imputed to it by AZ). The fourth point notes incorrectly that the market authorisation of Losec was published in the *Mémorial* (Luxembourg official journal) in March 1988. Publication in the *Mémorial* took place on 4 December 1987. The fifth point (no Losec sales prior to price negotiation) draws a logical conclusion from points two and three.

- (715) AZ argues that it was not clear from Mr Sulbout's fax whether the decision on Losec's price was published at all or not published until March 1988⁵⁸⁹.
- (716) The evidence does not support AZ's assertion. First, Mr Sulbout's fax of 3 March 1994 does not in any way qualify the statement "Price agreement (not published)" (point three in the fax). Point four simply refers to publication in the *Mémorial* without any mention of price. In any case, there is no suggestion by AZ that prices – as opposed to technical market authorisations – are published in the *Mémorial*. Second, on 17 May 1994, AZ again requests information from Mr Sulbout on *inter alia* the "[p]recise date for official publication of market authorisation" (but not on whether the first sale of Losec occurred on 11 March 1988). On 18 May 1994 Mr Sulbout resends his fax of 3 March 1994 (confirming *inter alia* that the price agreement was not published and that first sales took place on 11 March 1988). Third, on 30 May 1994, AZ again writes to Mr Sulbout thanking him for his input to its "recent inquiries regarding dates relevant to the planned omeprazole patent extension"⁵⁹⁰. AZ goes on: "In the enclosure we have compiled your [i.e. Mr Sulbout's] input to the following four questions: 1. The date of publication of the agreed price in an official state publication ... ". The enclosure – allegedly based on Mr Sulbout's input - presents "21 March 1988" to be the date of the "Official publication of price" in Luxembourg. Yet, in his previous communications, Mr Sulbout has given AZ no grounds to infer that the official publication of price occurred on 21 March 1988. Mr Sulbout has not even mentioned that date. He has also repeatedly pointed out to AZ that no price publication took place. Indeed, in his reply of 8 June 1994 to AZ's request of 30 May 1994, Mr Sulbout yet again reiterates that that the price agreement was not published.
- (717) As to the second reason given by AZ for its reliance on the date "21 March 1988", AZ's Belgian company did not – contrary to AZ's claims - provide any information on first Losec sales in Luxembourg, nor did it draw any attention to "21 March 1988" as a date which would in any way be relevant (see recital (704)).

(e) The real reasons for AZ's withdrawal of its SPC application in Denmark (November 1994)

- (718) On 30 November 1994, AZ withdraws its SPC application from the Danish patent office. It is clear from a record dated 15 November 1994 of an internal meeting in Copenhagen where the head of AZ's patent department gives the background of AZ's SPC Strategy for omeprazole to external Danish counsel, that AZ's withdrawal was – at least in part – tactically motivated ("[i]n Denmark the patent office informally pointed out that they did not consider Luxembourg as the first authorisation. They intended to argue as [the United Kingdom patent office] with which the authority has good and close contacts in SPC matters ...") (recital (219)). The record goes on: "DK

⁵⁸⁹ AZ reply to letter of facts, pp. 65-66.

⁵⁹⁰ Vol 8, Annex 6.3, Doc 37J AZ Reply.

came up with a different formal reason to reject the application and thereby avoid a dispute as to the ‘first country’ and that “on reflection, it was best not to do battle in DK, i.e. to preserve the arguments in Germany” (ibidem). The same record states that “following discussions with our Danish representatives, we therefore decided to withdraw the Danish applications and make it look as if it is due to our mistake in citing the patent number” (ibidem).

- (719) Even allowing for AZ’s argument that the incorrect patent number was a fundamental flaw in the application⁵⁹¹, the record of the meeting in Copenhagen is symptomatic of the persistent lack of transparency which characterises AZ’s SPC Strategy for omeprazole. AZ itself states that *“the question of the first authorisation in France” had been the subject of conversations between the Danish and United Kingdom patent offices*⁵⁹². Without the patent office’s contacts with the United Kingdom patent office, it is possible that AZ’s strategy would have worked in Denmark as well. AZ’s claim that it had already informed the Danish patent office in general terms of its theory is unsubstantiated.
- (720) Contrary to AZ’s claim⁵⁹³, that record cannot be regarded as legally privileged. The actual content of the record contains or reflects no evidence of advice from the external Danish counsel. The record is, in fact, a summary of AZ’s SPC Strategy for omeprazole and the events as they have unfolded so far by the head of AZ’s patent department to those present (including the external Danish counsel).

(f) Misleading representations in AZ’s second round of SPC applications (December 1994)

- (721) In the second round of SPC applications in December 1994, AZ makes misleading representations regarding the List and the first authorisation date despite the key information obtained from Astra Luxembourg showing that Losec was sold before 21 March 1988 and that the price decision was never published (see recitals (700), and (703)-(708)).
- (722) Moreover, when it files its second round of SPC applications in Austria, Finland and Norway, AZ knows that it must file the first authorisation date in the EEA and not only in the Community. This is clear from the provisions of Decision 7/94 of the Joint EEA Committee (see footnote 205) as well as from the SPC application forms (see recital (183)-(184)). On 5 February 1988 the Swedish authorities authorised AZ to effectively launch omeprazole capsules (see recital (232)). In other words, under the logic of its “effective marketing” theory, AZ should have referred to 5 February 1988 in the second round of SPC applications. Yet AZ persists in using the Luxembourg “21 March 1988” date. As a Swedish company, AZ could not conceivably have been unaware of the authorisation granted by the Swedish authorities in respect of Losec – its commercially most valuable product by far.
- (723) In respect of AZ’s claim that the non-use of the Swedish “effective marketing” date was an “oversight”, see the general response regarding AZ’s claims concerning “errors” in section 6 below.

⁵⁹¹ 6.126-130, 6.254 AZ Reply.

⁵⁹² 6.129-130 AZ Reply.

⁵⁹³ 6.222 (ii) AZ Reply.

- (724) As to AZ's argument that its failure to use the Swedish "effective marketing" date did not materially affect the duration of the SPC, see the Commission's response above at recitals (710)-(711).

(g) Misleading representations before the Irish patent office (October 1995)

- (725) When questioned by the patent office in Ireland during 1995 about the "March 1988" date, AZ, as in the United Kingdom, submits the earliest technical authorisation date in the Community (15 April 1987 in France) (recital (218)). AZ however persists in claiming that effective marketing in Luxembourg was not possible before 21 March 1988 (*ibidem*). The Commission has already explained why it does not accept AZ's claims that based on the information which AZ had at the time, it was able to say that effective marketing was not possible before 21 March 1988 (see recitals (703)-(708) above).

(h) Further misleading representations to the Belgian, Dutch, Finnish and Luxembourg patent offices (May 1998)

- (726) Moreover, when the head of AZ's patent department informs the Belgian, Dutch, Finnish and Luxembourg patent offices of its appeal to the German Federal Court of Justice⁵⁹⁴(see recital (227)) on 8 May 1998, he again claims "*that, for the purposes of [the SPC] Regulation, the first marketing authorisation within the Community was effective as of 21 March 1988. Only at this time, all authorisations necessary to enable the product to be placed on the market in the first member state (Luxembourg) had for the first time been granted.*" (recital (227)). It has already been shown that by the time it makes this statement AZ is in possession of information which unequivocally states that effective marketing in Luxembourg took place before 21 March 1988. Furthermore, AZ had already recognised in Germany that marketing was possible in Luxembourg before 21 March 1988 (see recital (730)). In fact, at that stage, AZ even possesses a fourth internal document to that effect. Specifically, the document (dated 23 February 1998) lists approval and launch dates and cites "1988-02-01" as the "*Launch Date*" for "*Omeprazole capsules 20 mg*" (recital (236)).

(i) Misleading representations in the context of proceedings brought before national courts by generic firms to invalidate AZ's SPCs in Germany, Norway and Finland

- (727) In three 1988 countries AZ obtains SPCs from the patent offices on the basis of the "*March 1988 date*": Germany in the first round and Norway and Finland in the second round. Generic firms (ratiopharm in Germany, Scand Pharm in Norway and Merck Generics in Finland) bring legal proceedings before the competent national courts with a view to invalidating AZ's Finnish, German and Norwegian SPCs for omeprazole (recitals (222), (234) and (244)). In the context of these court cases resulting from AZ's initial misleading representations to the patent offices, AZ continues to make misleading representations in order to preserve its SPC protection. In connection with the German proceedings, AZ also makes further misleading representations to the patent offices in the Benelux countries and Finland to preserve its SPC protection in those Member States (see points (j) to (m) below).

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6.166, 6.260 AZ Reply.

(j) Misleading representations in the German SPC proceedings

- (728) Before the Federal Patent Court, AZ again misrepresents certain facts and circumstances relating to its applications for SPCs as well as making clearly contradictory statements. To start with, on 9 October 1996 AZ contends that back in June 1993 when it filed its SPC application it was “*reassured in believing that March 21, 1988, being the date of publication of the authorization, including the ministerial price fixing ... was the decisive date for the first authorization to put on the market*” and that it was only from that date onwards that “*the product could be marketed*” (see AZ’s submission of 9 October 1996) (see recital (223)). It has been shown above that AZ had no reasonable basis for being reassured that that was the case.
- (729) Moreover, by the time it makes this statement, AZ has additional information in its possession according to which the Luxembourg price approval decision of 17 December 1987 has not been published and that omeprazole capsules has already been launched prior to 21 March 1988 (on 11 March 1988 according to the AZ’s Luxembourg subsidiary replies in 1994 and on 1 February 1988 or, in any event, on 11 March 1988 according to internal AZ notes of 19 August 1996 and 9 September 1996) (see recitals (211)-(212), (224) and (700)-(701)). In the internal note of 9 September 1996 AZ itself states that “[p]ublication of list by Health Ministry seemingly *not awaited* [before launch]” (recital (224)). That document further identifies a number of problems including: “*Both grant and publication of grant before 1988-01-01 ... Launch of product before publication of list*” (ibidem). To conclude, AZ continues to rely on the List despite possessing several sources stating that Losec was effectively marketed in Luxembourg before 21 March 1988.
- (730) In a later submission before the Federal Patent Court (4 April 1997), AZ repeats that it “*assumed that the product could be marketed legally only as of the publication of the ministerial price fixing on March 21, 1988*” and that its “*reasons for stating March 21, 1988 as the time of the first authorization in the Community are understandable enough even though, in the final analysis, February 8, 1988 is the date which is decisive for the fixing of the price*” (recitals (225)-(226)). It thus claims that it now believes that the correct effective marketing date for Luxembourg is “8 February 1988”, not “21 March 1988” (recital (225)), which necessarily implies that the List was not a *sine qua non* for launching the product. That crucial information is not communicated to the Belgian, Dutch, Finnish and Luxembourg patent offices on 8 May 1998 (see recital (726) above).
- (731) As regards AZ’s claim that the 8 February 1988 date put forward in the German proceedings was a forensic concession made by AZ’s counsel without instructions which did not bind AZ in other proceedings⁵⁹⁵, see the general response regarding AZ’s claims concerning “errors” in section 6 below. Apart from the fact that that AZ’s claim is unsubstantiated, it must be recalled that counsel was pleading on behalf of AZ. Unless the Commission is provided with clear-cut evidence to the contrary, it cannot presume that counsel’s explanations are not attributable to AZ. Moreover, what is at issue is not whether AZ’s statements before the German court “bind” AZ in other proceedings, but that the statements in question constitute further evidence of the fact that AZ knowingly misled other patent offices as well (see recital (727) above).

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- (732) As to AZ's claim that that concession did not go to AZ's entitlement to an SPC and that it does not in any event affect the duration of the SPC to any material extent⁵⁹⁶, see the Commission's response at recitals (710)-(711).

(k) Misleading representations in the Norwegian SPC proceedings (February-May 1999)

- (733) In the first half of 1999, AZ defends the relevance of the "21.03.1988" date supported by the List before the Oslo City Court (see submissions of 12 February, 12 April and 20 May 1999) although it is in possession of four internal documents stating that the product launch took place prior to 21 March 1988 (see recital (235)). AZ's presentation of the facts is also in contradiction with the position it set out before the Federal Patent Court, i.e. that 8 February 1988 was the decisive date in Luxembourg (recital (730)). Moreover, before the Norwegian court, AZ claims that publication in the List constitutes price approval, although it knows that the Luxembourg price approval was not published (recitals (235), (236) and (700)).
- (734) In the context of this litigation AZ also admits that it "*does not have the complete Liste ... or any part thereof comprising the price of Losec ...*" (recital (241)), despite having previously made positive statements about the alleged significance of that List to patent agents, patent offices and courts. Indeed, during the Norwegian proceedings the existence of another Luxembourg publication ("*Liste Luxembourgeoise des Prix Pharmaceutiques*") is revealed (see recital (241)). AZ itself submits a page from that price list dated 16 January 1988 containing an entry regarding Losec (see recital (241)). Moreover, two letters and one oral explanation from the Luxembourg authorities made perfectly clear that the List at the relevant point in time (March 1988) was an unofficial document aimed at informing doctors, pharmacists and pharmaceutical companies of authorised products, irrespective of whether they had received price approval (recitals (239)-(240)).

(l) Misleading representations in the Finnish SPC proceedings

- (735) During that period (the first half of 1999), AZ follows the same strategy before the Helsinki District Court (submission of 25 February 1999) (recital (244)). Here too AZ admits that "*both the defendant and the plaintiff have tried to obtain a full copy of the Liste and tried to find out the publication's status in Luxembourg*" and that "*it seems that the situation in Luxembourg was quite unclear*" (see recital (245)). AZ persists in maintaining that the List "*comprised the necessary price approval*" and that "*LOSEC couldn't be marketed in Luxembourg before March 21, 1988. Before that date LOSEC hasn't been marketed either in Luxembourg or another EEA country*" (ibidem), despite the number of documents stating unequivocally that sales took place before 21 March 1988, as well as its admission to that effect in the German proceedings (see recitals (703)-(708), (726) and (729)-(730)).

(m) General arguments by AZ and the Commission's responses regarding the court proceedings (points (i), (j), (k) and (l) above)

⁵⁹⁶ 6.263 (ii) AZ Reply.

- (736) As regards AZ contention that its legal submissions or conduct as a defendant cannot be abusive, it should first be stated that AZ's submissions before the three courts originate in and are the logical continuation of a proactive exclusionary strategy implemented at the latest as of 6 May 1993. AZ's misleading representations at this stage are not isolated elements in the court proceedings but form part of one single continuous abuse (see recitals (774)-(775)).
- (737) Contrary to the claims by AZ, relying on the judgment in *ITT Promedia*⁵⁹⁷, the Commission has not concluded that the conduct of defence cannot constitute an abuse. It simply argued that, by itself, such conduct could not be conceived as forming part of a plan to eliminate competition. In this case, the Commission has demonstrated that the misleading representations before certain national courts are part of the implementation of such a plan.
- (738) Furthermore, the conduct of a defence cannot be equated, as a matter of course, to the institution of legal proceedings. Initiating legal proceedings may, in certain circumstances, be abusive in so far as the aim is to harass the opposing party, as it imposes upon that party costs and delays. An abuse can only be established in wholly exceptional circumstances considering that such a finding would severely limit the right of access to courts. In this case, the costs and delays associated with legal proceedings are not the result of AZ's defence, but of AZ's initial misleading representations leading to the granting of SPCs. As explained below (see recital (748)), AZ's competitors' only remedy in such circumstances – i.e. where AZ's SPCs (including their duration) were presumed to be valid – was to engage in extensive and costly litigation. AZ's conduct of its defence before the national courts concerned was simply the continuation of the pattern of misleading representation initiated by AZ well before the competitors instituted proceedings, and not the cause of the costs and delays suffered by them. In addition, the German court proceedings were crucial as far as the maintenance of AZ's SPCs (including their duration) in other countries was concerned (see recital (727)).
- (739) In such circumstances it is not necessary to consider whether, by itself, the conduct of a defence based on misleading representations could qualify as abusive on its own, considering that AZ knew perfectly well at the time of making the misleading representations in question that Losec could have been launched (and indeed was launched) prior to 21 March 1988, and could therefore not be said to have asserted, at that moment, rights which it could reasonably have considered to be its own⁵⁹⁸.
- (740) The Commission disputes AZ's contention that the Commission's proceedings subvert the pending national litigation in Finland, German and Norway where the courts may have to engage in further fact-finding. The consequences of the judgment of the Court of Justice in *Hässle AB v ratiopharm GmbH* are clear in respect of the proceedings in the three countries concerned, all of which are 1988 countries with the cut-off date 1 January 1988 (see in particular paras 61 and 92 of the judgment). According to the judgment (see recital (666)) it is the technical authorisation which is decisive pursuant to Article 19 of the SPC Regulation. AZ has never disputed that the first technical authorisation in the Community and EEA is that of France (on 15 April 1987). Finally, the fact that other remedies may have limited the effects of AZ's exclusionary strategy

⁵⁹⁷ See 1.39, 6.290-292 AZ Reply. Case T-111/96 *ITT Promedia*, paragraph 42.

⁵⁹⁸ See *ITT Promedia*, paragraphs 73, 93, 111 and 116.

is not sufficient to exclude the existence of an infringement of Article 82 (see recitals (744)-(748) below).

5. THE COMMISSION'S RESPONSES TO AZ'S ARGUMENTS RELATED TO THE SPECIAL TREATMENT OF INTELLECTUAL PROPERTY RIGHTS AND THE USE OF PUBLIC PROCEDURES AND REGULATION

- (741) While the mere possession and enforcement of a patent or any other intellectual property right against a competitor does not, in principle, violate Article 82, the contention that the acquisition of an SPC cannot constitute an infringement of Article 82 of the Treaty, because it relates to the existence of an intellectual property right (as opposed to the exercise of that right) must be rejected. This dichotomy, which has gradually been abandoned in later case law, and been replaced by the concept of the subject-matter of the right in question⁵⁹⁹, reflects the principle that Community law does not affect the property laws in the different Member States (Article 295 of the Treaty). In the absence of harmonisation measures, it is for the national legislature to determine the conditions and rules regarding the protection conferred by intellectual property rights⁶⁰⁰. However, the laws of the Member States are not affected by qualifying as abusive misleading representations made in the context of applications for intellectual property rights, in the absence of which the right or rights in question would not normally have been granted.
- (742) In this case the pattern of misleading representations began well before the acquisition of the SPCs. Therefore AZ's conduct can hardly be described as belonging to the subject-matter of the rights in question. In any event, even following the granting of the SPCs, the making of misleading representations is not included in the bundle of rights forming part of the subject-matter of an SPC. Moreover, the acquisition of a right may amount to an abuse⁶⁰¹ and there is therefore no reason why the conduct in the procedure relating to the acquisition of the right cannot be considered as an abuse.
- (743) The use of public procedures and regulations, including administrative and judicial processes, may, in specific circumstances, constitute an abuse, as the concept of abuse – contrary to AZ's arguments – is not limited to behaviour in the market only⁶⁰².
- (744) The fact that the SPC Regulation provides for specific remedies cannot exclude the application of the Treaty rules of competition and their corresponding remedies. Even

⁵⁹⁹ See e.g. Case 238/87 *Volvo v Veng* [1988] ECR 6211, paragraph 8.

⁶⁰⁰ Case C-30/90 *Commission v United Kingdom* [1992] ECR I-829, paragraphs 16 and 17.

⁶⁰¹ See Case T-51/89 *Tetra Pak v Commission*, paragraphs 23-24 and Case T-111/96 *ITT Promedia*, paragraph 139. The latter judgment also makes clear that both the acquisition of a right and its enforcement may in themselves constitute an abuse. See also Joined Cases 56 and 58/64 *Grundig & Consten v Commission* [1966] ECR 299, at paragraph 343 (where the registration of a trade mark was an element of the infringement). In addition reference is made to *Bayer/Tanabe*, Eighth Report on Competition Policy (1978), point 125, and *Airam/Osram*, Eleventh Report on Competition Policy (1981), point 97.

⁶⁰² Case C-395/96 P and C-396/96 P *Compagnie maritime belge and others*, paragraphs 82-88; Case T-111/96 *ITT Promedia*; Decision 92/262/EEC (OJ L 134, 18.5.1992, p. 1). Besides, in the examination of the possible abusive nature of contacts with public authorities, the Court of Justice has drawn a distinction between requests from the public authorities in areas where they would have no margin of manoeuvre to act upon the request and “a simple attempt to influence the authority concerned in the exercise of its discretion”. Case C-395/96 P and C-396/96 P *Compagnie maritime belge and others*, paragraph 82.

if other remedies are available which address some aspects of the conduct under consideration, there is good reason why abusive conduct should not be limited to conduct which does not violate other laws or for which no other remedy is available. Competition law is specifically designed to control anticompetitive private conduct entailing restrictions of competition, in particular by excluding competitors. Where the conduct has anticompetitive objects and effects, it may give rise to liability under competition law, which is designed to prevent such effects, as well as under other laws intended to control such behaviour regardless of any anticompetitive effects it may have. The fact that other laws and remedies prohibit misleading representations or provide for remedies against them is irrelevant where the objective of competition enforcement is not to penalise such misconduct *per se*, but rather to prevent the anticompetitive effects of such misconduct in the marketplace. Such anticompetitive effects must fall within the scope of competition law, and the fact that otherwise prohibited means may have been used to achieve them cannot be decisive for the application of competition law.

- (745) Moreover, the remedy under the said applicable rules would involve the revocation or annulment of the SPC in question, through judicial review of the relevant act by the public authority. The scope of such a remedy is very limited, not only because it does not in any way punish the implementation of the exclusionary strategy when it did not result in the acquisition of an SPC (or an SPC of a longer duration), but also because such a remedy does not take into account the anticompetitive object and effects of the conduct in question. Indeed, AZ's Reply shows that it knew that the "only risk" it ran under the patent regime in supplying an incorrect date would be a reduction of the duration of the SPC, not its complete invalidity⁶⁰³ (see recital (200)). AZ does not mention the existence of other remedies, such as claims for damages.
- (746) Similarly, the possibility of infringement procedures against the Member States or legislative action on the part of the Community institutions does not exclude the applicability of Article 82 of the Treaty.
- (747) Furthermore, as regards AZ's assertion that the patent offices published details on applications and grants and this was closely monitored by competitors (see recital (613) above), it should be noted that the relevant information – notably information on market authorisations and the SPC applications and grants – was not easily accessible to competitors of the SPC applicants (see recitals (153)-(154)). This conclusion is also supported by the fact that several patent offices relevant to this case did not object to AZ's use of the date of publication of the technical authorisation (as opposed to the date of grant of the technical authorisation) in its SPC applications for felodipine (see recital (252)). In addition, considering the content of AZ's SPC applications, not only the technical authorisation date in Luxembourg was relevant to AZ's competitors, but also the date of actual marketing in Luxembourg. Indeed, AZ was – from its competitors' point of view - the only source of this information. In any event, the special responsibility incumbent on dominant undertakings not to impair genuine undistorted competition on the common market also covers the possible use of public procedures or regulations with the clear purpose of excluding competitors, in particular where the authorities or bodies applying such procedures or regulations have no or little discretion (see recitals (324)-(328)). The fact that a third party may

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6.82-83 AZ Reply.

discover misleading representations made by a competitor does not mean that such misleading representations constitute normal competition.

- (748) In any case, even if competitors could have challenged SPCs obtained by AZ, this would at most have resulted in the annulment of the SPC. There would be no sanction – taking account of the anticompetitive object or effect – for failed attempts not resulting in an SPC. In addition, such annulment would only intervene after intensive litigation, and at the initiative of competitors considering that the SPC would be presumed to be valid (see recital (765)). Indeed, AZ only advances its “effective marketing” theory as a defence in cases where its SPCs are challenged, but AZ never relies on that theory in order to challenge the refusal to grant an SPC, or a decision to grant it for a more limited period than the one resulting from its “effective marketing” theory.
- (749) Finally, it must be recalled that the misleading representations during the second stage of the abuse do not primarily relate to any interpretative theory in relation to the SPC Regulation. The date when Losec could be commercially brought to the market in Luxembourg was relevant even under AZ’s “effective marketing” theory. If Losec could have been launched before 21 March 1988 – as it indeed was – AZ would have obtained less SPC protection. Taking into consideration that, during the first stage of the abuse, AZ’s strategy is to hide rather than disclose its theory (see recital (667)), the pattern of misleading representations cannot be said to be instrumental to the submission vis-à-vis the authorities of any such interpretative theory.

6. THE COMMISSIONS RESPONSES TO AZ’S ARGUMENTS REGARDING ERRORS, PATENT AGENTS AND COUNSEL ACTING WITHOUT INSTRUCTIONS AND DOCUMENTS OF WHICH AZ DID NOT BECOME AWARE IN A TIMELY MANNER

- (750) In its Reply AZ attempts to portray a large number of acts or situations relevant to the finding of abuse in this case as “errors”, “oversights” or the result of independent action by patent agents or external counsel. It also claims that a number of key documents – relevant to the abuse – appear to have been lost or not to have attracted AZ’s attention in a timely manner. AZ’s claims relate to both stages of the abuse.
- (751) As regards the first stage, reference is made to the following claims by AZ: (a) the patent department’s request of 29 March 1993 to which Hässle replied by its memo of 30 March 1993 “*appears to have been lost*” (recitals (168) and (639)) and (b) the fact that the technical authorisation numbers were left in column C in the final instruction of 7 June 1993 was an “*error*” (recital (609)).
- (752) As regards the second stage, reference is made to the following claims by AZ in its Reply: (a) the French patent agent’s letter to the Luxembourg patent agent of 17 June 1993 has only recently been copied to AZ; (b) the submission of the Luxembourg technical authorisation date 16 November 1987 to the Dutch patent office was a “*genuine and inadvertent*” error; (c) when the Belgian patent agent submitted this date (16 November 1987) to the patent office he acted “*without instruction*”; (d) “*it is not clear if*” the Belgian patent agent’s letter to AZ of 29 September 1993 (stating that he will transmit the 16 November 1987 date to the patent office) “*came promptly to the attention of the addressee* [i.e. AZ]”; (e) in respect of the letter dated 25 November

1993 sent by the Belgian patent agent to inform AZ of the fact the patent office has granted the SPC based on 16 November 1987, AZ claims that “*the fact that had been granted by reference to the wrong date did not attract patent department’s attention at the time*”; (f) the omission to cite the first effective marketing date in the EEA in the second round was due to an “*oversight*”; and (g) AZ’s statement before the German Federal Patent Court that 8 February 1988 was the “*decisive*” date as regards the effective marketing of Losec Luxembourg was a “*forensic concession*” by AZ’s counsel acting without instructions.

- (753) AZ’s gives similar explanations of oversights and unauthorised action by patent agents in respect of omeprazole sodium. While AZ’s behaviour regarding omeprazole sodium is not impugned in this decision, it nevertheless sheds light on AZ’s behaviour regarding omeprazole. In fact, AZ did apply its effective marketing theory to omeprazole sodium save for two countries: France and Sweden (see recital (247)). For France, the patent agent filed the technical authorisation to the patent office. AZ claims that this action was not in line with its instructions. For Sweden, AZ also filed the technical authorisation claiming that this was due to an “*oversight*” due to Sweden’s unclear situation arising out of Sweden’s accession to the Community.
- (754) The Commission cannot accept AZ’s explanations regarding alleged mistakes, unauthorised actions by patent agents and external counsel and documents that – although clearly addressed to AZ – were lost or never came to its attention in sufficient time for AZ to react.
- (755) To start with, AZ’s claims are not substantiated. Moreover, AZ’s claims display a pattern undermining their credibility. First, whenever the documents in question concern incriminating elements for which AZ is undoubtedly responsible (such as the first and second round instructions and the two letters concerning omeprazole and omeprazole sodium to the Dutch patent agent both dated 16 November 1987), AZ refers to those elements as “*errors*”, “*mistakes*” or “*oversights*”. Second, whenever the action in question was undertaken by AZ’s patent agents or external counsel in relation to a third party (patent office or court), AZ claims that the agent or counsel acted “*without instruction*”. In this respect, it must be noted that such actions, even if they were “*without instructions*”, are explained by the fact that AZ had left some of the persons concerned “*in the dark*” as regards significant aspects of the SPC applications, such as the existence of a previous technical market authorisation in France (see e.g. recitals (185), (186)-(187), (193), (203), (205)-(206), (221) and (233)). Consequently, even if demonstrated, such actions are not inconsistent with the existence of a pattern of exclusionary behaviour. Third, whenever key documents have been submitted to AZ by its patent agents or transmitted within AZ’s corporate structure, AZ claims that the documents were lost or did not come to AZ’s attention at the relevant time. This third category includes *inter alia* AZ’s assertions that it did not come to its attention that the technical authorisation date in Luxembourg had in some cases been provided to patent offices and that SPCs had been granted on that basis. The fact that AZ – and in particularly its patent department – had been intensely focused on the issue of the decisive first date under the SPC Regulation detracts from the credibility of AZ’s claim.

- (756) In addition, the two last points in the preceding recital are inconsistent with AZ's centralisation of its SPC applications and the related subsequent litigation. In its reply, AZ admits that there was such a centralisation and coordination⁶⁰⁴.
- (757) AZ's claims must be viewed in the overall context of AZ's strategy involving numerous other misleading representations (other than the ones concerned by AZ's explanations on "errors" etc.). It is not necessary for every item of evidence produced by the Commission to satisfy the required standard of proof in relation to every aspect of the infringement. It is sufficient that the body of evidence relied on by the institution, viewed as a whole, meets that requirement⁶⁰⁵.

7. THE ANTICOMPETITIVE EFFECTS OF THE ABUSE

(a) Effects on competition

- (758) According to the case law of the Court, where one undertaking holding a dominant position actually implements a practice with the aim of keeping competitors away from the market, the fact that the result sought is not achieved is not enough to avoid the practice from being qualified as an abuse of a dominant position⁶⁰⁶. The Court of First Instance has also recently ruled that the effect required to prove an abuse pursuant to Article 82 of the Treaty "*does not necessarily relate to the actual effect of the abusive conduct complained of. For the purposes of establishing an infringement of Article 82 EC, it is sufficient to show that the abusive conduct of the undertaking tends to restrict competition or, in other words, that the conduct is capable of having that effect ... If it is shown that the object pursued by the conduct of an undertaking in a dominant position is to limit competition, that conduct will also be liable to have such an effect*"⁶⁰⁷.
- (759) In the four 1988 countries Denmark, Finland, Germany and Norway, AZ would not have obtained any SPC protection for omeprazole had it submitted the first technical authorisation date (15 April 1987 in France).
- (760) Yet in three of those countries (Germany, Norway and Finland), AZ's strategy of supplying misleading information to the patent offices led to the obtaining of such protection. It is true that the decisions of the German and Norwegian patent offices were overruled by the competent national courts as a result of legal proceedings by generic firms attempting to enter the market. However, in Norway that revocation did

⁶⁰⁴ 6.302-303 AZ Reply.

⁶⁰⁵ See, to that effect, Joined Cases T-305/94 to T-307/94, T-313/94 to T-316/94, T-318/94, T-325/94, T-328/94, T-329/94 and T-335/94 *Limburgse Vinyl Maatschaapij and Others v Commission* ("PVC II") [1999] ECR II-931, paragraphs 768 to 778, and in particular paragraph 777, confirmed on the relevant point by the Court of Justice, on appeal, in its judgment in Joined Cases C-238/99 P, C-244/99 P, C-245/99 P, C-247/99 P, C-250/99 P to C-252/99 P and C-254/99 P *Limburgse Vinyl Maatschaapij and Others v Commission* [2002] ECR I-8375, paragraphs 513 to 523. See also judgment of 8 July 2004 in Joined Cases T-67/00, T-68/00, T-71/00 and T-78/00 *JFE Engineering Corp. and Others v Commission*, not yet reported, paragraph 180.

⁶⁰⁶ Joined Cases T-24/93, T-25/93, T-26/93 and T-28/93 *Compagnie maritime belge and others v Commission*, paragraph 149.

⁶⁰⁷ See also Case T-228/97 *Irish Sugar v Commission* [1999] ECR II-2969, paragraph 191, and Case T-203/01 *Michelin v Commission* [2003] ECR, paragraphs 239, 241.

not occur until June 1999 (i.e. after the expiry of the substance patent in April 1999). Moreover, in Germany, the Federal Court of Justice was obliged to refer *inter alia* a question regarding the interpretation of Article 19 of the SPC Regulation to the Court of Justice for a preliminary ruling. As a result, with reference to the German court's referral to the Court of Justice, the competent Finnish court stayed its proceedings while leaving AZ's SPC in force (recital (245)). At the very least, this resulted in a situation of uncertainty where potential new entrants had to initiate legal proceedings against the SPCs granted to AZ. The SPCs granted also enabled AZ to threaten and sue competitors (even after the SPCs for Norway and Germany were revoked) (see footnote at recital (244) for Finland; footnote at recital (234) for Norway and recital (231) for Germany).

- (761) In four of the six 1982 and 1985 countries, AZ's strategy enabled it to obtain longer SPC protection: seven extra months (until November 2002) in the three Benelux countries on the basis of the Luxembourg technical authorisation date (16 November 1987) and nearly one year (until 24 August 2005) in Austria (see recital (233)) on the basis of the Luxembourg "21 March 1988" date. In Belgium AZ enjoyed most, but not all, of the extra seven months of SPC protection as a Belgian court set aside AZ's SPC on 25 September 2002 (see recital (190)). The same scenario unfolded in the Netherlands where, on 29 October 2002, the patent office found that the correct expiry date was 15 April 2002 (see recital (201)).
- (762) The extra SPC protection obtained by AZ prevents market entry by all potential competitors wishing to launch generic products based on omeprazole following expiry of the basic patents for that substance (see recitals (147)-(148)). The exclusionary effects are strengthened by the fact that the mere existence of the SPCs in question delays the preparations undertaken by potential generic producers with a view to launching omeprazole-based products. Such preparations often last several years.
- (763) Finally, the fact that AZ's SPC Strategy did not succeed in Denmark and the United Kingdom does not affect the qualification of the behaviour as an abuse, considering that the conduct was implemented with the aim of keeping competitors off the market. The finding of an abuse in this case does not simply rest on an intention to exclude. In Denmark and the United Kingdom AZ implemented its initial strategy in the same manner as in other countries, and there was a risk in those two countries that the SPC Strategy would succeed (as happened in Austria, Belgium, Finland, Germany, Luxembourg, the Netherlands and Norway) given the limited amount of verification carried out by the patent offices (see recital (153)).
- (764) Moreover, the finding of an abuse does not, in principle, require that it is established that the misleading representations were relied upon by patent agents, patent offices and courts (recital (758)). Whether or not the national patent offices or courts relied or not on AZ's misleading representations simply reflects AZ's success or lack thereof in the conduct it actually implemented.
- (765) Furthermore, the qualification of a practice as abusive does not require that the intended effects were achieved in full (recital (758)). In any event, it should be noted that an intellectual property right (such as an SPC) which has been granted is presumed to be valid. Thus, in this case potential generic entrants were obliged to spend time, effort and money in challenging the SPCs before national courts and patent offices in several countries where AZ's strategy had resulted in SPCs which

would not have been granted or which would have been granted for a shorter duration if AZ had provided the date of the first technical market authorisation (Belgium, Germany, Finland, the Netherlands and Norway).

- (766) Incidentally, the period during which AZ enjoyed SPC protection in Norway between the expiry of the substance patent and the revocation of the SPC (around two months) cannot be dismissed as being immaterial for the reasons explained above (see recitals (710)-(711)). Moreover, one important effect of the misleading representations in Germany (where the SPC was revoked prior to the expiry of the basic patent protection in April 1999) was that AZ was able to bring proceedings on the basis of its SPCs even after April 1999 (see recital (231))⁶⁰⁸. This was also the case in Belgium where AZ brought proceedings on the basis of its SPC in May 2002⁶⁰⁹.
- (767) As regards AZ argument that in some countries, generics suppliers have ignored the SPC and launched products after the date on which the Commission contends the SPC should have expired (see recital (624)), it should be mentioned that notwithstanding some generic entry prior to the expiry of the SPC, the existence of an SPC, as the existence of any other exclusive right, can be assumed to have had a deterrent effect on generic competition. Indeed, SPCs effectively extend the substance patent protection which constitutes the principal entry barrier to generic products. In fact, AZ, as stated in the previous recital, was able to bring proceedings against generic competitors on the basis of its SPC following expiry of the patent in Belgium in May 2002⁶¹⁰.
- (768) In respect of AZ's contention that there were other reasons, quite unrelated to AZ's alleged abuse, why generic competitors did not enter or were excluded from the market, it should first be noted that the fact that AZ owned formulation patents does not exclude the deterrent effect. A formulation patent is generally much weaker than a substance patent and an SPC⁶¹¹. A formulation patent thus has much less of a deterrent effect on market entry. In several cases generic products have been found by courts not to infringe AZ's formulation patent⁶¹². Its formulation patents have also been declared invalid⁶¹³. It should also be noted that AZ expended considerable time and effort in trying to obtain and preserve SPCs as part of its SPC Strategy for omeprazole. This shows that AZ itself felt that such additional protection was a significant value added to the patent protection surrounding Losec.
- (769) Moreover, the fact that there may have been commercial factors acting as a disincentive to generic entry in certain markets cannot be decisive to determine effects (see recital (625)). The findings in this case show that virtually all EEA Contracting Parties (except Luxembourg) maintained or introduced cost-containment measures (including measures to promote generic products) during the 1990s (see recitals (116) - (132)).

⁶⁰⁸ 6.177, 6.340 AZ Reply.

⁶⁰⁹ 6.329 AZ Reply.

⁶¹⁰ 6.329 AZ Reply.

⁶¹¹ See the following documents expressing uncertainty as regards the strength of AZ's formulations patents: [3691], [4348] and [4420].

⁶¹² See in respect of Finland 6.335 AZ Reply and in respect of Norway 6.348-349 AZ Reply.

⁶¹³ See in respect of Belgium 6.329 AZ Reply.

- (770) It appears from the foregoing that, contrary to AZ's submissions, the SPC abuse did have appreciable effects on competition. Therefore, the abuse also adversely affected national health systems and consumers.

(b) Effects on national health systems

- (771) Generic market entry at patent/SPC expiry normally entails a considerable lowering of the prices at which medicines are publicly reimbursed (either directly through the existence of generic products on the home market or indirectly through lower prices in other countries, feeding through into the setting of prices and reimbursement levels in the home market) (see recitals (116)-(127)). Market forces put further downward pressure on reimbursable medicines following generic entry (see recital (129)), as the example in Germany (the only Member State where generic producers of omeprazole entered the market during the period relevant to this Decision) shows. The entry of generic products thus entails savings for the national health systems and the taxpayers and contributors who finance them (see recital (116)). Moreover, especially for blockbuster medicines like Losec, the generic versions are, in general, readily available when the patent expires. In view of the foregoing, the extra SPC protection obtained by AZ thus adversely affects national health systems in the EEA Contracting Parties concerned as the savings envisaged by the regulatory and market mechanisms as well as various incentives to encourage generics (see e.g. recitals (113)-(114), (130), (131) and (132)) are not achieved.

(c) Effects on consumers

- (772) The prevention of the market entry of generic omeprazole-based products also directly affect consumers to their detriment – i.e. not only indirectly in their capacity as taxpayers and contributors to the national health systems – but also by virtue of the fact that a number of EEA Contracting Parties (such as Belgium, Denmark, Finland, Germany, the Netherlands and Norway) apply copayment systems under which the use of cheaper generic products involve savings for consumers (see recitals (136)-(138)).

8. CONCLUSION ON THE FIRST ABUSE

- (773) In view of the foregoing, it is concluded that AZ has abused its dominant position within the meaning of Article 82 of the Treaty (see recital (601)) in Belgium, Denmark, Germany, the Netherlands and the United Kingdom and within the meaning Article 54 of the EEA Agreement in Norway. The abuse consists of AZ's pattern of misleading representations as part of its SPC Strategy for omeprazole during two stages with a view to preventing, or at least delaying, generic market entry (see in particular sections 3 and 4 above). The misleading representations were initially made by AZ in the form of its instructions to patent agents and applications to patent offices in relation to omeprazole in June 1993 and November-December 1994 in *inter alia* the six countries mentioned above. Later, AZ also persisted in its misleading representations before the patent offices in Belgium, the Netherlands and the United Kingdom as well as before national courts in Germany and Norway.
- (774) The said abuse is of a single and continuous nature. The abuse within the meaning of Article 82 of the Treaty in Belgium, Denmark, Germany the Netherlands and the

United Kingdom begins on 7 June 1993 with AZ's transmission of its instructions. In Germany, the abuse lasts until the end of 1997 (the last year for which dominance can be established in that country). In Belgium and the Netherlands the abuse lasts until the end of 2000 (the last year for which dominance can be established in these two countries). In Denmark the abuse ends on 30 November 1994 with AZ's withdrawal of its SPC application. In the United Kingdom the abuse ends on 16 June 1994 with the submission by AZ to the patent office of the date of the technical authorisation in France. The abuse within the meaning of Article 54 of the EEA Agreement in Norway starts on 21 December 1994 and continues until the end of 2000 (the last year for which dominance can be established in Norway).

- (775) The single and continuous nature of the abuse follows from the high degree of centralisation and coordination which characterises the abusive behaviour (see recitals (811)-(816) and (878)-(881)). There is no legal requirement that the abusive behaviour is implemented in the relevant geographic market where dominance exists. Indeed, what is relevant is that the behaviour, even if implemented in another relevant geographic market, has the purpose of excluding competitors in a relevant market where the undertaking is dominant. Indeed, AZ's misleading representations are highly interdependent as AZ's behaviour in one and or more EEA Contracting Parties affects – at least potentially – its SPC protection (or its likelihood of obtaining such protection) in other EEA Contracting Parties. In particular, reference is made to the misleading representations before the German patent office and courts (see recitals (222) *et seq.*). The SPC protection that AZ obtained in *inter alia* Belgium, the Netherlands and Norway was dependent on the outcome of those proceedings, as the head of AZ's patent department itself admits in a memorandum of 21 October 1999 (“*If successful [in the German case before the Court of Justice] ... we would indeed secure all the other EU markets where we have SPCs until 2002-2004*”) (recital (230)).
- (776) For further illustrations of the interrelationship between the components in the abuse see recitals (200), (227), (234) and (245). It may also be added that the majority of the countries where the SPC abuse has been established, namely Belgium, Denmark, the Netherlands and Norway, apply cross-country comparisons when determining pharmaceutical prices. Thus, an impact on the competitive situation and prices in one of those countries could potentially spill over into another of those countries (see recital (120) and the related footnote). The fact that AZ's misleading representations continued to produce effects until - in exceptional cases – it corrected them (in the United Kingdom on 16 June 1994 and in Denmark on 30 November 1994) as well as the fact that the misleading representations were liable to have effects in other countries, means that, in so far as it concerned Belgium, Germany, the Netherlands and Norway, the abuse cannot be limited to the last misleading representation that has been established in respect of those countries⁶¹⁴.

*E. THE SECOND ABUSE – THE SELECTIVE CAPSULE DEREGISTRATION
COMBINED WITH THE TABLET/CAPSULE SWITCH AS PART OF AZ'S LOSEC
POST PATENT STRATEGY*

⁶¹⁴ See Cases 243/83 *Binon & Cie SA v Agence et Messagerie de la Presse SA* [1985] ECR 2015, paragraph 17, and T-14/89 *Montedipe v Commission* [1992] ECR II-1155, paragraph 231 where, in the context of Article 81, it was ruled that Article 81 is also applicable to agreements which are no longer in force but which continue to produce their effects after they have formally ceased to be in force.

(777) In the following sections, the Commission will first summarise AZ's main arguments in its reply to the Statement of Objections (section 1). It will then describe the elements forming part of AZ's abusive conduct (section 2). Finally, the negative effects that AZ's action has produced or was capable of producing on competition will be presented (section 3).

1. SUMMARY OF AZ'S ARGUMENTS

(778) First, AZ argues that competition in pharmaceutical markets is characterized by continuing rivalry to produce better medicines. Accordingly, following the successful launch of Losec capsules in 1988, AZ had to persist in its research effort. The several years' work necessary for the development of Losec MUPS accounted for the fact that AZ was unable to launch that new formulation earlier than at a time which broadly coincided with the expiry of the substance patents covering omeprazole.

(779) Losec MUPS offers a number of advantages over Losec capsules (dispersible, suitable for presentation in blister packs, gelatine-free and lactose-free, more efficient packaging). Losec MUPS is different from Losec capsules: it employs a different active ingredient (the magnesium salt of omeprazole, rather than omeprazole itself) and has a different pharmaceutical form. As a result, to obtain marketing authorisations for Losec MUPS AZ used the hybrid abridged procedure (see footnote at the end of recital (259)), under which it provided bridging data to address potentially material differences between the efficacy and safety of the two products.

(780) The fact that AZ's local marketing companies in some 48 national markets chose to launch Losec MUPS, on the basis that it provided a marked improvement over Losec capsules, reflects the significance of Losec MUPS benefits. It belies any suggestion that it was launched in various Member States simply to take advantage of an opportunity, under Community regulatory rules, of disrupting generic competition and parallel trade by withdrawing the marketing authorisations for Losec capsules.

(781) Second, AZ denies the existence of an exclusionary strategy adopted at the centralised level of the group and, therefore, of any selective policy. As a result of its decentralised management and decision-making structure, AZ left it to local marketing companies in each country to decide whether to launch Losec MUPS and, if so, whether to withdraw Losec capsules. Beyond the centrally-adopted decisions to develop a MUPS product, the role of AZ's central teams was limited to assistance, guidance and support tasks and was based on recommendations.

(782) In this context, AZ refers to an AZ memo dating from June 1995, sent to its marketing companies worldwide (the "minisignal") informing them of the development of Losec MUPS and adding a questionnaire regarding the respective marketing companies' plans as to the new product. The replies of the marketing companies (which were later compiled in the "Losec MUPS Stepsum" document of January 1997) illustrate that their decision would be adopted on the basis of perfectly legitimate reasons (such as the advantages of Losec MUPS over Losec capsules or the wish to avoid any confusion among GPs and patients).

(783) Most of the relevant documentation at the level of the local marketing companies in Denmark, Norway and Sweden has not been kept. However, in Sweden, the switch

from capsules to tablets was based on a series of marketing studies. AZ UK took the initiative to look into the possibility of launching Losec MUPS in the United Kingdom as soon as it was ready. During a meeting with representatives of the Medicines Control Agency (MCA) in April 1996, the latter suggested that AZ should consider withdrawing its marketing authorisation for Losec capsules and pointed out that that might prevent entry of generic producers. That suggestion was then referred to AZ's central teams which started to look at the implications of launching Losec MUPS and withdrawing capsules. However, the decision to launch MUPS and to withdraw capsules only belonged to the local marketing companies. The decisions not to launch in some Member States (Spain, Italy, Portugal, Greece, Austria and France) were taken centrally for legitimate commercial reasons.

(784) Third, AZ argues that it was normal and reasonable for AZ's local marketing companies to decide to launch Losec MUPS, to withdraw Losec capsules and to withdraw the capsule marketing authorisations.

(785) Fourth, AZ argues that the withdrawal of the marketing authorisations had little, or no, impact on competition or trade, for the following reasons:

- Had they wished to, generic entrants could have relied on published literature to secure their own marketing authorisation pursuant to the well established medicinal use procedure. Indeed, according to point 8(a)(ii) of the third paragraph of Article 4 of Directive 65/65/EEC, as amended by Directive 87/21/EEC, an applicant for marketing authorisation was not required to provide the results of pharmacological and toxicological tests or the result of clinical trials if he could demonstrate by detailed references to published scientific literature that the constituent of the product had a well established medicinal use with recognised efficacy and an acceptable level of safety. Indeed, omeprazole had been the subject of an unusually large volume of published material. The withdrawal of the marketing authorisations did not therefore prevent, and need not have delayed, market entry of generic producers. Further, generic entrants would in any event have infringed AZ's formulation and other patent rights.

- In addition, parallel traders continued to operate in Sweden and Norway. In Denmark, parallel import licences were withdrawn, but it is unlikely that, if they had been maintained, there would have been significant parallel trade, since evidence from other markets (including Sweden and Norway), shows that the popularity of Losec MUPS would have been likely to dampen demand for Losec capsules. The benefits for the consumer derived from parallel trade in Denmark would have been marginal in any event.

(786) Fifth, the Commission's legal analysis is in any event erroneous. It is only in the most exceptional circumstances that a dominant firm is obliged to assist competitors by allowing them the use of its rights. Article 82 does not prohibit normal competition on the merits. In withdrawing its marketing authorisation AZ was merely exercising rights lawfully available to it under Directive 65/65/EEC, as amended by Directive 87/21/EEC. Indeed, that Directive, which was not designed to promote competition between innovative products and generics, nor to promote parallel trade, allows the holder of a marketing authorisation to withdraw it at will, without giving any reasons (unless they relate to concerns as to the efficacy of the product or to the protection of public health). If the Commission intends to question that right of the holder, the

proper way of doing so is to amend the existing directives (as has since been done) and not to extend the scope of Article 82.

- (787) Sixth, in view of the foregoing, AZ argues that there is no need to adduce any objective justification for its conduct. But if AZ needed an objective justification, it consists in AZ's legitimate protection of the specific subject matter of its intellectual property rights.

2. THE SECOND ABUSE – THE COMMISSION'S ASSESSMENT

(a) Overall assessment

- (788) The second abuse in this case which concerns Denmark, Norway and Sweden essentially derives from AZ's Losec Post Patent Strategy ("LPPS Strategy"), the overall aim of which is to minimise the impact of the patent/SPC expiry for omeprazole. That strategy involves a number of actions with a view to delaying generic market entry through various "*technical and legal hurdles*" (recital (271)) and to preventing parallel trade of Losec capsules.
- (789) The abuse defined in this decision only concerns one of those actions: AZ's selective requests for deregistration of Losec capsules in Denmark, Norway and Sweden combined with the Losec MUPS tablet/Losec capsule switch as part of its LPPS Strategy. The exclusionary intent of the action follows from the following three main factors which will be elaborated below:
- First, there is abundant documentary evidence that two key purposes underlying AZ's elaboration and implementation of the capsule deregistration and the tablet/capsule switch as part of its LPPS Strategy were to prevent or at least delay generic omeprazole market entry as well as to stop parallel trade in Losec capsules thereby artificially partitioning markets,
 - Second, the deregistration and switch operation is selectively planned for those countries where AZ believes it stands good chances of achieving its exclusionary aims, and is implemented accordingly,
 - Third, the elimination of generic omeprazole and parallel traded Losec capsules serves the longer-term goal of filling the gap between the expiry of patent/SPC protection for omeprazole and the market launch of its successor substance esomeprazole.
- (790) Furthermore, no objective justifications for AZ's behaviour in this case can be found in AZ's use of public procedures and regulations, the uncertain nature of the law or legal disputes or in the relevant pharmaceutical legislation.
- (791) It should be emphasised from the outset that AZ's behaviour did not – at least at the relevant point in time – constitute standard industry practice (see recitals (821)-(829)).
- (792) It should be noted that single acts involving the launch, withdrawal or requests for deregistration of a pharmaceutical product would not normally be regarded as an abuse.

- (793) It should also be emphasised from the outset that, despite AZ's numerous and lengthy statements to the contrary (see recitals (778)-(780)), it is not the Commission's case that the launch of a new formulation of Losec (Losec MUPS) and/or the withdrawal of Losec capsules would as such constitute an abuse.

(b) AZ's repeatedly stated aim to prevent or at least delay generic market entry and parallel trade

- (794) AZ's general LPPS Strategy documents contain numerous references to the need to keep generic omeprazole away from the market. The memorandum of 20 December 1996, the fundamental LPPS Strategy document of 29 April 1997 and the draft MUPS Strategy document of 3 October 1997 provide documentary evidence of the aim to block market entry for generic omeprazole (see respectively recitals (267), (271) and (280), which all refer to the need to "*delay generic introduction*", to create barriers against generics as a "*major priority*" and to the need to put "*more resource and time pressure*" on potential generic entrants). In the documents of 3 October 1997 and 22 October 1997, AZ reiterates that aim of the capsule deregistration to block generic market access but does not appear optimistic as regards its effectiveness. However, AZ indicates that it will continue to pursue its anti-generic blocking strategy by investigating "*if there are any discrepancies between the European health authorities in deciding on essential similarity and the documentation needed for generics*" (recital (284)).
- (795) Later documents confirm this antigeneric goal. In a fax of 29 May 1998 to its Nordic marketing companies, AZ confirms that the national LPPS Strategy documents – which are to be adopted later that year or in early 1999 – must "*secure as far as possible that generics do not enter the field*" (recital (296)). The said national LPPS Strategy documents emphasise the huge business threat that generic competition poses, to AZ's mind; for example the Swedish LPPS Strategy document considers it to be of "*the utmost importance*" that no generic products are marketed in the medium term (see recitals (298)-(301)). AZ's GI Franchise Plan of 12 May 1999 confirms that "*the overall aim*" of the switch is "*to prevent or delay market entry*" (see recitals (291)-(293)).
- (796) In addition, the bundle of documents which specifically concerns the MUPS Strategy (an integrated part of the LPPS Strategy) identifies the prevention of parallel trade as another key objective of the switch and deregistration operation. References to "*parallel importation*" and the willingness to "*prevent*" such imports already appear in an enclosure to the minutes of an internal meeting on 9 August 1996 (attended by several members of AZ's senior management, including its then CEO), and in a set of slides from 26 May 1997 (see recitals (266) and (274)).
- (797) The draft MUPS Strategy document of 3 October 1997 lists a number of "*issues that need clarification*", one of which concerns the effect of the MUPS Strategy on parallel imports. In that context, AZ also explicitly acknowledges the relevance of certain Treaty provisions on competition law ("*articles 85 and 86*") and free movement of goods ("*articles 30 and 36*") (recital (281)). A follow-up document of 22 October 1997 on the MUPS Strategy reveals that AZ believes that the deregistration of Losec capsules will be effective in preventing parallel trade in the said product (recital (283)).

- (798) AZ's national LPPS Strategy documents and actions undertaken in Denmark, Finland, Norway and Sweden also show that the MUPS Strategy was designed to block parallel trade in Losec capsules (see recitals (302), (311), (314)-(315) and (321)).
- (799) It may be added that part of the GI Franchise Plan of 12 May 1999 involves the monitoring of the "*regulatory impact of the Losec MUPS on generic/parallel imports and generic substitution*" (recital (294)).

(c) Geographic selectivity of the Losec capsule deregistration combined with the Losec MUPS tablet/Losec capsule switch

- (800) The fact that AZ limited its plans to request deregistration of the capsule and implement the switch only to some countries constitutes further evidence that a key aim pursued by AZ was to combat generic market entry and parallel imports, although in the MUPS Strategy document of 22 October 1997, two AZ inhouse counsel warn against a geographically selective launch of the Losec MUPS tablets (recital (285)).
- (801) However, from the outset, AZ plans to implement the request for deregistration and tablet/capsule switch only in those countries where AZ believes it stands a good chance of keeping generics and parallel traded products away from the market. Thus in its basic LPPS Strategy document of 29 April 1997, AZ contemplates the total tablet/capsule switch only "*where local substitution rules would make such an action effective*". It considers that action as "*probably relevant for markets with early patent expiry considering the timing of [esomeprazole] market availability (e.g. ... Denmark, Norway, Germany)*" (see recital (271) under f)).
- (802) Later documents confirm AZ's intention to implement the switch only in those countries whose regulatory rules are likely to assist AZ in pursuing its exclusionary strategy successfully. At the brainstorming meeting of 18 September 1997, which involves AZ's senior management in Sweden, including its CEO, AZ refers to "*regulatory rules on a country-by-country basis relevant for total MUPS switch*" and queries "*how can we exploit these [rules] and where?*" (recital (278)). Similarly, on 30 November 1998, AZ reports that "*a survey is ongoing to capture the different national Health Authorities interpretation of the regulatory impact of the MUPS/capsule switch*" (see recital (294)) and, a few months later, it repeats in its GI Franchise Plan that it will "*monitor regulatory impact of the Losec MUPS switch on generic/parallel imports and generic substitution*" (recital (294)).
- (803) More specifically, AZ's supply strategy – as set out in the draft MUPS Strategy document from 3 October 1997 – is that "*markets with early patent expiry or having special strategic needs (e.g. Sweden) should be prioritized regarding delivery of Losec MUPS in the wallet pack*". One recommendation states that "*it is important that the first launch of Losec MUPS does not occur in a low price market*" and that "*Losec MUPS not be filed in Italy/Spain*" (recital (282)). On 25 September 1997, AZ had also excluded "*possibly*" Portugal and Greece from its plan to convert all sales from the Losec capsules to the Losec MUPS tablets (recital (279)). Moreover, in the follow-up document to the MUPS Strategy of 22 October 1997, AZ identifies the Scandinavian countries as jurisdictions where the relevant national authorities would be likely to revoke parallel import licences for Losec capsules, if AZ "*surrendered*" (i.e. deregistered) its market authorisation for the said product ("*There are indications that*

several of the Scandinavian authorities generally would take this position") (recital (283)). Thus, by planning to deregister the capsules in only some of the countries where it will implement the switch between tablets and capsules (which does not necessitate deregistration), AZ takes the selectivity underlying its MUPS Strategy one step further.

- (804) AZ's plan to selectively implement the tablet/capsule switch contrasts with the commercial views expressed by a clear majority of its national marketing companies within the EEA (recital (277)). Only two EEA marketing companies (Greece and Norway) want immediate withdrawal of the capsules. Nine other marketing companies in the Community recommend that both products be retained or that the capsules only be gradually withdrawn. No EEA marketing company regards the switch as a means to combat generic products and parallel trade. Instead, AZ's national marketing companies refer to "*depending on acceptance*", "*limit potential confusion*", "*Class competition, market acceptance of capsule*", "*run down inventory stocks*", "*inventory run out*", "*acceptance*", "*competitive advantage it needs to be EU decision*", "*limit potential confusion; pricing; preference for tablet*" and "*strong launch message*" as justifications for their recommendations (recital (277)). None of those considerations feature in the subsequent internal strategy documents elaborated by AZ's central headquarters.
- (805) In line with those plans, AZ implements requests for deregistration of Losec capsules combined with the tablet/capsule switch in Denmark, Finland, Norway and Sweden. Indeed, as it appears clearly from the facts, AZ has requested the deregistration of Losec capsules in those four countries, and only in these four countries, shortly after the launch of Losec MUPS (recital (304)). In Germany and the Netherlands AZ launches the tablets and withdraws the capsules from the market but without requesting deregistration (recital (305)). In three other countries (Belgium, Ireland and the United Kingdom) AZ markets both products (except for a brief withdrawal – without deregistration – of the capsules in the United Kingdom) (*ibidem*). Moreover, AZ does not even bring the tablets to the market in Italy, Portugal, Spain, Greece, France and Austria despite the fact that it holds market authorisations for the tablets in the four latter countries (recital (306)). In the countries where AZ does not launch the tablets, pharmaceutical price levels are generally lower (compared with prices in the rest of the Community). In addition, in those "low price" countries, either AZ's substance patents/SPCs expire later than in the group of countries where the MUPS tablets are launched or there is no such protection at all (recital (306)). This pattern confirms the selective character of the capsule deregistration and the tablet/capsule switch.
- (806) AZ admits that the decisions not to launch Losec MUPS in those countries had been taken centrally, but argues that the decisions had been adopted for perfectly legitimate reasons (see recital (782)). However, not a single piece of evidence, for any of those countries, has been provided by AZ to support that assertion. None of the documents produced by AZ to support its explanations concerning the MUPS abuse in general even hints at the allegedly legitimate reasons. Moreover, Losec MUPS may have been launched in nearly 50 countries. However, AZ does not claim that it requested the deregistration of the capsules in any of those other countries.

(d) Blocking generic products and parallel imports to fill the gap in patent/SPC protection before the launch of esomeprazole

- (807) The long term objective of AZ's LPPS Strategy, as set out in the central strategy document of 29 April 1997, is to establish omeprazole's successor esomeprazole on the market. To facilitate the transition to esomeprazole, AZ needs to keep generic and parallel-imported omeprazole away from the market for as long as possible (see recitals (268)-(269)). AZ's view is that it will be in a position to build momentum for the introduction of its new generation product esomeprazole if it can "*minimize sales erosion*" for omeprazole following patent expiry (see recitals (268)-(269)).
- (808) More specifically, the MUPS Strategy and other measures situated in the second "*short/medium term*" phase of the LPPS Strategy (recital (272)) aim at bridging the gap between the expiry dates for the omeprazole substance patent (including, in certain jurisdictions, the SPC protection) and the time when AZ intends to launch esomeprazole. This gap-filling strategy is most clearly articulated in the LPPS Strategy for Norway ("*If there are no generics on the market at that time we expect no difficulties in obtaining price and reimbursement at a level comparable to the price of Losec® at that time, if that price is not significantly higher than the price of [esomeprazole] in other EEA member states. If there are generics on the market, however, the price might be set according to the price of generics ... It is therefore critical that both price is set and reimbursement is granted before the entrance of generics*") (recital (300)).
- (809) Under the heading "*DO NOTHING SCENARIO*" the Danish LPPS Strategy concludes that "[i]t will be very difficult to launch [esomeprazole] successfully, since Astra by this time will not be the market leader and the price gap between [esomeprazole] and generics will be large" (recital (299)). Like the Norwegian and Danish document, the Swedish LPPS Strategy also emphasises the critical importance of blocking market access for generic omeprazole to ensure a successful launch of esomeprazole ("*[i]t is of the utmost importance that [esomeprazole] can be marketed without generic omeprazole being available for the longest period possible ... The idea is to maximize the speed of conversion [to esomeprazole] not to optimize the omeprazole sales*") (recital (301)).
- (810) **[confidential]** In a speech in October 1999, the head of AZ's patent department states that the "*aim is to slow down generic market penetration to give time for the new esomeprazole ...*" (see recital (273)).

(e) Alleged absence of centralised strategy

- (811) The evidence contained in the file does not support AZ's contention that no strategy was adopted at a centralised level and that decisions were adopted by local marketing companies on their own motion. This is consistent with the fact that the market companies concerned in Denmark, Norway and Sweden were wholly owned by AZ at the relevant time (see the relevant footnote at recital (8)). Indeed, references to documents confirming the existence of a centralised strategy have already been made above (see in particular statements in documents emanating from AZ's central headquarters and involving AZ's senior management listed in sections (b) and (c) above).

- (812) AZ's senior management, including its CEO, had requested a pan-European MUPS strategy at the brainstorming meeting of 18 September 1997. At that meeting, a member of AZ's senior management was assigned the task of defining and preparing country-by-country plans in detail to handle the patent expiry. Section 11 of the LPPS Strategy document referred to the "*Astra Hässle process*" and not the national marketing companies. The same section indicates that the LPPS Strategy "*at Astra Hässle will be handled through four separate functions, the Losec Board, the Working Party, the Task Force and the [esomeprazole] project*". It goes on: "*based on priorities set by SMT [Senior Management Team], LB [Losec Board] is the decision making body in matters of key strategic and budgetary importance related to Losec*". Reference can also be made to the draft MUPS Strategy document of 3 October 1997 (recital (280)), the MUPS strategy document of 22 October 1997 (recital (283)) and the GI Franchise Plan (recital (291)) which were all sent to at least some senior managers at Astra AB. A letter dated 22 October 1998 from AZ's Norwegian marketing company to one of AZ's Swedish subsidiaries (Astra Sverige AB) explicitly states that "*the first draft version [of the Norwegian Losec Patent Strategy] was submitted to Astra Hässle on August 15, 1998 and an updated version resubmitted October 1, 1998*" (see recital (300)).
- (813) The documents referred to by AZ in its Reply to the Statement of Objections, such as the "minisignal" of December 1995 and the Stepsum document (see recital (782)), simply reveal that the deregistration of Losec capsules was not even envisaged at that time and that no marketing company seemed to have had such a deregistration in mind. AZ has underlined that several marketing companies replied to the minisignal by giving some legitimate and reasonable business reasons regarding the decision to launch Losec MUPS, the timing for such a launch and the decision to withdraw capsules. None of them, however, referred to a possible deregistration of the capsules. Yet, AZ's subsidiaries in Norway, Sweden and Denmark did deregister Losec capsules soon after the launch of Losec MUPS, or shortly thereafter. In addition, both the minisignal and Stepsum documents precede the "brainstorming" decision of 18 September 1997 where AZ centrally assigned the task of preparing detailed national LPPS strategies to a member of AZ's senior management.
- (814) Moreover, it is clear from the content of the national LPPS strategy documents for the Nordic countries, that they include many, if not most, of the elements in AZ's overall LPPS and MUPS Strategy documents (see recitals (296) *et seq.*). The links between the national strategies are apparent from the statement in the Norwegian strategy document that as regards parallel trade the situation will mimic the exclusion of parallel trade which has already taken place in Denmark (see recital (302)). In that context reference may also be made to a meeting held on 25 March 1998 chaired by a member of AZ's central senior management with representatives of AZ's Finnish marketing company. The minutes, which are entitled "Post Patent Strategy for Astra Finland", further confirm that the national strategies were centrally directed by AZ (see footnote at recital (296)).
- (815) The fax dated 29 May 1998 from the managing director of AZ's Swedish marketing company (who is also part of AZ's central senior management as regional director for the Nordic countries) to the managing directors of the marketing companies in Denmark, Finland and Norway reveals that the national LPPS strategies in those countries were elaborated on a centralised basis (see recital (296)). Contrary to AZ's submission in its letter of 8 March 2004 (see recital (12)), the fax merely shows that –

following the decision to centralise the elaboration of the national LPPS strategies at the brainstorming meeting on 18 September 1997 – senior members of AZ’s central management were unsatisfied with the measures taken until then at the local level. This shows that the fax of 29 May 1998 was simply part of a centralisation process which had already been centrally decided by AZ.

- (816) Furthermore, no evidence of any kind has been produced to support AZ’s allegations that Losec MUPS had not been launched in several Member States for legitimate reasons (see recital (783)). Similarly, no evidence has been produced to support AZ’s contention that the decision was autonomously taken for Norway and Denmark by the local marketing companies for legitimate reasons (see recitals (783)-(784)). Finally, the decision not to market Losec MUPS in the Member States with the lowest pharmaceutical prices, a necessary counterpart for the strategy to exclude parallel imports into the Member States where deregistration is requested to succeed, is adopted centrally.

(f) No objective justifications for the exclusionary behaviour

The use of public procedures and regulations

- (817) The fact that the anticompetitive effects are also dependent on actions by public authorities (i.e. national medicines authorities) does not by itself exclude the existence of an abuse in this case (see recital (328)). Even when the behaviour is implemented in the market, the effect of exclusionary practices is often dependent on the reactions of other operators in the market. It should be emphasised that the abuse concerns AZ’s misuse of government procedures. It does not concern AZ’s use of its intellectual property rights. AZ’s argument that its behaviour was objectively justified as a legitimate protection of the specific subject matter of its intellectual property rights cannot be accepted.
- (818) In any event, the special responsibility incumbent on dominant undertakings not to impair genuine undistorted competition on the common market also covers the possible use of public procedures or regulations with the clear purpose of excluding competitors, in particular where the authorities or bodies applying such procedures or regulations have no or little discretion (see recitals (324)-(328)). In this case it need to be emphasised that the marketing of medicinal products is heavily regulated and leaves little, if any, discretion to the authorities involved⁶¹⁵, for example, as regards the consequences for parallel importers and generic producers of a request by the holder for the deregistration of the reference market authorisation.
- (819) In this case, it should be recalled that AZ’s requests to the public authorities to deregister the market authorisations are not requests addressed to the public authorities in the framework of an overtly political process or an attempt to influence decisions taken in a field where such authorities have a margin of discretion, or in general in order to receive an independent review of the merits of the petition. In the case at hand, the national authorities concerned considered, as expected by AZ, that they did

⁶¹⁵ See, as regards Directive 65/65/EEC, Case C-440/93 *The Queen v Licensing Authority of the Department of Health and Norgine Ltd, ex parte Scotia Pharmaceuticals* [1995] ECR I-2851, paragraphs 21-24; Case C-201/94, *Swith & Nephew* [1996] I-5819, paragraph 30.

not have discretion to maintain the marketing authorisation when its withdrawal was requested. In such circumstances the ensuing anticompetitive effect will not be the result of an independent review of the merits of the petition as regards its anticompetitive effect, but rather the automatic (or almost automatic) effect of a private request, made in the form of an exercise of a specific entitlement.

- (820) The Court of First Instance has already considered that “*an undertaking in a dominant position which enjoys an exclusive right with an entitlement to agree to waive that right is under a duty to make reasonable use of the right of veto conferred on it by the agreement in respect of third parties' access to the market*”⁶¹⁶. Moreover, when an undertaking in a dominant position has a specific entitlement (*in casu* a marketing authorisation), be it private or public, it has a duty, under its special responsibility mentioned above to make reasonable use of it (see recital (327)) and not to use it with the clear purpose of excluding competitors.

AZ's conduct was not standard practice

- (821) The exclusionary strategy involving requests for selective deregistration of marketing authorisations for reasons unrelated to interests protected by the legislation cannot be deemed as normal competition or reasonable steps to protect the dominant undertaking's own commercial interests (see recitals (325)-(327)). In this context reference is made to AZ's Losec Post Patent Strategy document (Losec/H 199) dated 29 April 1998 in which the “*formulation conversion [i.e. the MUPS operation]*” is described as “*not precedented*” (recital (286)). Reference is also made to AZ's admission before a Danish court on 27 April 1999 concerning the Danish Medicines Agency's deregistration of Losec capsules in Denmark at AZ's request that “*the original marketing authorisation ... would normally ... in most cases*” remain in force “*where a commercial market exists for the product*” (see recital (307)). It is clear from AZ's continued sales of Losec capsules in those EEA markets where its market authorisation for that product was not deregistered that such a commercial market for Losec capsules existed.
- (822) AZ claims that the views expressed in the Losec/H 199 document cannot be attributed to AZ as it was prepared for AZ by the management consultant McKinsey & Co⁶¹⁷. Moreover, AZ argues that the document neither refers to deregistration of market authorisations nor states that such deregistration (or “surrender”) would be abnormal. In AZ's view, the document therefore does not support the Commission's allegations. AZ thinks that what McKinsey & Co are saying in the document concerned is that since AZ had no precedent for a formulation change to Losec, or at least in the PPI field, and although projections had been made for some countries, launch plans were currently unclear, and it was therefore difficult for McKinsey & Co to project the likely impact of MUPS for AZ's organic growth.
- (823) Internal AZ documents relating to its LPPS Strategy often refers to the concept of “conversion”. These include the LPPS Strategy documents for two of the three

⁶¹⁶ Joined Cases T-24/93, T-25/93, T-26/93 and T-28/93 *Compagnie maritime belge and others v Commission*, paragraph 108. See also Case 226/84 *British Leyland v Commission* [1986] ECR 3263, paragraphs 21-24, as evidence that dominant undertakings must use public entitlements reasonably. In addition reference is made to Case T-30/89 *Hilti AG v Commission*, paragraph 99.

⁶¹⁷ AZ reply to letter of facts, p. 70.

Scandinavian countries where the Commission considers there to be an abuse in this case⁶¹⁸. The Norwegian strategy document predicts that the conversion and deregistration will lead to the exclusion of parallel trade, as had already happened in Denmark (see recital (302)). That evidence shows that by “conversion”, AZ did not simply refer to the standard industry practice of promoting a new product vis-à-vis prescribing physicians but to an exceptional strategy, a key component of which involved the exclusion of generic omeprazole and parallel traded Losec capsules.

- (824) Furthermore, numerous AZ strategy documents relating to the Losec Post Patent and MUPS Strategies reveal that both the regulatory and legal consequences of AZ’s planned switch and deregistration operation were unclear at the relevant point in time (see e.g. recitals (267), (278), (281) and (283)-(285). This constitutes additional evidence that AZ was trading on untested ground.
- (825) In respect of the Norwegian strategy document, reference, is in particular made to a heading in the table of contents (“Regulatory/marketing issues MUPS®/capsules convection” (sic))⁶¹⁹ as well as to the text in the document under that heading⁶²⁰ which reads: *“We assume that the Norwegian Authorities will allow introduction of Losec MUPS® and a concomitant withdrawal of the capsule Marketing Authorization, most probably allowing a proper interim period of 3 months. The conversion will mimic the situation that has already taken place during the MUPS® introduction in Astra Denmark. Thus, we expect that parallel trade of Losec® capsules will gradually cease and be virtually non existing from February 1, 1999”*.
- (826) The Swedish strategy document states under the headings “Marketing” and *“To do under all circumstances”* that *“[b]oth from a marketing [i.e. withdrawal of capsules from the market] and regulatory [i.e. deregistration of capsule market authorisation] perspective the capsules are replaced with MUPS® from January 1, 1999. Whether there will be parallel import of capsules after June 20, 1999 is decided by the court and this will not affect the marketing strategy, however tactics will be different. The next step will be conversion from Losec® to MUPS® to H199/18. It is of utmost importance that H199/18 can be marketed without generic omeprazole being available for the longest period possible. [...] All possibilities of enforcing the conversion will be validated. One year after launch of H199/18 Losec® MUPS® will be withdrawn from the Rx-market and made available OTC. The idea behind this is to maximise the speed of conversion, not to optimise the omeprazole sales”*⁶²¹.
- (827) AZ also argues that the Commission has misrepresented the submission by AZ’s Danish lawyers cited in recital (821) above (i.e. that *“the original marketing authorisation ... would normally ... in most cases”* remain in force *“where a commercial market exists for the product”*). In AZ’s view its Danish lawyer was not making a point about a particular product or about the specific factual history in Denmark relating to the marketing of Losec capsules/MUPS⁶²².

⁶¹⁸ See in respect Norway [4070, [4076], Sweden [3902] (see also recital (301)) and the Netherlands (“POST PATENT STRATEGY® THE NETHERLANDS”) (dated 14 December 1998) [4100]. See also (“Marketing Company Plan ASTRA The Netherlands 1991-2001”) (dated October 1998) [2264-2265].

⁶¹⁹ [4070].

⁶²⁰ [4076].

⁶²¹ [3902].

⁶²² AZ reply to letter of facts, p. 74.

- (828) AZ's criticism is misplaced. In so far as the document reveals that it is unusual to deregister a market authorisation for a product for which there is a commercial market, it supports the Commission's conclusion that AZ's deregistration was not industry practice at the time. AZ's contacts with the Medicines Control Agency in the United Kingdom in 1996 further reinforces the conclusion that the switch and selective deregistration later engaged in by AZ were not standard industry at the time (see recital (835)).
- (829) All in all, although AZ contests the probative value of the documents relied on by the Commission and insists that it was allowed to act as it did under Community pharmaceutical law, it does not contest that deregistration for reasons unrelated to public health was not standard practice. Moreover, the file contains no evidence to the effect that such practices were standard in the industry.

Uncertain nature of the law or existence of legal disputes constitute no objective justification

- (830) This decision does not take issue with AZ's interpretations of Community pharmaceutical law (in particular Directive 65/65/EEC) or the interpretation of the national rules on parallel trade licences in the light of Articles 28, 29 and 30 of the Treaty. The objections raised regarding the second abuse in this case concerns AZ's selective behaviour as part of its LPPS Strategy aimed at excluding generic firms and parallel importers, as well as at artificially partitioning the internal market. Therefore the finding of an abuse under Article 82 of the Treaty in this case is not dependent on the interpretation of the regulatory frameworks in question, nor on the outcome of any legal disputes regarding AZ's behaviour or interpretations regarding those regulatory frameworks.
- (831) The uncertainty surrounding the interpretation of certain provisions of Community law (regarding the actual impact of the withdrawal of marketing authorisations on generic producers under Directive 65/65/EEC and on parallel trade licences under Articles 28 and 30 of the Treaty) has certainly created the conditions for AZ to devise and implement its exclusionary strategy. However, the final outcome of the Court cases, by clarifying the interpretation of the provisions in question, is only decisive in defining the extent to which AZ's strategy has been successful. In any event, the legal uncertainty has caused a large amount of litigation, delaying entry and making competitors incur substantial expenses. Such uncertainty is obviously no objective justification for the behaviour in question.

No justification in the relevant legislation on the marketing of medicinal products in the light of the actual motives underlying the exclusionary behaviour

- (832) AZ's behaviour finds no justification in the relevant legal texts concerning the marketing of medicinal products. The Commission does not deny that pharmaceutical law (at the relevant time, Directive 65/65/EEC, as amended by Directive 87/21/EEC) does not prevent the holder of a marketing authorisation from withdrawing that authorisation.

- (833) However, contrary to AZ's suggestion, this cannot exclude the application of Article 82 of the Treaty⁶²³. An act of secondary legislation, such as a Directive, cannot be construed as excluding the applicability of a provision of the Treaty itself. In other words, even if Directive 65/65/EEC does not prevent the holder of a marketing authorisation from requesting the withdrawal of that authorisation, such a request may, in certain circumstances, be qualified as an abuse within the meaning of Article 82 of the Treaty.
- (834) Even if the deregistration of capsules in the United Kingdom had been suggested by the United Kingdom medicines authority, as AZ contends, without adducing any evidence (see recital (783))⁶²⁴, it does not follow from that that AZ's conduct (in Norway, Sweden and Denmark) falls outside the scope of Article 82 of the Treaty. Indeed, since pharmaceutical law does not prevent the surrender of the marketing authorisation, the suggestion by the authorities in the United Kingdom, if ever made, could only be understood as examining the question from the point of view of that law. Nothing indicates that the authorities in the United Kingdom had examined the question of AZ's responsibilities as a dominant undertaking under competition law.
- (835) In fact, it emerges from the minutes of the meeting on 26 April 1996 between AZ representatives and the Medicines Control Agency (MCA) in the United Kingdom, that the MCA did not – contrary to AZ's claims - suggest that AZ should consider withdrawing its marketing authorisation for Losec capsules as a way of counteracting generic entry⁶²⁵. The minutes show that the MCA's statements concerned the consequences of “*allowing the [market authorisation for Losec capsules] to lapse*”. There is a clear difference between simply allowing the market authorisation to lapse and actively requesting the deregistration of the product. If anything, the minutes of the meeting constitute further confirmation that deregistration was not – at the relevant point in time - perceived as standard practice by the relevant authorities in the United Kingdom.
- (836) AZ moreover argues that legislation, and not misapplication of competition law, should address any incorrect balancing of interests. AZ's argument must be dismissed. The mere possibility of legislative changes does not rule out the applicability of Article 82, a provision of primary Community law. See also the Commission's reply to a similar argument by AZ as regards the SPC abuse (recitals (741)-(748)).
- (837) In this regard, it should be recalled that dominant companies must use specific entitlements (such as market authorisations) in a reasonable way (see above recitals (325)-(327)). AZ's conduct described in this decision cannot be deemed to be reasonable. In fact, its requests undermine the delicate balance between the interests of research based and generic manufacturers struck by the legislator in this area (see recitals (258) *et seq.*).
- (838) First, in this case, it is not disputed that AZ's requests for deregistration of the market authorisations of Losec capsules are unrelated to public health concerns, as the Court

⁶²³ Contrary to AZ's claim (see 7.55 AZ Reply), the question as to whether a withdrawal of the market authorisation is allowed by Directive 65/65/EEC or competition law in general was not addressed in Case C-94/98 *Rhône-Poulenc Rorer and May & Baker*.

⁶²⁴ The only document provided by AZ are internal minutes of a meeting between AZ's and the medicines authority's representatives.

⁶²⁵ Vol 11, Annex 7.8 AZ Reply.

explicitly noted in its two *Paranova* judgments of 8 May 2003⁶²⁶ and in its judgment concerning the withdrawal of AZ's market authorisation for Losec in Denmark⁶²⁷. Losec capsules continue to be marketed in a number of Member States (recitals (305) and (306)). The file contains abundant documentary evidence showing that a key reason for AZ's deregistration of the capsules in the Nordic countries was a desire to block parallel imports of Losec capsules, in addition to blocking generic products.

- (839) In that context, it is worth recalling that AZ was conscious that its conduct was susceptible to scrutiny under the rules on competition and the free movement of goods (see recitals (281) and (285)).
- (840) Second, AZ's behaviour cannot find any justification in the relevant legal texts or in the principles underlying them. Generic producers can obtain market authorisations for their products under the generic procedure, provided that: (a) they can demonstrate that their product is "*essentially similar*" to the original reference product; (b) the reference product "*is marketed*" in the Member State where the application is filed and (c) the *exclusivity protecting the data* has expired (see recitals (260)-(261)).
- (841) The objective of the generic procedure is to enable generic manufacturers to demonstrate that their products fully comply with all requirements of safety, quality and efficacy without the need for the generic manufacturers to take their products through preclinical and clinical tests and submit the relevant data to the competent national authority (see recital (260))⁶²⁸. The objective of the generic procedure is also to avoid unnecessary tests on animals and humans (see recital (260)). By the requests for the deregistration of the market authorisation for the capsules combined with the implementation of the switch between the original reference product (Losec capsules) and the Losec MUPS tablets, AZ in fact seeks to undermine the very *raison d'être* of the generic procedure and to extend *de facto* the protection afforded by patents, SPCs and data exclusivity well beyond the period provided for in the applicable rules and considered reasonable by the legislator. For this reason, AZ's argument that Directive 65/65/EEC does not aim to promote competition between innovators and generics cannot be accepted.
- (842) The Commission does not contend that the purpose of market authorisations is to facilitate entry of generic products but that, in the specific circumstances of this case, the surrender of the market authorisation may be an element of the abuse. It must also be recalled that, at the time when generic entry could have been possible in the absence of the exclusionary strategy, both patent protection and data exclusivity protection, the two means whereby innovation in the pharmaceutical industry is rewarded, had expired. Therefore, both the technology and the data necessary for a generic application to succeed were available to generic firms. The additional hurdle – strategically exploited by AZ in this case – was that, at the time of filing the generic application, the market authorisation arguably had to be in force as well. This was indeed the position taken by the Danish Medicines Agency (see recital (310)).
- (843) In that regard, contrary to AZ's claims, it must be stressed that market authorisations are not aimed at rewarding innovation, as they are granted to innovators as well as

⁶²⁶ See Case C-15/01 *Paranova Läkemedel AB and others and Läkemedelsverket*, paragraph 20 and Case C-113/01 *Paranova Oy*, paragraph 21.

⁶²⁷ Case C-223/01 *AstraZeneca A/S v Laegemiddelstyrelsen*, paragraph 45.

⁶²⁸ Case C-223/01 *AstraZeneca A/S v Laegemiddelstyrelsen*, paragraphs 42 and 52.

non-innovators provided the legal requirements are met. As opposed to patents and data exclusivity, the economic value of a market authorisation resides in the possibility to market the medicine in question. It does not confer any right to prevent other parties from entering or acting in the marketplace. A market authorisation is exclusive in the sense that the holder is allowed to market the product concerned but, contrary to property rights, it does not create rights to prevent other parties from acting autonomously. Its strategic value in this case does not derive from its exclusive exploitation by the holder but from its suppression aimed at excluding competitors from the market. It is the legal rules governing patent protection and data exclusivity which are intended to create incentives for the development of medicines. It should be noted that the requirement that the original market authorisation is in force when a generic application is filed has been removed from the relevant EC pharmaceutical legislation⁶²⁹. This constitutes further proof that the strategic use of a market authorisation (i.e. by deregistering it to prevent or delay generic entry) does not form part of the “subject-matter” of the market authorisation. Therefore, and in view of this and the fact that the purpose of a market authorisation – as opposed to patent, SPC and data exclusivity protection – is not to provide rewards for research and development, the finding of an abuse in this case will not have any effect on incentives for innovation.

- (844) The underlying aims pursued by AZ appear already at the very inception of the MUPS Strategy (“*Regulatory rules on a country-by-country basis relevant for total MUPS switch*”; “*How can we exploit these [rules] and where? Shall the capsule be withdrawn or shall it be maintained?*”) (see minutes of 18 September 1997 at recital (278)) and are clearly in line with the general MUPS Strategy of 3 October 1997 (which states that one of the primary purposes of Losec MUPS is to put “*more resource and time pressure on companies developing generic omeprazole*”) (see recital (280)). In fact, the MUPS Strategy is an integral part of phase two of the overall LPPS Strategy of 29 April 1997 which is intended to operate in the short and medium term to “*Delay generic introduction through technical and legal hurdles*” (see recital (271)). The longer term aim of blocking the generic products is to ensure that esomeprazole, at its launch, obtains a high price reimbursed by the public authorities.
- (845) As regards actions against generic omeprazole, AZ’s MUPS Strategy documents of 3 and 22 October 1997 illustrate that it examines thoroughly how the competent national authorities are likely to interpret the requirements of the generic procedure in the case of “*a withdrawal and de-registration of Losec® capsules when Losec® MUPS is authorised*” (see recitals (281) and (284)). Even though AZ’s preliminary conclusion at that stage is that the prospects of eliminating parallel imports are better than those of keeping generics off the market, it intends to pursue its investigations to establish “*if there are any discrepancies between the European health authorities in deciding essential similarity and the documentation needed for generics*” (recital (284)). AZ’s aim is therefore clearly to deprive generic manufacturers of the possibility of availing themselves of the generic procedure and consequently, critically, to delay the market entry of generic omeprazole.

⁶²⁹ See article 10 (1) of Directive 2004/27/EC of the European Parliament and the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, pp. 34-57).

- (846) More specifically, in terms of Community pharmaceutical law, AZ designs the selective total switch, combined in the four Nordic countries with the complete deregistration of its Losec capsules, in order to prevent generic omeprazole manufacturers from showing that their products are essentially similar within the meaning of point (8)(a)(iii) of the third paragraph of Article 4 (see e.g. recitals (281) and (284)).
- (847) As regards its action to prevent parallel trade in Losec capsules, AZ also sought to “*exploit*” the lack of clarity of the case-law on free movement of goods (see minutes of 18 September 1997 at recital (278)) in this case. In its document of 22 October 1997, which follows up the MUPS Strategy document of 3 October of the same year, AZ is by and large optimistic as to its chances of success in combating market entry of parallel-imported products (see recital (283)). Appeals by parallel traders (e.g. Paranova) against the Swedish and Finnish authorities’ decisions to revoke – following AZ’s deregistration of Losec capsules – parallel trade licences for the same product, brought the two countries’ highest administrative courts to request preliminary rulings from the Court of Justice. Again, the final rulings by the Court of Justice delivered on 8 May 2003 in those cases (see recital (317)) are not relevant as far as the finding of an abuse in this case is concerned. The rulings only determine the extent to which exclusionary strategies of the type in which AZ has engaged were successful and are likely to be successful in the future.

3. THE ANTICOMPETITIVE EFFECTS OF THE ABUSE

- (848) Although as explained at recital (758) evidence of actual effects are, strictly speaking, not needed to establish an infringement of Article 82, it is clear that AZ’s behaviour was intended to produce, was capable of producing and did indeed produce harmful effects for generic firms and parallel traders, and, thereby, indirectly for the national health care systems and consumers. In that context, it should be recalled that the documentary evidence shows that a key purpose of AZ’s practice was to prevent, or delay entry by, or create extra hurdles for, generic producers and parallel traders. In other words, the strategy was implemented precisely because it was capable of having the effect sought.
- (849) ***Generic products:*** In Denmark, AZ’s MUPS Strategy foreclosed market access for some generic manufacturers or at least delayed such access. Indeed, the Danish authority (DMA) rejected the generic manufacturer GEA’s application for a market authorisation with reference to AZ’s deregistration (recital (310)). Another generic manufacturer, ratiopharm, obtained a market authorisation in Denmark on 25 May 2001 (more than two years after AZ’s deregistration), based on additional data provided to the DMA as it could only refer to AZ’s Losec MUPS tablet authorisation (recital (310)). In Sweden – with the exception of the complainant’s product – no generic omeprazole products received market authorisation until January 2003 (more than three years after AZ’s deregistration) (recital (313)). In Norway, at most one generic omeprazole version has been launched, again a ratiopharm product which received market authorisation on 2 July 2001 (recital (320)).
- (850) In Sweden, Denmark and Norway, AZ’s deregistration and tablet/capsule switch did not prevent Scand Pharm from launching generic omeprazole versions since it had

already applied for market authorisation under the generic procedure before AZ deregistered the capsules (recitals (307), (312) and (320)).

- (851) In its Reply to the Statement of Objections, AZ argues that, even in the absence of a pending marketing authorisation for capsules, generic producers could have obtained their own marketing authorisations on the basis of the so-called well-established medicinal use procedure.
- (852) However, as AZ itself admits, the well-established medicinal use procedure is seldom applied, since it requires a high standard of published literature. Further, the exception requires a well established use. At the Oral Hearing, AZ did not deny that the Commission already back in 1997 took the view that such well established use meant at least 10 years' use⁶³⁰. In any case, considering that Losec was not put into "use" before the early part of 1988, any generic application in respect of an omeprazole product during the first part of 1998 would have constituted very much a borderline case. Moreover, AZ's representatives at the Oral Hearing conceded that the "well established use" condition involved complex assessments. As far as the Commission knows, there have been no applications based on the well-established medicinal use procedure for products containing omeprazole as their active substance.
- (853) More fundamentally, no reference has ever been made to the well-established medicinal use procedure in AZ's contemporaneous strategy documents in the Commission's possession⁶³¹. This is all the more surprising as, as AZ itself explains, AZ's central teams looked carefully into the implications of a withdrawal of marketing authorisations. If there had been perceived threats that generic producers might, in any event, use the well-established medicinal use procedure to obtain their own marketing authorisations, one would have expected to find at least a reference to that in AZ's strategy documents.
- (854) Finally, even if, contrary to AZ's well informed assessments at the time, generic manufacturers could have relied on that procedure (described as "*an extensive and costly study of literature which cannot necessarily be carried out*" by the relevant Danish authority)⁶³², the key issue of timing remains. Since the generic firms were not informed of AZ's intent to withdraw its marketing authorisation, the countries where such withdrawal was planned or of its actual requests for such withdrawal, the generic firms would only at a late stage have discovered that the marketing authorisations had been withdrawn. In other words, the generic firms would have had to start the process of collecting the information and preparing an application based on the well-established medicinal use procedure only at that moment. This would at the very least have caused a delay in any applications from generic manufacturers.

⁶³⁰ Commission Directive 1999/83/EC of 8 September 1999 amending the Annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products (OJ L 243, 15.9.1999, p. 9) introduced an explicit reference to a well-established medicinal use of at least a decade from the first systematic and documented use of the substance in the Community (see Annex, point 1(a)).

⁶³¹ In a submission dated 27 April 1999 before a Danish court, AZ's Danish external counsel refers to well-established medicinal use procedure as a route to market authorisation for generic firms (see recital (307)) [1196, 1199].

⁶³² [1206].

- (855) AZ also argues that it could have prevented (and in fact did prevent) generic firms from entering the market on other grounds, linked to intellectual property rights such as formulation patents or SPCs (see recital (785) above). The Commission has already replied to a similar argument advanced by AZ in the context of the first abuse (see recital (768)). Moreover, it should be borne in mind that a key purpose of AZ's strategy and conduct was to raise as many obstacles against generic producers for as long a time as possible. Therefore, the fact that AZ in some cases has obtained injunctions based on its intellectual property rights does not detract from the fact that deregistration by itself was one additional tool within AZ's discretion. Finally, as shown above (see recital (849)), the deregistration did prevent and delay the granting of marketing authorisation to generic firms. Here it should be recalled that it is precisely because the complainant in this case applied before deregistration that it swiftly obtained market authorisations in Denmark, Sweden and Norway. Although it is not apparent to what extent market authorisations for other generic firms were obstructed – as the sole result of the deregistration of Losec capsules - in Norway and Sweden, it is at least clear that there was a long delay in the authorisation of generic omeprazole based products in those two countries following the deregistration of Losec capsules.
- (856) In any event, as a result of the deregistration, a generic firm (GEA) in Denmark felt obliged to challenge the Danish Medical Agency's decision to reject its generic application. AZ's own decision to challenge the Danish Medical Agency's decision to grant the complainant a market authorisation (for which the complainant had applied before the deregistration), was also a result of AZ's own request to deregister Losec in Denmark. In other words, by withdrawing its marketing authorisations, AZ created additional hurdles for generic producers to enter the market.
- (857) **Parallel-traded products:** AZ's tablet/capsule switch and capsule deregistration was successful in completely eliminating parallel trade in capsules in *Denmark* (recital (311)). In *Sweden* (recitals (314)-(319)) AZ was successful in the sense that the deregistration caused the Swedish Medicines Products Agency to first revoke the parallel trade licences for Losec capsules, a decision which was later reversed by the Swedish Administrative Court. AZ's action thus created a situation of legal uncertainty. Further, AZ does not deny that the sales of parallel imported Losec in Sweden sharply decreased in 1999 and 2000. Although the Commission is not in a position to exactly measure the effects that other events (such as the popularity of the MUPS formulation as claimed by AZ⁶³³) may have had on the decrease in sales of parallel traded capsules, it is clear that AZ's behaviour was both intended to produce and capable of producing such effects. AZ has not provided any concrete evidence that the decrease in capsule sales was exclusively attributable to the alleged success of the MUPS formulation. In any event, any popularity of the MUPS formulation was mainly the result of AZ's switch strategy. Following the withdrawal from the market of the capsules, AZ was only promoting the tablets and the supply of capsules – given the lack of legal clarity – could be perceived as uncertain.
- (858) In *Norway* parallel imports dropped dramatically; AZ's strategy was, however, unsuccessful in that the Norwegian Medicines Control Agency upheld the parallel trade licences for Losec capsules with reference to AZ's market authorisation for Losec MUPS (recital (321)). AZ's argument that parallel importers could have relied

⁶³³

See 7.254 AZ Reply.

on the authorisation for Losec MUPS (see recital (785), second indent, above) can, however, not be accepted in view of the uncertainty as to whether Losec MUPS could constitute the basis for parallel import licenses for capsules, since such a position on the part of the Norwegian authorities could have been interpreted as being in contradiction with Directive 65/65/EEC. Moreover, AZ's arguments are disingenuous as AZ has constantly maintained that such a position would be illegal (recitals (316)-(317)). It is clear that AZ's deregistration of the capsules constituted a further hurdle to parallel importers.

- (859) **National health systems and consumers:** In preventing or delaying potential competition from generic products and parallel-imported capsules, AZ's measures have also affected – actually or potentially – the interests of final consumers and the public interest (i.e. the national health care systems and the taxpayers and contributors funding them). The Nordic countries concerned have taken initiatives to promote the sale of generics and parallel imports to achieve savings for both national health systems and consumers (see recitals (113)-(142) and (318)). AZ's LPPS Strategy documents for Denmark and Norway give an indication of the considerable savings that would result from the entry of generic omeprazole in those markets (see recitals (299)-(300)).

4. CONCLUSION ON THE SECOND ABUSE

- (860) In view of the foregoing, AZ has abused its dominant position within the meaning of Article 82 of the Treaty (see recital (601)) in Denmark and Sweden, and within the meaning of Article 54 of the EEA Agreement, in Norway. The abuse consists of AZ's requests for deregistration of capsules in Denmark, Norway and Sweden combined with the tablet/capsule switch (i.e. the launch of Losec MUPS tablets and the withdrawal from the market of Losec capsules), as part of its LPPS Strategy with a view to preventing, or at least delaying, generic market entry and parallel trade.
- (861) The abuse is of a single and continuous nature, the duration of which begins on 19 March 1998 with AZ's request for deregistration of Losec capsules in Denmark. It goes on until at least the end of 2000 in Norway and Sweden and 1999 in Denmark (see recital (601)). The single and continuous nature of the abuse follows in part from the high degree of centralisation and coordination at the top level within AZ which characterises the abusive behaviour (see e.g. recitals (811)-(816)). Moreover, the abusive behaviour forms part of a common strategy of a pan-European nature (see e.g. recitals (267), (268), (271) f) and (278)-(280)). Finally, the elements of the abusive behaviour are interdependent in the sense that AZ's behaviour in one country has – at least potentially – an impact on other countries (see e.g. recitals (268) and (319)). The three countries where the second abuse has been established - Denmark, Norway and Sweden - apply cross-country comparisons when determining pharmaceutical prices. Thus, an impact on the competitive situation and prices in one of these countries could potentially spill over into the other countries (see recitals (120), (122), (125)-(126) and recital (268))⁶³⁴.

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See 7.276 AZ Reply on the Norwegian pricing system based on cross-country comparisons.

- (862) The finding that the infringement is of a single and continuous nature does not preclude that individual elements of the said behaviour constitute separate infringements⁶³⁵.

F. EFFECT ON TRADE BETWEEN MEMBER STATES

- (863) Article 82 of the Treaty prohibits an abuse of a dominant position “*in so far as it may affect trade between Member States*”. This criterion has three basic elements.
- (864) First, “*trade between Member States*” must be affected. The concept of trade covers all forms of economic activity including establishment⁶³⁶. According to settled case law the concept also encompasses the competitive structure covering e.g. abusive behaviour aimed at eliminating a competitor operating in several Member States⁶³⁷. Abuses that have an impact on the competitive structure in more than one Member State are by their very nature capable of affecting trade between Member States⁶³⁸.
- (865) Second, it is sufficient that the abuse “*may affect trade*”, i.e. that it is sufficiently probable that the practices are capable of having an effect⁶³⁹ on the patterns of trade based on an objective assessment (as well as subjective elements, if any)⁶⁴⁰. Trade must not necessarily be reduced⁶⁴¹. The pattern of trade must simply be capable of being affected by the abusive practices.
- (866) Third, the effect on trade of the abuse must be appreciable. This element requires that the effect on trade between Member States must not be insignificant and it is assessed primarily with reference to the position of the undertaking(s) on the market for the products concerned⁶⁴². The same considerations apply to Article 54 of the EEA Agreement (see recital (324)).
- (867) AZ argues that the Commission has failed to show an appreciable effect on trade between Member States which is actual or likely to occur. AZ refers to its Reply regarding the effects of the alleged abuses on competition which AZ considers to be non-existent or, in any event, not appreciable (see recitals (621) *et seq.* and (785)). Specifically, AZ contends that there was no appreciable effect on the competitive structure on the market. In connection with the second abuse, AZ claims that its behaviour had no or no appreciable effects on parallel trade in the relevant markets. Moreover, in AZ’s view, even if AZ’s conduct did eliminate the possibility of parallel trade, it cannot be inferred that it would thereby have had an appreciable effect on

⁶³⁵ See Case C-49/92 P *Commission v Anic Partecipazioni SpA* [1999] ECR I-4125, paragraph 81.

⁶³⁶ Case 172/80 *Gerhard Züchner v Bayerische Vereinsbank AG* [1981] ECR 2021, paragraph 18; Case C-309/99 *Wouters and others v Algemene Raad van de Nederlandse Orde van Advocaten* [2002] ECR I-1577, paragraph 95; Case C-475/99 *Firma Ambulanz Glöckner v Landkreis Südwestpfalz* [2001] ECR I-8089, paragraph 49; Joined Cases C-215/96 and 216/96 *Bagnasco and others v BNP and others* [1999] ECR I-135, paragraph 51.

⁶³⁷ Case 6/72 *Continental Can v Commission*; Joined Case T-24/93 *Companie maritime belge and others v Commission*, paragraph 203.

⁶³⁸ Joined Cases 6 and 7/73 *Commercial Solvents v Commission* [1974] ECR 223; Case 6/72 *Continental Can*.

⁶³⁹ Joined Cases C-241/91 P and C-242/91 P *RTE and ITP v Commission* [1995] ECR I-743, paragraph 69.

⁶⁴⁰ See e.g. Case T-228/97 *Irish Sugar v Commission*, paragraph 170.

⁶⁴¹ See e.g. Case T-141/89 *Tréfileurope v Commission* [1995] ECR II-791.

⁶⁴² Case 5/69 *Völk v Vervaecke* [1969] ECR 295.

trade within the meaning of Article 82 of the Treaty. According to AZ it is much more likely that there would have been only a very small demand for parallel traded Losec capsules.

- (868) AZ's arguments regarding the lack of appreciable effects on trade cannot be accepted. The concept of "trade" within the meaning of Article 82 of the Treaty (and Article 54 of the EEA Agreement) also encompasses conduct which affects the competitive structure, actually or potentially. Moreover, abuses that have an impact on the competitive structure in more than one Member State are, by their very nature, capable of affecting trade between Member States.
- (869) As regards the first abuse, it should be noted that AZ's abuse is exclusionary in nature in that it aimed to exclude (or at least delay) generic competition in the markets concerned. AZ's behaviour resulted in SPCs in three 1988 countries (Finland, Germany and Norway) as well as extended SPC protection in the Benelux countries and Austria (see recitals (760)-(762)). This, by itself, is capable of having at least a potential effect on the competitive structure and thereby on trade between at least more than one EEA Contracting Parties. It should also be noted that AZ's Norwegian SPC was only revoked after the expiry of the substance patent. Although AZ's German SPC was revoked before the expiry of the substance patent, AZ was still able to bring patent infringement proceedings against generic firms even after the expiry of the substance patent (see recital (231)). As a result, by preventing – actually or potentially – market entry for competitors operating in several EEA Contracting Parties (such as the complainant in this case and other generic producers of omeprazole based products such as ratiopharm), the economic activities in which such undertakings are engaging in several EEA Contracting Parties are affected. Considering that generic medicines are often manufactured in other EEA Contracting Parties patterns of trade were at the very least potentially disrupted.
- (870) As regards the second abuse, through its tablet/capsule switch and the capsule deregistration in Denmark, Norway and Sweden, AZ intended to delay market entry of generic omeprazole. For the reasons set out in the previous recital, this necessarily had at least a potential effect on trade between EEA Contracting Parties. As the infringement did produce effects on the market (see recitals (848)-(859)), it must of necessarily have had an effect on trade between EEA Contracting Parties.
- (871) Moreover, an explicit aim of the tablet/capsule switch and capsule deregistration as well as the overall strategies of which that operation formed an important and integral part (in particular the MUPS Strategy and the national LPPS strategies), was to prevent parallel importation of Losec capsules into the Nordic countries concerned (see recitals (796)-(797)). In part, AZ's strategy succeeded (see recital (857)).

G. LIABILITY FOR THE INFRINGEMENTS AND THE ADDRESSEES OF THIS DECISION

- (872) In order to identify the addressees of this decision, it is necessary to determine the legal entity or entities which are liable for the infringement.

1. THE CASE LAW REGARDING THE DETERMINATION OF LIABILITY

- (873) In principle it is for the legal person managing an undertaking when that undertaking commits the infringement to answer for that infringement, even if, when the decision finding the infringement is adopted, another person has assumed responsibility for operating the undertaking⁶⁴³.
- (874) It is also settled case law that the anticompetitive conduct of an undertaking can be attributed to another undertaking where it has not decided independently upon its own conduct on the market, but carried out, in all material respects, the instructions given to it by that other undertaking having regard in particular to the economic links between them⁶⁴⁴. In such a scenario, both legal entities can be considered, as a single economic entity, liable for the infringement.
- (875) In the case of wholly owned undertakings, the Commission is entitled to assume that the infringement committed by the wholly owned subsidiary is attributable to the parent company, as the parent company is presumed to have exercised decisive influence over the wholly owned undertaking⁶⁴⁵. The presumption is all the more apparent when the parent company presents itself during the administrative procedure as being the Commission's sole interlocutor concerning the infringement in question⁶⁴⁶. A parent company can also be held accountable if it has been aware (or could have been unaware) of the behaviour in question and did not intervene. In such a case, it is for the parent company to adopt, in regard to its subsidiary, any measure necessary to prevent the continuation of the infringement of which it was not unaware⁶⁴⁷.

2. LIABILITY FOR THE INFRINGEMENTS PRIOR TO THE MERGER ON 6 APRIL 1999

- (876) In this case, the abusive practices relate mainly to the period prior to the merger between Astra AB and Zeneca Plc on 6 April 1999. Abundant documentary evidence proves that it is Astra AB, the Swedish parent company, which is responsible for planning and implementing the misleading representations as part of its SPC Strategy for omeprazole (the first abuse) as well as the selective tablet/capsule switch and deregistration action as part of its LPPS Strategy (the second abuse).
- (877) In its Reply, AZ does not dispute that Astra AB (currently AstraZeneca AB) is the correct addressee as regards the alleged SPC abuse (the first abuse).
- (878) Indeed, as regards the first stage of the first abuse, it is Astra AB's patent department that originally conceives the SPC Strategy for omeprazole (see e.g. the three

⁶⁴³ Case C-286/98 P *Stora Kopparbergs Bergslags AB v Commission* [2000] ECR I-9925, paragraph 37; Case C-279/98 P *Cascades SA* [2000] ECR I-9693, paragraph 78.

⁶⁴⁴ Case C-294/98 P *Metsä-Serla Oyj* [2000] ECR I-10065, paragraph 27; Case 107/82 *AEG v Commission* [1983] ECR 3151, para 49; Case 48/69 *Imperial Chemical Industries* [1972] ECR 619, paragraphs 132-133.

⁶⁴⁵ Case T-305/94 *PVC*, paragraphs 961 and 984; Case 107/82 *AEG v Commission*, paragraph 50. Recent case law extends this presumption to a shareholding below 100%, but above 99%. See Case T-203/01 *Michelin v Commission*, paragraph 290.

⁶⁴⁶ Case C-286/98 P *Stora Kopparbergs Bergslags AB*, paragraph 29.

⁶⁴⁷ Case T-308/94 *Cascades v Commission* [1998] ECR II-925, paragraph 158; Case T-347/94 *Mayr-Melnhof v Commission* [1998] ECR II-1751, paragraphs 397-398; Case T-354/94 *Stora v Commission* [1998] ECR II-2122, paragraph 83.

memoranda of 16 March 1993 from Astra AB's patent department) (recitals (164)-(166)). The involvement in that preparatory work by the Swedish research and development company Astra Hässle AB (wholly owned by Astra AB) also takes place under the direction of Astra AB's patent department (see memoranda of 29-30 March and 7 April 1993 at recitals (167)-(174)). Indeed, it is Astra AB's patent department that signs all instructions sent to the patent agents (recitals (180)-(184)). The reason the applications are made in the name of the research and development company AB Hässle is purely formal, as AB Hässle is the proprietor of the relevant omeprazole patents. Moreover, as examples of the close links between Astra AB and Astra Hässle AB and AB Hässle, it may be noted that the managing director of these latter two companies was also a member of Astra's senior management and that both Astra AB's CEO and head of R & D were also board members of Astra Hässle AB and AB Hässle respectively since 1991. The central role of Astra AB's patent department in masterminding the SPC Strategy for omeprazole is confirmed by AZ in subsequent court proceedings in Norway and Finland (see recitals (235) and (244)).

- (879) The patent agents who file the omeprazole applications simply carry out AZ's instructions (with the partial exception of Luxembourg: see recitals (207)-(208)); with regard to Belgium see recitals (688), (750)-(757)); for example, before the German Federal Patent Court on 9 September 1996, AZ submits that the head of Astra AB's patent department back in 1993 "*did not know otherwise when he filed his applications also in Germany*" (underlining added) (see recital (223)).
- (880) Moreover, it is the head of Astra AB's patent department that requests the information on the dates of the actual launch of Losec capsules in various jurisdictions, including Luxembourg (recitals (210)-(211)), and it is he who outlines the SPC Strategy for omeprazole at a meeting in Copenhagen in November 1994 (recitals (219)-(220)). In November 1999 – following the merger - the head of Astra AB's patent department explains to the new AstraZeneca Plc Group CEO that it was he who, back in 1993, proposed to Astra AB's head of R & D and to its head of legal affairs the SPC Strategy for omeprazole (see recital (230)). Moreover, it was Astra AB's patent department that centralised the SPC applications for the seven other products for which AZ filed SPC applications pursuant to Article 19 of the SPC Regulation. AZ's patent department was thus aware that it was basing its SPC applications on different types of dates for different products (see recital (246) *et seq.*).
- (881) Throughout the second stage of the first abuse, Astra AB's patent department continues to play the centralising role (see Astra AB's letter to the Dutch patent agent in October 1996 at recital (200) and the letters from the head of Astra AB's patent department to the Belgian, Dutch and Finnish patent offices on 8 May 1998 at recital (227) as well as the document dated 9 September 1996 from Astra AB's litigation department dated one month before AZ's first submission in the German SPC case at recital (224)). The centralised nature of the SPC Strategy for omeprazole is further demonstrated by identical submissions to courts in Norway and Finland relating to the validity of AZ's SPC for omeprazole in those countries (see recitals (235) and (244)).
- (882) As regards the second abuse, AZ, however, denies that Astra AB (currently AstraZeneca AB) is the correct addressee on the grounds that there was no centralisation and that each local marketing company decided whether and when to launch MUPS tables and whether to withdraw Losec capsules and the related authorisation. AZ also claims that the test for imputing liability for the conduct of a

subsidiary to a parent company is whether, as a matter of fact, the undertakings concerned act as one economic unit.

- (883) A similar argument has already been rejected by the Commission in the analysis of the second abuse (see notably recitals (811)-(816). Indeed, it appears from the evidence that the second abuse was highly centralised by Astra AB at the level of the CEO and senior management, aided by Astra AB's wholly owned subsidiaries (mainly Astra Hässle AB).
- (884) Considering that Astra AB, following the merger between Astra AB and Zeneca Plc on 6 April 1999, has not been simply and purely absorbed by the new merged entity but continues to exist in Swedish law and in fact exists and operates in Södertälje under the name of AstraZeneca AB, the liability for the infringements relating to the period prior to the said merger must be imputed to AstraZeneca AB only⁶⁴⁸.

3. LIABILITY FOR THE INFRINGEMENTS FOLLOWING THE MERGER ON 6 APRIL 1999

- (885) For the reasons explained and considering the single and continuous nature of the abuses, AstraZeneca AB should also be held liable for the infringements for the period after 6 April 1999.
- (886) AZ argues that no liability for the alleged infringements in respect of the period following the merger on 6 April 1999 can be imputed to AstraZeneca Plc. In AZ's opinion, the Commission has advanced no evidence that the "SPC Strategy" as alleged by the Commission was disclosed to the AstraZeneca Group CEO. According to AZ the Commission in particular misconstrues the purpose of the action team set up to address the public policy elements of the German SPC litigation. There is, in AZ's view, nothing in the handwritten notes from the in-house counsel of AstraZeneca Plc which shows that he was put on notice of the alleged SPC abuse. Similarly, there is, according to AZ, no evidence to support the Commission's allegations that AstraZeneca Plc was made aware of the circumstances said to constitute the alleged second abuse.
- (887) There is, according to AZ, virtually no allegation of infringements or potentially abusive conduct taking place after 6 April 1999 on the part of Astra AB which could be subject to the instructions or control of AstraZeneca Plc and therefore attributed to it. The evidence cited by the Commission (see recitals (230) and (291)) does not amount to instructions given by AstraZeneca Plc to Astra AB. In AZ's view, it is not possible to impute liability to AstraZeneca Plc based on what amounts to, at best, fragmentary briefings since those briefings do not convey sufficient information to put AstraZeneca Plc on notice that Astra AB has engaged in the conduct as alleged by the Commission and/or conduct that was illegitimate. In summary, AZ therefore considers that there is no basis on which liability can be attributed to AstraZeneca Plc for Astra AB's conduct prior to 6 April 1999, even where such conduct may have continuing effects after 6 April 1999.

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See e.g. Case C-279/98 P *Cascades v Commission*, paragraph 79.

- (888) AZ's arguments as regards the liability of AstraZeneca Plc for the parts of the infringement relating to the period after 6 April 1999 must be dismissed. It should be noted that, following the merger, AstraZeneca Plc has owned 99.7% and later 100% of the shares in Astra AB (AstraZeneca AB as from 3 January 2000). According to the caselaw cited above (see recital (873)), AstraZeneca Plc can be held accountable for the infringement in respect of the post-merger period.
- (889) Moreover, the evidence shows that AstraZeneca Plc had indeed been informed of certain key features of the infringements.
- (890) In this context, reference is made to documentary evidence proving that AstraZeneca Plc – in the months following the merger – was informed of the existence of Astra AB's SPC Strategy for omeprazole and the LPPS Strategy, by Astra AB representatives who have played a central role in conceiving and executing the two infringements established in this case. Indeed, the CEO of AstraZeneca Plc is at the latest informed about the existence of the SPC Strategy for omeprazole on 21 October 1999 by the head of Astra AB's patent department (part of AstraZeneca AB as of 3 January 2000) (recital (230)). As a result of that information, the CEO of AstraZeneca Plc orders that an action team be set up under the auspices of AstraZeneca Plc in London in relation to Astra AB's defence of its German SPC for omeprazole (*ibidem*).
- (891) AstraZeneca Plc's awareness of certain key elements of AZ's conduct and state of mind emerges from the handwritten notes taken by an inhouse counsel at AstraZeneca Plc's London headquarters. The notes show that the said inhouse counsel meets the head of Astra AB's patent department (part of AstraZeneca AB as of 3 January 2000) in early 2000 and that the SPC Strategy for omeprazole is discussed in depth at that meeting (*ibidem*). The notes includes *inter alia* elements which suggest that AZ initially did not volunteer the French technical authorisation date ("*UK picked up the French authorisation first ... weakness ... do get an SPC for UK but ½ shorter*"), that the SPCs for Belgium and the Netherlands rest on shaky ground ("*Blgm & NL SPC not counted from the French so may be ½ year too long & subsequently shortened*") and that the factual basis for the SPC Strategy was not clear despite positive statements by AZ on the nature of the Luxembourg List ("*Luxembourg system unclear : March 88 launch*") (*ibidem*).
- (892) As for the second abuse, it should be noted that a copy of AZ's longterm GI Franchise Plan dated 12 May 1999, incorporating the central elements of the LPPS Strategy to combat generic omeprazole, is copied to AstraZeneca Plc's CEO (recital (291)). That Plan clearly refers to the first of the three features of the abuse: i.e. the intention to block generic market entry (see recital (795)). The second feature of the abuse – the selectivity – emerges from an internal AZ email dated 20 January 2000 copied to the head of legal affairs at AstraZeneca Plc showing the selective nature of the deregistration of the Losec capsules in the Nordic countries (see footnote at the end of recital (305)). As regards the third feature of abuse (bridging the gap between omeprazole's patent/SPC expiry and the launch of esomeprazole), reference is made to a speech by the head of Astra AB's patent department before AstraZeneca Plc's senior management in October 1999 ("*aim is to slow down generic market penetration to give time for the new esomeprazole*") (see recital (273)).
- (893) Moreover, the fact that AstraZeneca Plc's executive team appointed in 1999 is made up of *inter alia* four members of Astra AB's senior management, including the CEO

and the head of R & D (see recital (230)) and that AZ has chosen to communicate with the Commission through Astra Zeneca UK, which has the same registered office in London as AstraZeneca Plc, supports the finding that AstraZeneca Plc can be held accountable for the infringement⁶⁴⁹.

- (894) All in all, AZ limits itself to contesting the probative value of the pieces of evidence relied upon by the Commission to hold AstraZeneca Plc accountable but it has not submitted any evidence to the effect that AstraZeneca AB carried on its business on pharmaceutical markets as an autonomous legal entity which determined its commercial policy largely on its own.
- (895) In view of the foregoing considerations both AstraZeneca Plc and AstraZeneca AB should be held jointly and severally liable for the infringements relating to the period following the merger on 6 April 1999.

H. REMEDIES

1. ARTICLE 15 (2) OF REGULATION NO 17 AND ARTICLE 23 (2) OF REGULATION (EC) NO 1/2003

- (896) Under Article 23 (2) of Regulation (EC) No 1/2003, the Commission may by decision impose fines on undertakings, where, either intentionally or negligently, they infringe Article 82 of the Treaty and/or Article 54 of the EEA Agreement. Regulation (EC) No 1/2003 was incorporated into the EEA Agreement by EEA Joint Committee Decision No 130/04.
- (897) Under Article 15 (2) of Regulation No 17, which was applicable at the time of the infringement, the fine for each undertaking participating in the infringement cannot exceed 10% of its total turnover in the preceding business year. The same limitation results from Article 23 (2) of Regulation (EC) No 1/2003.
- (898) Pursuant to both Article 15 (2) of Regulation No 17 and Article 23 (3) of Regulation (EC) No 1/2003, the Commission must, in fixing the amount of the fine, have regard to all relevant circumstances and particularly the gravity and duration of the infringement, which are the two criteria explicitly referred to in those Regulations. In doing so, the Commission will set the fines at a level sufficient to ensure deterrence.

2. THE BASIC AMOUNT OF THE FINE

- (899) The basic amount of the fine is determined according to the gravity and duration of the infringement. Due to the fact that both abuses have the same objective of preventing or delaying market entry of generic omeprazole based products, the Commission considers it appropriate to impose a single basic amount for the fine.

(a) Gravity of the infringements

⁶⁴⁹ See e.g. [6385].

- (900) In assessing the gravity of each infringement, consideration must be given to the nature of the infringement, its actual impact on the market (where it can be measured) and the size of the relevant geographic market.

Nature of the infringements

- (901) AZ argues that there is no basis for the imposition of a fine or any significant fine on AstraZeneca AB or AstraZeneca Plc for the following reasons. First, the Commission has failed to show that AZ committed the alleged abuses intentionally or negligently. Second, AZ did not regard itself as dominant in the market comprising PPIs and H2 blockers. Third, both abuses had limited or no appreciable effects. Fourth, both abuses are novel.
- (902) In any event, the limited effects of the alleged SPC abuse ceased once the SPC expired (which they have all done except for the SPC for Austria). The MUPS abuse, if committed at all, was of short duration and even the limited effects of the alleged abuse ceased once the Court of Justice clarified the scope of the rights of generic entrants and parallel traders to obtain market authorisations under the procedure for generic products and parallel trade licenses. Furthermore, the alleged MUPS abuse was committed, if at all, by the local marketing companies, which in AZ's view reduces the gravity of the infringement and suggests that any fine should be calculated primarily by reference to the revenues of the Danish, Norwegian and Sweden marketing companies.
- (903) Finally, AZ invokes various mitigating factors to be taken into account in respect of the alleged abuses. First, AZ has cooperated fully with the Commission in its investigation. Second, with regard to the SPC abuse, AZ has relied on legal advice in support of its interpretation of the SPC Regulation. Third, with regard to the MUPS abuse, AZ was aware of the Commission's view that it was open to any company holding a marketing authorisation to withdraw it at will. It was therefore misled into believing that its conduct was inherently lawful. Furthermore, senior officials in the regulatory authority in the United Kingdom suggested to AZ that it would be legitimate to withdraw the capsule authorisation without suggesting that there would be any risk of an infringement of Article 82.
- (904) As to AZ's general argument that the infringements of Article 82 in this case are novel under Community competition law and that, as a consequence, it cannot be assumed that AZ knew that its SPC applications and/or its withdrawal of market authorisations infringed Article 82, it should be noted that the aim of AZ's behaviour was to keep its competitors out of the market, and, for the second abuse, also to artificially partition markets and drive its competitors out of the market. Behaviour which was intended to prevent competitors from entering the market, or at least delay such entry, should not *a priori* escape the possibility of significant fines⁶⁵⁰. In any case, a high degree of awareness of antitrust laws is to be expected from major undertakings⁶⁵¹.

⁶⁵⁰ Joined Cases T-24/93, T-25/93, T-26/93 and T-28/93 *Compagnie maritime belge and others v Commission*, paragraph 248; Opinion of Advocate-General Fennelly in Joined Cases C-395/96 P and C-396/96 P *Compagnie maritime belge and others v Commission*, paragraph 187; Case T-228/97 *Irish Sugar v Commission*, paragraph 292. See also Case 322/81 *Michelin v Commission*, paragraph 107.

⁶⁵¹ Case 27/76 *United Brands v Commission*, paragraph 299, and, along the very same lines, Case 85/76 *Hoffman-La Roche v Commission*, paragraphs 128-134.

- (905) The abuse of a dominant position is an objective concept (see recital (326)). The fact that AZ did not regard itself as dominant at the relevant time on the wider market consisting of PPIs and H2 blockers is therefore not relevant. For an infringement to be committed “intentionally” within the meaning of Article 15(2) of Regulation 17, it is not necessary for the undertaking to have been aware that it was infringing a prohibition laid down by Article 82; it is sufficient that it was aware that the object of the offending conduct was to restrict competition. Taking into account *inter alia* the fact that AZ was able to extract much higher prices for Losec than for H2 blockers and that it was actually able to exclude the main source of competition, i.e. generic firms, AZ had a reasonable basis to consider that it was itself dominant. Furthermore, the Commission already indicated in its early decisional practice in the area of mergers that appropriate pharmaceutical markets could be defined on the basis of the fourth level of the ATC system⁶⁵².
- (906) The first abuse aimed at preventing market entry of all generic firms marketing generic omeprazole based products, to the clear detriment of the public finances and consumers on the markets concerned. AZ was conscious that the behaviour in question would inflict damage on the public finances and consumers (see e.g. AZ’s predictions at recitals (298)-(300) in respect of Denmark and Norway). The infringement was centralised at the level of AZ’s senior management.
- (907) Similarly, the second abuse involved the systematic misuse of Community pharmaceutical law to exclude competition from generic and parallel traded products. AZ’s aim was to lengthen *de facto* the economic protection which the legislator has considered reasonable to create the necessary incentives to innovate in the pharmaceutical industry. That abuse also jeopardises the proper functioning of the internal market, as its aim is to artificially partition markets. The second infringement was also centralised and coordinated at the highest levels within AZ (see e.g. recital (278)). Moreover, AZ was aware of the need for an objective justification for its behaviour and that its conduct potentially infringed the competition rules of the Treaty (see recital (281)).
- (908) It must be recalled that the artificial partitioning of the market has been considered as an abuse in previous cases⁶⁵³. However, even if the use of public procedures and regulation with an exclusionary intent has been considered abusive (see case law cited at recitals (328), (742)-(743) and (820)), the abuses in this case present some specific and novel features regarding the means used, and cannot be said to have been clear-cut ones.

Actual impact on the market

⁶⁵² Case M.72 Sanofi/Sterling Drug (Decision of 10 June 1991), point 14; Case M.323 Procordia/Erbamont (Decision of 29 April 1993), point 9; Case M.457 La Roche/Syntex (Decision of 20 June 1994), point 6; M.500 AHP/American Cyanamid (Decision of 19 September 1993), point 10.

⁶⁵³ See e.g. Case T-83/91 *Tetra Pak v Commission*, paragraphs 92-95, and Commission Decision 1988/138/EEC in case IV/30.787 and 31.488 - *Eurofix-Bauco v Hilti*, paragraph 76 (OJ L 65, 11.3.1988, p. 19). Artificial partitioning by product differentiation was condemned under Article 81 in Commission Decision 93/554/EEC in case IV/31.550 - *Zera/Montedison* and IV/31.898 - *Hinkens/Stähler*, paragraphs 123-124, 127, 129 (OJ L 272, 4.11.1993, p. 28).

- (909) As to AZ's argument that the first and second abuses had no appreciable effects, reference is made to the Commission's earlier responses to that argument (see recitals (758)-(772) and (848)-(859)).
- (910) As regards AZ's contention that the allegedly limited effects of the abuse ceased once the Court of Justice clarified the scope of the rights of generic entrants and parallel traders to obtain respectively market authorisations for generic products and parallel trade licences, it should be borne in mind that the abuse in the three countries concerned started in 1998, while the judgments by the Court of Justice clarifying the rules regarding market access for generic firms and parallel trade were issued around five years after the start of the abuse (recitals (310) and (838)).
- (911) Admittedly, the actual impact on the market – which undoubtedly took place – cannot be precisely measured considering the number of elements which may have been liable to influence this impact.

Extent of the relevant geographic market

- (912) The assessment of the gravity of the SPC abuse must also take account of its wide geographic scope, encompassing six EEA Contracting Parties. The geographic scope of the second abuse is also significant, encompassing three EEA Contracting Parties.

Conclusion

- (913) In view of the foregoing, the Commission considers that AZ has committed two serious infringements. In the view of the Commission, the nature of the infringements and their geographic scope are such that the infringements must be qualified as serious, irrespective of whether or not the impact of the infringement on the market can be precisely measured. In any case, it is clear that the anticompetitive strategy was implemented and did have an impact on the market, even if that impact cannot be precisely measured.
- (914) It is also clear from settled case law that factors relating to the object of a course of conduct may be more significant for the purposes of setting the amount of the fine than those relating to its effects⁶⁵⁴. Indeed, for the fine to have a deterrent effect, account must be taken of the profits AZ expected to draw from the abuse, even if the implementation of the strategies may not have been as successful as initially envisaged. In this regard, it is important to bear in mind that Losec was the best-selling prescription pharmaceutical product in the world for several years (see recital (9)), that sales of Losec in the countries where the abuse took place were considerable (see tables 24-30 in the Annex and the footnote at recital (297)) and that, if the strategy had been fully successful, AZ would have been able to benefit from much higher prices than those that would have prevailed in a situation where generic firms could have entered the markets concerned. However, the Commission also takes into account subsequent changes in the regulatory frameworks in question.

⁶⁵⁴ Case T-203/01 *Michelin v Commission*, paragraph 259; Case T-141/94 *Thyssen Stahl v Commission* [1999] ECR II-347, paragraph 636 and Joined Cases T-45/98 and T-45/98 *Krupp Thyssen Stainless and Acciai speciali v Commission* [2001] ECR II-3757, paragraph 199.

- (915) Consequently, taking into account that a single amount is fixed for the two abuses, the basic amount of the fine should be EUR 40,000,000 for AstraZeneca AB and AstraZeneca Plc.

(b) Duration of the infringement

- (916) The long duration of the single and continuous SPC abuse also needs to be taken into account in determining the fine. The abuse started on 7 June 1993 in Belgium, Denmark, Germany, the Netherlands and the United Kingdom and on 21 December 1994 in Norway. It lasted until the end of 2000 in Belgium, the Netherlands and Norway, until the end of 1997 in Germany, until 30 November 1994 in Denmark and until 16 June 1994 in the United Kingdom.
- (917) The duration of the single and continuous second abuse was also significant. The abuse started on 19 March 1998 in Denmark, on 20 August 1998 in Sweden and on 1 November 1998 in Norway. It lasted until the end of 2000 in Norway and Sweden and until the end of 1999 in Denmark.
- (918) A single starting amount is imposed for both abuses. However, over a substantial period only the first abuse was implemented and under the relevant legislation it could deploy its main effects only at a much later date, i.e. when the patents expired. Therefore, although some effects could be felt even during that first period, the Commission considers that due to the specificities of the case, it is appropriate to apply different percentages for the first and the second period. The starting amount of the fines should consequently be increased by 10% for each full year of the infringements. They should be further increased by 5% for any remaining period of six months or more but less than one year. The increase will be only 5% for years for the period before 1998 and 2.5% for any remaining period of six months or more but less than one year.
- (919) Moreover, account must be taken of the fact that AstraZeneca Plc is only accountable for the infringement since 6 April 1999. Therefore, the increase for duration as regards the fine to be paid by AstraZeneca Plc should therefore be limited to the period for which AstraZeneca Plc can be held accountable.
- (920) This leads to a percentage increase of 50% for AstraZeneca AB and of 15% for AstraZeneca Plc.

3. AGGRAVATING AND MITIGATING CIRCUMSTANCES

- (921) As to AZ's argument that it relied on legal advice in support of its interpretation of the SPC Regulation and that this constitutes a mitigating circumstance, it should be noted that this Decision does not take issue with AZ's interpretation of the SPC Regulation (see recital (666)). Moreover, AZ has – despite its assertion to the contrary – provided no evidence in support of the alleged nature of the Luxembourg List as an instrument enabling effective marketing in Luxembourg. In spite of considerable unequivocal evidence suggesting that the List did not have the function alleged by AZ, AZ has tenaciously defended the validity of the 21 March 1988 date (see e.g. recitals (703)-(708), (726) and (729)).

(922) In addition, as the assessment in connection with gravity already takes account of the novel features of the infringements, the Commission considers that there is no reason to treat these features as a mitigating circumstance.

4. APPLICATION OF THE LENIENCY NOTICE

(923) AZ does not claim that its cooperation in the investigation went any further than that which it was required to provide under Article 11 of Regulation No 17. In fact, AZ even refused for almost one whole year to fully reply to a request sent by the Commission pursuant to Article 11 of Regulation No 17 (see recital (12)). In such circumstances, there is no reason why the Commission should take account of AZ's alleged cooperation either under the Commission notice on immunity from fines and reduction of fines in cartel cases⁶⁵⁵ or, even if it were possible in this case, as a mitigating factor for cooperation outside that Notice⁶⁵⁶.

5. AMOUNT OF THE FINES

(924) For the above reasons, the amount of the fine should be fixed at EUR 46,000,000 in respect of AstraZeneca AB and AstraZeneca Plc, jointly and severally liable, and EUR 14,000,000 in respect of AstraZeneca AB.

HAS ADOPTED THIS DECISION:

Article 1

1. AstraZeneca AB and AstraZeneca Plc have infringed Article 82 of the Treaty and Article 54 of the EEA Agreement by the pattern of misleading representations before patent offices in Belgium, Denmark, Germany, the Netherlands, Norway and the United Kingdom and before national courts in Germany and Norway.

2. AstraZeneca AB and AstraZeneca Plc have infringed Article 82 of the Treaty and Article 54 of the EEA Agreement by their requests for the surrender of the market authorisations for Losec capsules in Denmark, Norway and Sweden combined with their withdrawal from the market of Losec capsules and launch of Losec MUPS tablets in those three countries.

Article 2

For the infringements referred to in Article 1, the following fines are imposed:

(a) a fine of EUR 46,000,000 on AstraZeneca AB and AstraZeneca Plc, jointly and severally liable,

(b) a fine of EUR 14,000,000 on AstraZeneca AB.

⁶⁵⁵ OJ C 45, 19.2.2002, p. 3.

⁶⁵⁶ See for instance Case T-12/89 *Solvay v Commission* [1999] ECR II-907, paragraphs 341 and 342.

Within three months of the notification of this decision, the fine shall be paid in euro into Bank Account N° 001-3953713-69 of the European Commission with FORTIS BANK SA, Rue Montagne du Parc, 3 at B-1000 Brussels (IBAN Code: BE71 0013 9537 1369; SWIFT Code: GEBABEBB).

After expiry of that period, interest shall automatically be payable at the interest rate applied by the European Central Bank to its main refinancing operations on the first day of the month in which this decision was adopted, plus 3.5 percentage points, namely 5.55% .

Article 3

This decision is addressed to AstraZeneca AB (S-151 85 Södertälje, Sweden) and AstraZeneca Plc (15 Stanhope Gate, London W1K 1LN, the United Kingdom).

This decision shall be enforceable pursuant to Article 256 of the Treaty.

Done at Brussels, 15 June 2005

For the Commission

Neelie KROES

Member of the Commission

ANNEX

PPI and H2 blocker prices (cost of 28 day treatment)

Table 1: Belgium: Cost of 28 day treatment (USD); Price difference PPI/H2⁶⁵⁷

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Average PPI Treatment Cost	67.65	71.61	66.11	69.11	78.11	68.39	55.05	47.34	44.66	38.99
Average H2 Treatment Cost	46.67	49.50	46.29	47.99	54.46	51.32	37.82	36.21	33.56	23.80
Price difference PPI/H2	45%	45%	43%	44%	43%	33%	46%	31%	33%	64%

Table 2: Denmark: Cost of 28 day treatment (USD); Price difference PPI/H2⁶⁵⁸

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Average PPI Treatment Cost	73.49	71.42	61.99	62.06	54.79	47.69	43.18	43.68	41.37	
Average H2 Treatment Cost	35.16	37.73	35.08	34.34	28.42	18.13	14.84	14.13	13.29	
Price difference PPI/H2	109%	89%	77%	81%	93%	163%	191%	209%	211%	

Table 3: Germany: Cost of 28 day treatment (USD); Price difference PPI/H2⁶⁵⁹

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Average PPI Treatment Cost	62.06	65.91	61.38	58.93	57.07	54.21	47.30	46.66	40.69	29.85
Average H2 Treatment Cost	60.31	61.39	53.29	52.15	51.00	32.45	19.92	15.19	12.76	10.01
Price difference PPI/H2	3%	7%	15%	13%	12%	67%	137%	207%	219%	198%

Table 4: The Netherlands: Cost of 28 day treatment (USD); Price difference PPI/H2⁶⁶⁰

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Average PPI Treatment Cost	75.84	80.12	70.03	61.97	67.88	58.15	46.60	45.91	43.09	38.29
Average H2 Treatment Cost	49.41	52.32	49.80	50.26	55.87	39.86	30.23	25.24	24.04	19.52
Price difference PPI/H2	53%	53%	40%	23%	21%	46%	54%	82%	79%	96%

Table 5: Norway: Cost of 28 day treatment (USD); Price difference PPI/H2⁶⁶¹

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Average PPI Treatment Cost		89.93	70.30	70.79	69.88	60.53	54.37	49.74	49.44	39.96
Average H2 Treatment Cost		46.71	36.67	35.66	41.69	40.40	36.63	25.79	20.95	17.81
Price difference PPI/H2		93%	92%	99%	68%	50%	48%	93%	136%	124%

Table 6: Sweden: Cost of 28 day treatment (USD); Price difference PPI/H2⁶⁶²

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Average PPI Treatment Cost	83.68	85.74	62.30	62.57	66.23	66.60	55.29	50.05	47.35	40.46
Average H2 Treatment Cost	43.20	44.78	33.07	33.22	36.32	37.63	32.06	21.87	19.93	17.53
Price difference PPI/H2	94%	91%	88%	88%	82%	77%	72%	129%	138%	131%

Table 7: The United Kingdom: Cost of 28 day treatment (USD); Price difference PPI/H2⁶⁶³

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Average PPI Treatment Cost	56.13	55.70	47.72	48.12	48.75	48.09	49.49	44.03	41.63	35.80
Average H2 Treatment Cost	37.72	37.48	30.95	30.19	31.26	30.88	30.70	28.48	25.30	19.48
Price difference PPI/H2	49%	49%	54%	59%	56%	56%	61%	55%	65%	84%

657 [6297– 6299].

658 [6300– 6304].

659 [6309– 6312].

660 [6313– 6315].

661 [10117-10121].

662 [6316-6318].

663 [6319-6321].

Price range of PPIs (per 28 day treatment course)

Table 8: Price range PPIs (USD) (per treatment course)⁶⁶⁴

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Belgium				69-73	78	68-73	47-57	47-48	45	36-39
Denmark				59-62	54-59	51	40-45	39-45	34-43	
Germany (including generic PPIs in 1999 and 2000)			57-59	53-59	51-57	48-54	46-47	43-49	29-47	22-39
Germany (non-generic PPIs)			39-47	34-39
The Netherlands			58-73	56-65	60-72	52-74	42-47	43-47	41-45	32-40
Norway				63-71	64-71	57-61	51-56	47-53	44-51	34-42
Sweden			53-62	56-63	60-84	62-67	54-58	43-54	33-48	28-44
The United Kingdom				46-48	46-49	43-48	43-51	35-44	34-42	31-38

Sales of PPIs and H2 blockers (USD 000s)

Table 9: Sales (USD 000s) in Belgium⁶⁶⁵

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs	13164	17732	25575	41790	57120	65941	65617	70366	81868	83769
H2s	47996	55848	42230	35513	39550	36820	33135	28462	22971	15752

Table 10: Sales (USD 000s) in Denmark⁶⁶⁶

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs	5524	8927	11957	17139	22073	25993	26826	34053	35991	37792
H2s	17838	20639	18916	17910	14191	8915	7238	6816	6186	

Table 11: Sales (USD 000s) in Germany⁶⁶⁷

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs	73055	112223	103394	141054	197787	246875	262428	346058	388533	388558
H2s	344195	370750	274877	294065	270393	184045	127212	114280	104316	88819

Table 12: Sales (USD 000s) in the Netherlands⁶⁶⁸

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs	27031	44317	54426	71312	107489	121586	133386	165659	188851	204615
H2s	79882	98566	101413	102608	103220	83763	65551	54415	42615	30539

Table 13: Sales (USD 000s) in Norway⁶⁶⁹

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs		7592	9083	13212	17737	19706	24879	29719	36888	34992
H2s		16735	13803	13796	15492	10883	10503	8981	8263	7587

Table 14: Sales (USD 000s) in Sweden⁶⁷⁰

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs	22648	36529	45601	69756	94684	129841	95650	117213	129733	121384
H2s	32032	35775	26439	26206	29429	35825	26350	23496	21456	17458

Table 15: Sales (USD 000s) in the United Kingdom⁶⁷¹

664 [6294-6321, 10103-10104, 10117-10118].

665 [6259-6263].

666 [6264-6268].

667 [6274-6278].

668 [6279-6283].

669 [10122-10227].

670 [6284-6288].

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs	43589	107159	163882	258377	351610	433591	494941	531782	568837	545536
H2s	368748	392233	331514	336588	337703	338971	324746	283145	240015	173592

Comparison of PPI and H2 blocker sales in value

Table 16: Comparison (%) of PPI sales and H2s sales in value⁶⁷²

	1991		1992		1993		1994		1995		1996		1997		1998		1999		2000	
	P P I	H 2	P P I	H 2	P P I	H 2	P P I	H 2	P P I	H 2	P P I	H 2	P P I	H 2	P P I	H 2	P P I	H 2	P P I	H 2
Germany	18	82	23	77	27	73	32	68	42	58	57	43	67	33	75	25	79	21	81	19
Denmark	24	76	30	70	39	61	49	51	61	39	74	26	79	21	83	17	85	15		
Sweden	41	59	51	49	63	37	73	27	76	24	78	22	78	22	83	17	86	14	87	13
Netherlands	25	75	31	69	35	65	41	59	51	49	59	41	67	33	75	25	82	18	87	13
Belgium	22	78	24	76	38	62	54	46	59	41	64	36	66	34	71	29	78	22	84	16
United Kingdom	11	89	21	79	33	67	43	57	51	49	56	44	60	40	65	35	70	30	76	24
Norway			31	69	40	60	49	51	53	47	64	36	70	30	77	23	82	18	82	18

Number of PPI and H2 blocker treatment (000s)

Table 17: Treatments (000s) in Belgium⁶⁷³

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs	131	167	257	399	498	661	780	653	731	889
H2s	828	905	703	546	511	490	584	508	434	410

Table 18: Treatments (000s) in Denmark⁶⁷⁴

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs	68	117	174	240	221	342	393	583	649	
H2s	348	387	392	380	363	364	363	368	356	

Table 19: Treatments (000s) in Germany⁶⁷⁵

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs	1049	1584	1613	2008	2458	2944	3361	4193	4283	5072
H2s	3101	3344	2752	3116	3016	2991	2901	3292	3369	3242

Table 20: Treatments (000s) in the Netherlands⁶⁷⁶

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs	314	357	417	550	681	830	1296	1611	2172	3450
H2s	1235	1163	1236	1115	861	1138	1353	647	551	432

Table 21: Treatments (000s) in Norway⁶⁷⁷

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs		81	120	167	221	284	396	500	645	725
H2s		313	329	330	311	216	214	218	213	206

Table 22: Treatments (000s) in Sweden⁶⁷⁸

671 [6289–6293].

672 [272-277, 6254–6293, 10122-10127].

673 [6297–6299].

674 [6300–6304].

675 [6309-6312].

676 [6313-6315].

677 [10171-10121].

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs	262	412	714	1094	1407	1904	1090	1012	1763	2093
H2s	694	748	744	705	633	646	476	488	439	402

Table 23: Treatments (000s) in the United Kingdom⁶⁷⁹

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
PPIs	777	1924	3429	5217	6509	7734	8104	9210	10177	10860
H2s	8978	9650	9922	10320	9939	10098	9571	8823	8434	7540

Market shares and sales value on the PPI market

Table 24: Belgium: Markets shares and sales value (USD 000s)

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Total PPI market	13164	17732	25575	41790	57120	65941	65617	70366	81868	83769
Omeprazole	100% 13164	100% 17732	100% 25575	99.83% 41721	94.80% 54148	93.42% 61604	89.64% 58818	80.66% 56760	70.63% 57822	68.36% 57262
AstraZeneca	67.18% 8843	67.30% 11933	66.46% 16997	65.88% 27530	63.00% 35983	61.95% 40849	59.04% 38739	54.17% 38114	47.18% 38629	45.80% 38369
Bio-Therabel (licensee of AstraZeneca)	32.82% 4321	32.70% 5799	33.54% 8578	33.96% 14191	31.87% 18205	31.48% 20755	30.60% 20079	26.50% 18646	23.44% 19193	22.55% 18894
Lansoprazole				0.17% 70	5.13% 2933	6.58% 4336	6.60% 4332	14.57% 10254	25.52% 20895	26.74% 22401
Aventis (licensee of Takeda)				0.17% 70	5.13% 2933	6.58% 4336	6.60% 4332	14.57% 10254	25.52% 20895	26.74% 22401
Pantoprazole							3.76% 2468	4.76% 3352	3.85% 3151	4.90% 4105
Byk Gulden							1.66% 1090	2.19% 1538	2.03% 1663	2.47% 2067
Exel Pharma (licensee of Byk Gulden)							2.10% 1378	2.58% 1814	1.82% 1488	2.43% 2038

Table 25: Denmark: Markets shares and sales value (USD 000s)

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Total PPI market	5224	8927	11957	17139	22073	25993	26826	34053	35991	37792
Omeprazole	100% 5224	100% 8927	100% 11957	97.47% 16705	85.16% 18797	79.75% 20730	75.44% 20237	80.19% 27308	74.67% 26874	
AstraZeneca	100% 5224	100% 8927	100% 11957	97.47% 16705	57.14% 12613	63.44% 16491	61.24% 16429	79.67% 27129	74.00% 26632	27295
Orifarm (Losec) (parallel importer)					4.91% 1083	8.08% 2100	9.82% 2633	0.52% 177	0.59% 211	
Paranova (Losec) (parallel importer)					22.83% 5039	8.01% 2081	4.16% 1116	0.01% 2		
Lansoprazole				2.53% 434	14.73% 3252	18.12% 4710	19.71% 5288	16.79% 5717	18.50% 6658	
Wyeth (licensee of Takeda)				2.53% 434	14.73% 3252	18.12% 4710	15.70% 4212	10.41% 3545	12.68% 4565	
Orifarm (Lanzo) (parallel importer)							1.43% 384	5.23% 1780	5.32% 1914	
Pantoprazole					0.10% 23	2.12% 552	4.85% 1300	3.02% 1027	6.74% 2425	
Byk Gulden					0.10% 23	2.12% 552	4.85% 1300	3.02% 1027	6.74% 2425	
Rabeprazole									0.09% 34	
Janssen-Cilag (licensee of Eisai)									0.09% 34	

Table 26: Germany: Market shares and sales value (USD 000s)

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Total PPI market	73055	112223	103394	141054	197787	246875	262428	346058	388533	388558
Omeprazole	100% 73055	100% 112223	96.09% 99349	82.57% 116463	66.31% 131156	62.66% 154693	59.33% 155702	57.02% 197320	61.26% 238019	65.06% 252778
AstraZeneca	100% 73055	100% 112223	96.09% 99349	82.57% 116464	64.94% 128434	58.27% 143853	53.99% 141691	51.76% 179128	35.31% 137191	24.82% 96450

678 [6316-6318].

679 [6319-6321].

Hexal (Omeprazole)								8.39%	14.38%
								32584	55864
Ratiopharm (Omeprazole)								5.48%	6.55%
								21287	25447
Lansoprazole	3.91%	12.10%	13.03%	15.83%	17.11%	16.10%	12.18%	9.28%	9.28%
	4046	17064	25777	39080	44913	55723	47304	36039	36039
Takeda	3.91%	12.10%	12.38%	12.57%	14.10%	13.32%	9.90%	7.09%	7.09%
	4046	17064	24495	31021	37007	46111	38476	27554	27554
Aventis (licensee of Takeda)			0.65%	3.26%	3.01%	2.78%	2.00%	1.22%	1.22%
			1282	8059	7906	9612	7753	4728	4728
Pantoprazole	5.34%	20.66%	21.51%	23.55%	26.75%	24.25%	21.85%	21.85%	21.85%
	7527	40855	53102	61813	92569	94206	84905	84905	84905
Byk Gulden	2.96%	10.88%	11.50%	12.91%	14.90%	14.38%	14.10%	14.10%	14.10%
	4179	21528	28385	33882	51569	55859	54798	54798	54798
Schwartz Pharma (licensee of Byk Gulden)	2.37%	9.77%	10.01%	10.64%	11.85%	9.87%	7.75%	7.75%	7.75%
	3348	19327	24717	27931	41000	38347	30098	30098	30098
Rabeprazole							0.11%	2.17%	1.84%
							369	8435	7145
Eisai							0.11%	2.17%	1.84%
							369	8435	7145

Table 27: The Netherlands: Market shares and sales value (USD 000s)

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Total PPI market	27031	44317	54426	71312	107489	121586	133386	165659	188851	204615
Omeprazole	100%	100%	99.66%	95.20%	91.82%	89.54%	88.48%	87.71%	87.18%	85.87%
	27031	44317	54239	67892	98700	108870	118021	145301	164632	175707
AstraZeneca	89.36%	72.94%	74.25%	69.47%	62.41%	58.83%	63.46%	62.42%	68.34%	83.84%
	24154	32327	40411	49544	67080	71529	84646	103411	129065	171556
Polyfarma (Losec) (parallel importer)	0.74%	12.61%	13.31%	14.87%	13.75%	13.51%	11.75%	11.52%	8.27%	0.17%
	200	5590	7242	10606	14778	16421	15675	19088	15623	341
Magnafarma (Losec) (parallel importer)	7.78%	11.20%	12.10%	10.86%	11.62%	11.79%	6.22%	7.10%	3.22%	1.13%
	2103	4965	6586	7742	12492	14331	8296	11755	6087	2303
Stephar (Losec)						0.99%	3.96%	3.76%	5.99%	0.60%
						1205	5277	6232	11306	1226
Lansoprazole			0.34%	4.80%	8.18%	10.25%	8.90%	7.34%	5.98%	4.87%
			187	3421	8789	12465	11867	12157	11301	9956
Aventis (licensee of Takeda)			0.34%	4.80%	8.18%	10.25%	8.90%	7.34%	5.97%	4.17%
			187	3421	8789	12465	11867	12157	11265	8528
Pantoprazole						0.21%	2.62%	4.95%	6.58%	7.80%
						251	3498	8201	12419	15956
Byk Gulden						0.21%	2.62%	4.95%	6.21%	6.04%
						251	3498	8201	11720	12365
Rabeprazole										1.00%
										2050
Eisai										1.00%
										2050

Table 28: Norway: Market shares and sales value (USD 000s)

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Total PPI market		7592	9083	13212	17737	19706	24879	29719	36888	34992
Omeprazole		100%	100%	95.43%	87.03%	83.95%	81.28%	79.78%	77.28%	73.68%
		7593	9083	12608	15436	16542	20222	23709	28509	25782
AstraZeneca		100%	100%	95.43%	86.01%	81.64%	70.27%	45.01%	74.63%	64.40%
		7593	9083	12608	15255	16088	17483	13376	27531	22535
Paranova (Losec) (parallel importer)						1.11%	9.51%	26.33%	2.15%	4.64%
						218	2367	7825	794	1623
Farmagon (Losec) (parallel importer)						1.08%	1.10%	5.71%	0.49%	3.70%
						213	273	1698	180	1294
Lansoprazole				4.57%	12.97%	15.48%	16.99%	18.44%	21.10%	22.21%
				604	2301	3050	4227	5479	7785	7771
Wyeth (licensee of Takeda)				4.57%	12.97%	15.48%	16.99%	18.44%	18.99%	14.88%
				604	2301	3050	4227	5479	7007	5206
Paranova (Lanzo) (parallel importer)									2.11%	7.29%
									778	2552
Pantoprazole						0.58%	1.73%	1.78%	1.61%	1.65%
						113	431	530	594	577
Pharmacia (licensee of Byk Gulden)						0.58%	1.73%	1.78%	1.61%	1.65%
						113	431	530	594	577
Esomeprazole										2.45%
										858
AstraZeneca										2.45%
										858

Table 29: Sweden: Market shares and sales value (USD 000s)

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Total PPI market	22648	36529	45601	69756	94684	129841	95650	117213	129733	121384
Omeprazole	100% 22648	100% 36529	99.08% 45180	96.54% 67342	95.33% 90266	94.22% 122330	92.37% 88355	92.41% 108317	92.28% 119714	81.15% 98507
AstraZeneca	100%	100%	99.08%	96.54%	95.33%	94.21%	63.55%	43.99%	64.96%	63.88%
Cross Pharma (Losec) (parallel importer)							24.52%	26.80%	12.37%	6.08%
Medartuum (Losec) (parallel importer)							23457	31417	16054	7379
Lansoprazole			0.92% 421	3.46% 2415	4.66% 4415	5.68% 7371	6.90% 6600	6.41% 7512	6.17% 8011	15.13% 18364
Wyeth (licensee of Takeda)			0.92%	3.46%	4.66%	5.68%	6.60%	4.60%	2.81%	11.81%
Cross Pharma (Lanzo) (parallel importer)			421	2415	4415	7371	6309	5395	3645	14331
Pantoprazole					0.00% 3	0.11% 139	0.73% 695	1.18% 1383	1.48% 1921	2.37% 2871
Byk Gulden					0.00%	0.11%	0.73%	1.18%	1.48%	2.37%
Rabeprazole					3	139	695	1383	1921	2871
Janssen-Cilag (licensee of Eisai)									0.07% 87	0.77% 932

Table 30: The United Kingdom: Market shares and sales data (USD 000s)

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Total PPI market	43589	107159	163882	258377	351610	433591	494941	531782	568837	545536
Omeprazole	100% 43589	100% 107159	100% 163882	96.91% 250397	93.45% 328573	87.99% 381505	77.95% 385829	68.05% 361865	63.13% 359097	57.28% 312466
AstraZeneca	100%	100%	100%	96.91%	93.45%	87.99%	77.95%	68.05%	63.13%	57.28%
Lansoprazole				3.09% 7980	6.55% 23037	11.86% 51415	19.82% 98076	28.65% 152335	31.23% 177645	33.25% 181384
Wyeth (licensee of Takeda)				3.09%	6.55%	11.86%	19.82%	28.65%	31.23%	33.25%
Pantoprazole				7980	23037	51415	98076	152335	177645	181384
Knoll (licensee of Byk Gulden)						0.15%	2.23%	3.08%	3.25%	3.59%
Rabeprazole						671	11036	16392	18506	19586
Eisai								0.22%	2.04%	4.84%
								1190	11607	26387

PPI prices (cost of 28 day treatment)

Table 31: Belgium: Cost of 28 day treatment (USD); PPI prices

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Losec 20 mg capsules (omeprazole)	67.65	71.61	66.11	69.10	78.08	67.91	55.06	47.19	44.66	38.83
Losec 20 mg MUPS tablets (omeprazole)										36.46
Bio-Therabel Logastric 20 mg capsules (omeprazole)				69.08	78.10	67.91	55.05	47.18	44.65	38.79
Bio-Therabel Logastric MUPS 20 mg tablets (omeprazole)										36.42
Dakar 30 mg (lansoprazole)				72.59	78.36	73.23	57.49	48.18	44.63	38.66
Pantozol 40 mg tablets (pantoprazole)							46.81	46.78	44.73	38.84

Table 32: Denmark: Cost of 28 day treatment (USD); PPI prices

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Losec 20 mg capsules (omeprazole)	73.49	71.42	61.99	62.15	58.36	51.27	45.14	43.17		
Losec 20 mg MUPS tablets (omeprazole)								45.11	42.57	
Paranova Losec 20 mg capsules (omeprazole) (parallel importer)					59.43	50.73	45.36			
Orifarm Losec 20 mg capsules (omeprazole) (parallel importer)					55.64	50.60	44.60	42.00		

Lanzo 30 mg capsules (lansoprazole)	59.28	56.70	51.45	42.41	40.30	37.87			
Lanzo Orifarm 30 mg capsules (lansoprazole)				40.12	38.94	37.68			
Pantoloc 40 mg tablets (pantoprazole)		53.67	51.18	44.77	40.11	37.55			
Pariet 20 mg tablets (rabeprazole)								34.09	

Table 33: Germany: Cost of 28 day treatment (USD); PPI prices

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Antra 20 mg capsules (omeprazole)	62.06	65.91	58.91	59.35	57.04	54.19	47.30	46.49	46.85	
Antra 20 mg MUPS tablets (omeprazole)								49.12	44.93	38.52
Antra Kohl Pharma 20 mg capsules (omeprazole) (parallel importer)					51.39	48.37	45.59	44.06		
Hexal 20 mg (omeprazole)									29.40	21.72
Agopton 30 mg capsules (lansoprazole)			57.43	57.23	57.11	54.20	47.31	46.64	44.70	38.48
Rifun 40 mg tablets (pantoprazole)			53.17	57.21	54.29	47.26	46.66	44.85	44.85	38.15
Pariet 20 mg tablets (rabeprazole)								42.93	39.21	33.75

Table 34: The Netherlands: Cost of 28 day treatment (USD); PPI prices

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Losec 20 mg capsules (omeprazole)	76.91	81.58	72.83	64.69	71.71	60.91	47.43	46.67	44.93	40.25
Losec 20 mg MUPS tablets (omeprazole)									43.42	38.89
Polyfarma Losec 20 mg capsules (omeprazole) (parallel importer)	64.37	73.28	60.38	55.59	60.35	52.94	44.45	44.38	41.26	37.59
Magnafarma Losec 20 mg capsules (omeprazole) (parallel importer)	65.43	73.16	64.57	56.82	62.70	53.93	45.18	43.25	40.52	34.05
Stephar Losec 20 mg capsules (omeprazole) (parallel importer)		75.14				73.77	42.02	43.29	41.31	38.27
Prezal 30 mg capsules (lansoprazole)			57.54	59.72	65.99	57.58	47.49	46.09	41.99	36.16
Pantozol 40 mg tablets (pantoprazole)						52.06	43.30	44.33	41.30	35.14
Pariet 20 mg tablets (rabeprazole)										32.22

Table 35: Norway: Cost of 28 day treatment (USD); PPI prices

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Losec 20 mg capsules (omeprazole)		89.93	70.30	71.23	71.08	61.45	55.89	51.92		
Losec 20 mg MUPS tablets (omeprazole)								52.96	50.90	41.58
Paranova Losec 20 mg capsules (omeprazole) (parallel importer)						60.02	50.90	48.26	43.91	41.14
Faramagon Losec 20 mg capsules (omeprazole) (parallel importer)						58.90	54.11	50.38	47.71	40.63
Lanzo 30 mg capsules (lansoprazole)				63.42	63.76	57.01	51.90	48.05	46.47	34.48
Paranova Lanzo 40 mg tablets (lansoprazole)									45.88	40.08
Somac 40 mg tablets (pantoprazole)						56.79	51.38	47.35	45.25	40.32

Table 36: Sweden: Cost of 28 day treatment (USD); PPI prices

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Losec 20 mg capsules (omeprazole)	83.68	85.74	62.41	62.87	66.58	66.84	57.90	54.47		
Losec 20 mg MUPS tablets (omeprazole)								48.76	48.14	43.52
Cross Pharma Losec 20 mg capsules (omeprazole) (parallel importer)							50.03	47.92	46.30	41.97

Medartuum Losec 20 mg capsules (omeprazole) (parallel importer)							48.03	46.37	42.23
Lanzo 30 mg capsules (lansoprazole)	52.86	55.52	59.92	62.82	54.53	51.90	40.73	28.40	
Pantoloc 40 mg tablets (pantoprazole)			84.00	61.78	53.91	43.41	39.65	34.24	
Pariet 20 mg tablets (rabeprazole)							32.87	29.47	

Table 37: The UK: Cost of 28 day treatment (USD); PPI prices

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
Losec 20 mg capsules (omeprazole)	56.13	55.70	47.72	48.21	48.96	48.42	50.96	44.42	42.15	37.82
Losec 20 mg MUPS tablets (omeprazole)									40.68	37.88
Zoton 30 mg capsules (lansoprazole)				45.54	46.18	45.79	44.57	43.12	41.42	33.19
Protium 40 mg tablets (pantoprazole)						42.51	42.85	43.21	40.90	33.22
Pariet 20 mg tablets (rabeprazole)								34.83	33.64	30.59

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