JUDGMENT OF THE GENERAL COURT (Sixth Chamber, Extended Composition)

1 July 2010 *

In Case T-321/05,

AstraZeneca AB, established in Södertälje (Sweden),

AstraZeneca plc, established in London (United Kingdom),

represented initially by M. Brealey QC, M. Hoskins, D. Jowell, Barristers, F. Murphy, G. Sproul, I. MacCallum and C. Brown, Solicitors, and subsequently by M. Brealey, M. Hoskins, D. Jowell, F. Murphy and C. Brown, and lastly by M. Brealey, M. Hoskins, D. Jowell and F. Murphy,

applicants,

supported by

European Federation of Pharmaceutical Industries and Associations (EFPIA), established in Geneva (Switzerland), represented by M. Van Kerckhove, lawyer,

intervener,

* Language of the case: English.

European Commission, represented initially by F. Castillo de la Torre, É. Gippini Fournier and A. Whelan, and subsequently by F. Castillo de la Torre, É. Gippini Fournier and J. Bourke, acting as Agents,

defendant,

APPLICATION for annulment of Commission Decision C(2005) 1757 final of 15 June 2005 relating to a proceeding under Article 82 [EC] and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 — AstraZeneca),

THE GENERAL COURT (Sixth Chamber, Extended Composition),

composed of A.W.H. Meij (Rapporteur), President, V. Vadapalas, N. Wahl, L. Truchot and S. Frimodt Nielsen, Judges,

Registrar: C. Kristensen, Administrator,

having regard to the written procedure and further to the hearing on 26 and 27 November 2008,

gives the following

Judgment

Background to the dispute

1 Astra AB was a company incorporated under Swedish law established in Södertälje (Sweden) and was the parent company of a pharmaceutical group including, inter alia, AB Hässle and Astra Hässle AB, two wholly-owned subsidiaries established in Mölndal (Sweden). With effect from 6 April 1999, Astra merged with Zeneca Group plc to form AstraZeneca plc, the second applicant in this case, a holding company established in London (United Kingdom). As a result of that merger, Astra, which was wholly owned by AstraZeneca plc, acquired the name AstraZeneca AB, the first applicant in this case, and became a research and development, marketing and production company. The companies which belonged to the Astra group and those now in the AstraZeneca plc group will be called 'AZ'. However, in so far as AstraZeneca plc and AstraZeneca AB are being referred to in their capacity as parties to these proceedings, they will be called together 'the applicants'.

2 AZ is a pharmaceutical group active, worldwide, in the sector of inventing, developing and marketing innovative products. Its business is focused on a number of pharmaceutical areas including, in particular, that of gastrointestinal conditions. In

that regard, one of the major products marketed by AZ is known as 'Losec', a brand name used in most European markets for that omeprazole product.

3 On 12 May 1999, Generics (UK) Ltd and Scandinavian Pharmaceuticals Generics AB ('the complainants') lodged a complaint pursuant to Article 3 of Regulation No 17 of the Council of 6 February 1962, First Regulation implementing Articles [81 EC] and [82 EC] (OJ, English Special Edition 1959-1962, p. 87) against Astra, by which they complained of AZ's conduct aimed at preventing them from introducing generic versions of omeprazole on a number of European Economic Area (EEA) markets.

4 By decision of 9 February 2000, adopted pursuant to Article 14(3) of Regulation No 17, the European Commission ordered AZ to submit to investigations at its premises in London and Södertälje. In 2002 and 2003, AZ also replied to three requests for information pursuant to Article 11 of Regulation No 17.

5 On 25 July 2003, the Commission adopted a decision to initiate the procedure. On 29 July 2003, the Commission sent a statement of objections to AZ, to which it replied on 3 December 2003. A meeting was held on 29 January 2004 to discuss certain evidence submitted by AZ in its reply to the statement of objections. AZ also submitted various documents, including, inter alia, the memoranda of 27 January and 11 February 2004, in order to address issues raised by the Commission at the abovementioned meeting. On 13 February 2004, AZ provided the Commission with materials relating to the second alleged abusive course of conduct.

6 A hearing took place on 16 and 17 February 2004. On 26 February 2004, the Commission sent AZ a request for information, pursuant to Article 11 of Regulation No 17, relating to the issue of dominance. AZ replied to the request on 12 March 2004. On 23 November 2004, the Commission offered AZ the opportunity to comment on a number of factual elements and considerations which had not been included in the statement of objections. AZ provided its observations on those matters by letter of 21 January 2005.

7 On 15 June 2005, the Commission adopted a decision relating to a proceeding under Article 82 [EC] and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 — AstraZeneca) ('the contested decision'), by which it found that AstraZeneca AB and AstraZeneca plc had committed two abuses of a dominant position, in breach of Article 82 EC and Article 54 of the EEA Agreement.

8 The first alleged abuse consisted of a pattern of allegedly misleading representations made before the patent offices in Germany, Belgium, Denmark, Norway, the Netherlands and the United Kingdom, and before the national courts in Germany and Norway (Article 1(1) of the contested decision). The second alleged abuse consisted of the submission of requests for deregistration of the marketing authorisations for Losec capsules in Denmark, Norway and Sweden combined with the withdrawal from the market of Losec capsules and the launch of Losec MUPS tablets in those three countries (Article 1(2) of the contested decision).

9 The Commission imposed on the applicants jointly and severally a fine of EUR 46 million and on AstraZeneca AB a fine of EUR 14 million (Article 2 of the contested decision).

Procedure and forms of order sought by the parties

10 By application lodged at the Registry of the Court on 25 August 2005, the applicants brought the present action.

11 By document lodged at the Registry of the Court on 7 December 2005, Generics (UK) and Merck NM AB applied for leave to intervene in support of the form of order sought by the Commission.

12 By document lodged at the Registry of the Court on 15 December 2005, the European Federation of Pharmaceutical Industries Associations ('the EFPIA') applied for leave to intervene in support of the form of order sought by the applicants.

13 By document lodged on 10 February 2006, the applicants made an application for confidential treatment vis-à-vis the interveners. That application for confidential treatment was not contested.

14 By orders of 4 July and 29 November 2006, the President of the Second Chamber of the Court allowed the EFPIA to intervene in the proceedings in support of the form of order sought by the applicants, and Generics (UK) and Merck NM to intervene in support of the form of order sought by the Commission.

15 On 26 January 2007, Generics (UK) and Merck NM waived their right to lodge a statement in intervention.

16 By letter lodged at the Registry of the Court on 24 November 2008, Generics (UK) and Merck NM withdrew their intervention in support of the form of order sought by the Commission.

17 By order of the President of the Sixth Chamber of the Court of 17 December 2008, Generics (UK) and Merck NM were removed from the case as interveners in support of the form of order sought by the Commission.

18 Upon hearing the Judge-Rapporteur, the Court (Sixth Chamber, Extended Composition) decided to open the oral procedure and, pursuant to Article 64 of its Rules of Procedure, invited the main parties to answer a series of questions. They complied with those requests within the prescribed periods.

19 At the hearing on 26 and 27 November 2008, the parties presented oral argument and replied to questions put by the Court.

20 The applicants claim that the Court should:

— annul the contested decision;

— order the Commission to pay the costs.

21 The EFPIA contends that the Court should:

— annul the contested decision;

— order the Commission to pay the costs.

22 The Commission contends that the Court should:

— dismiss the action;

— order the applicants to pay the costs.

Law

23 By their action, the applicants call in question the lawfulness of the contested decision as regards the definition of the relevant market, the assessment of the dominant position, the first abuse of a dominant position, the second abuse of a dominant position and the amount of the fines imposed. The Court will examine in turn the pleas put forward by the applicants in the context of each of these issues.

24 As a preliminary point, the Court notes, first of all, that the applicants have submitted an application for confidential treatment in respect of a large quantity of information relating, inter alia, to documentary evidence of conduct which, according to the Commission, amounts to an abuse of a dominant position.

25 The Court grants that application for confidential treatment in so far as the information in question does not appear in the non-confidential version of the contested decision, which is published on the internet site of the Directorate-General for Competition of the Commission and which is therefore accessible to the public. However, the application for confidential treatment must be dismissed in so far as it concerns information which appears in the non-confidential version of the contested decision. That information has in any event lost any confidential character it may have had, because it has been accessible to the public (see, to that effect, Case T-99/04 *AC-Treuhand* v *Commission* [2008] ECR II-1501, paragraph 19).

26 The Court notes, next, that, at the hearing, the applicants expressed reservations about the Commission's use of a document submitted on 24 November 2008, which included, first, graphs reproducing, according to the Commission, data contained in tables annexed to the contested decision and, second, extracts from the application and from the annexes to the pleadings submitted by the parties in the course of the written procedure.

27 In this regard, the document submitted by the Commission a few days prior to the hearing essentially reproduces information which was already in the documents before the Court. That is true of the graphs set out at pages 2 to 8, 10 to 16 and 18 to 24 of that document, which reproduce the data presented in the tables annexed to the contested decision, and also the extracts from the application and the annexes to the pleadings cited in the document. The use made by the Commission of that document at the hearing therefore forms part of the oral presentation of the arguments previously expounded during the written procedure before the Court. Accordingly, the reservations expressed by the applicants on those points must be disregarded. The

position is different as regards the graphs set out at pages 26 to 32 of the aforementioned document, which contain information relating to a price differential in percentage terms, which do not appear in tables 24 to 30 in the Annex to the contested decision to which those figures refer. To the extent that the graphs contain more information than is contained in the tables to which they refer, the document submitted by the Commission must be declared inadmissible on that point and the Court will not take account of those data in its findings.

A — *Relevant product market*

28 In the contested decision, the Commission found in essence that antihistamines ('H2 blockers') did not exercise significant competitive constraints over proton pump inhibitors ('PPIs') and that, consequently, the relevant product market was composed exclusively of the latter. The Commission based that finding on a series of considerations which took account of the features of competition in the pharmaceutical sector and which concerned, principally, the intrinsic features of the products, their therapeutic uses, the continuous increase of PPI sales at the expense of H2 blockers, price factors, and 'natural' events which occurred in Germany and the United Kingdom.

29 The applicants contest the soundness of the Commission's definition of the relevant market and put forward, to that effect, two pleas in law. The first plea in law alleges a manifest error of assessment as to the relevance of the gradual nature of the increase

in use of PPIs at the expense of H2 blockers. The second plea in law alleges various inconsistencies and errors of assessment.

1. *Preliminary observations*

30 It should be borne in mind, first of all, that, as is apparent inter alia from paragraph 2 of the Commission Notice on the definition of relevant market for the purposes of Community competition law (OJ 1997 C 372, p. 5; 'the Notice on market definition'), the definition of the relevant market is carried out, in the context of the application of Article 82 EC, in order to define the boundaries within which it must be assessed whether a given undertaking is able to behave, to an appreciable extent, independently of its competitors, its customers and, ultimately, consumers (see, to that effect, Case 322/81 *Nederlandsche Banden-Industrie-Michelin* v *Commission* [1983] ECR 3461, paragraph 37).

31 According to settled case-law, for the purposes of investigating the possibly dominant position of an undertaking, the possibilities of competition must be judged in the context of the market comprising the totality of the products which, with respect to their characteristics, are particularly suitable for satisfying constant needs and are only to a limited extent interchangeable with other products; those possibilities of competition must also be assessed in the light of the competitive conditions and of the structure of supply and demand (*Nederlandsche Banden-Industrie-Michelin* v *Commission*, paragraph 30 above, paragraph 37; Cases T-229/94 *Deutsche Bahn* v *Commission* [1997] ECR II-1689, paragraph 54; and T-219/99 *British Airways* v *Commission* [2003] ECR II-5917, paragraph 91). As is apparent inter alia from paragraph 7 of the Notice on market definition, the relevant product market therefore comprises

all those products or services which are regarded as substitutable by consumers, by reason of the products' characteristics, their prices and their intended use.

32 Next, it follows from settled case-law that, although as a general rule the Community judicature undertakes a comprehensive review of the question as to whether or not the conditions for the application of the competition rules are met, the review of complex economic appraisals made by the Commission is necessarily limited to checking whether the relevant rules on procedure and on stating reasons have been complied with, whether the facts have been accurately stated and whether there has been any manifest error of assessment or a misuse of powers. Likewise, in so far as the Commission's decision is the result of complex technical appraisals, those appraisals are in principle subject to only limited review by the Court, which means that the Court cannot substitute its own assessment of matters of fact for the Commission's (see Case T-201/04 *Microsoft* v *Commission* [2007] ECR II-3601, paragraphs 87 and 88 and the case-law cited).

33 However, while the Community judicature recognises that the Commission has a margin of assessment in economic or technical matters, that does not mean that it must decline to review the Commission's interpretation of economic or technical data. In order to take due account of the parties' arguments, the Community judicature must not only establish whether the evidence put forward is factually accurate, reliable and consistent but must also determine whether that evidence contains all the relevant data that must be taken into consideration in appraising a complex situation and whether it is capable of substantiating the conclusions drawn from it (see, to that effect, in relation to control of concentrations, Case C-12/03 P *Commission* v *Tetra Laval* [2005] ECR I-987, paragraph 39; see also, to that effect, *Microsoft* v *Commission*, paragraph 32 above, paragraph 89).

2. *First plea in law, alleging a manifest error of assessment as to the relevance of the gradual nature of the increase in use of PPIs at the expense of H2 blockers*

(a) Arguments of the applicants and of the EFPIA

34 The applicants and the EFPIA argue that competition in the pharmaceutical sector has a number of specific features. The applicants claim, first, that the markets for pharmaceutical products in the relevant Member States are characterised by public regulation of pricing and reimbursement. Secondly, in those markets, the consumer (patient) differs from the decision maker (doctor) and, most of the time, from the payer (national insurance service or private health insurance). Since doctors and patients do not bear the bulk of the cost of prescription medicines, doctors are usually only slightly sensitive to the price of medicines when prescribing them. During the relevant period, prescribing doctors were primarily guided by the therapeutic appropriateness and effectiveness of medicines rather than by their price. Moreover, actual trends in the consumption of prescribed medicines constitute a key factor in assessing whether medicines are in the same product market. Finally, doctors' prescribing practice is characterised by a certain 'inertia'. The EFPIA adds that, in the pharmaceutical sector, competition takes place primarily at the level of innovation, rather than at the level of price. It therefore stresses the importance of intellectual property protection in order to encourage the investment necessary for innovation.

35 According to the applicants, it is common ground that PPIs are therapeutically superior to H2 blockers. That therapeutic superiority was accepted by the scientific community from the early 1990s. However, prescribing doctors did not recognise that superiority immediately. The increase in use of PPIs over the relevant period was gradual and took place at the expense of H2 blockers. PPIs and H2 blockers thus have similar therapeutic uses and were prescribed on fundamentally identical medical grounds.

36 The applicants and the EFPIA assert that H2 blockers must have exerted a significant competitive constraint on Losec, since sales of Losec increased at the expense of H2 blockers in a gradual manner. They therefore dispute that PPIs and H2 blockers belonged to separate product markets from 1993 onwards.

37 In support of that assertion, the applicants refer, first, to a report prepared by IMS Health concerning the use of PPIs and H2 blockers to treat acid-related gastric disease in the major European markets in the period 1990-2000. That report concluded that the increased use of PPIs had been a gradual process and that, at the end of the relevant period, there were major micro-diagnoses in most countries for which a significant percentage of prescriptions (20% or more) were H2 blockers. Moreover, H2 blockers were never completely replaced by PPIs in any country. With the exception of Sweden, even for micro-diagnoses at the more severe end of the spectrum of acid-related conditions, such as gastric and duodenal ulcers, a significant percentage (10% or more) of patients received a prescription for an H2 blocker. In Sweden, all patients diagnosed with gastric ulcer received PPIs.

38 To the same effect, the EFPIA also points out that PPIs gradually, and only partly, replaced H2 blockers due to concerns about their safety and side effects and that the contested decision contains no evidence to support the Commission's contention that scientific and clinical studies carried out between the launch date of Losec and the start of the material period demonstrated the efficacy of the product relative to existing treatments.

39 Second, statements from four independent medical experts in the field of acid-related gastrointestinal diseases establish that acceptance of Losec by prescribing doctors was hindered by, inter alia, their reluctance to prescribe PPIs because of the fact that they were perceived as much stronger medicines than H2 blockers, arousing some suspicion as to their possible side effects. Those witness statements confirm that the acceptance of PPIs by doctors was a gradual process.

40 Third, the applicants refer to the Lexecon report, according to which doctors and patients have incomplete information about the characteristics of new medicines and only learn about these qualities slowly, on the basis of their personal experience or published medical literature. It therefore follows that new medicines usually require time to gain substantial market shares. Moreover, companies which are among the early market entrants enjoy a competitive advantage.

41 The applicants dispute that the 'inertia' characterising doctors' prescribing practices is a factor exogenous to competition, since, in their view, it is, on the contrary, a relevant feature of the analysis of competition in the pharmaceutical product markets, as the Commission recognised in recital 362 of the contested decision. They argue that 'inertia' on the part of the doctor depends, inter alia, on how good the incumbent

medicine is, what advantages the new product has and how quickly doctors get to know about that new product. The EFPIA submits, in this regard, that, if prescribing doctors are satisfied with the existing treatments their patients are receiving and those patients are adequately stabilised with those existing treatments, they will be cautious about switching to the use of another product unless the clinical data convincingly demonstrate that there are clinical advantages in doing so. Consequently, in the submission of the applicants, since 'inertia' is one of the principal obstacles which has to be overcome by a new entrant, comparative clinical studies, promotional activities and visits to doctors are important aspects of competition, of which the manufacturer of the new product will have to make use.

42 The EFPIA adds that the applicants undertook a range of work which produced consistent findings, according to which overcoming the 'inertia' in prescribing practices required a considerable time and H2 blockers exerted continuous competitive pressure on PPIs during the period 1993-2000. It claims that the Commission has failed to provide any refuting evidence demonstrating that H2 blockers stopped exerting competitive pressure on PPIs as from 1993 so that those products belonged to separate product markets.

43 Fourth, AZ's contemporaneous internal strategy documents demonstrate that demand for H2 blockers showed resilience and that they were AZ's primary competitive focus for Losec. The fact that the use of PPIs gradually increased at the expense of H2 blockers, and that the competitive challenge for AZ was for Losec to take market shares from H2 blockers, demonstrates that, during the relevant period, Losec and H2 blockers were substitute products that competed with each other. That view is supported by the fact that, even by the end of the relevant period, H2 blockers were still prescribed in substantial quantities for all the major micro-diagnoses.

44 Fifth, the applicants maintain that the Commission shows inconsistency by accepting the relevance of 'inertia' in the context of assessing dominance (recital 542 of the contested decision), while rejecting its relevance in the context of market definition, on the ground that it is an exogenous factor (recital 467 of the contested decision). In their view, 'inertia' not only cushions H2 blockers from competition but is also a competitive constraint on PPIs. They also dispute that, once overcome, 'inertia' is no longer a relevant factor in a doctor's decision-making process and that it does not serve to reverse the process of substitution of H2 blockers by PPIs. Moreover, by stating that 'inertia' protected H2 blockers from a more rapid decline, the Commission implicitly accepts that it played a role by constraining prescribing practices during the relevant period. The applicants also state that, in recitals 541 to 543 and 551 of the contested decision, the Commission emphasises the advantages associated with first-mover status in the pharmaceutical sector and with having an established product.

45 They submit, in addition, that the Commission's arguments that, on the one hand, a considerable proportion of sales of PPIs were not substituting for former sales of H2 blockers and, on the other hand, doctors prescribe H2 blockers or PPIs depending on the step-down or step-up in treatment desired, cannot be taken into consideration since they are not included in the contested decision and are being raised for the first time at the stage of proceedings before the Court. With regard to the first of those two arguments, they add that it is not supported by the contested decision, which does not contain any consideration, in recitals 381 to 385 and 37 to 47, of actual prescribing practices during the period between 1993 and 2000, and that it even departs from recital 386 of the contested decision. This argument is, moreover, contradicted by the conclusions of the IMS Health study. With regard to the second argument, the applicants point out that the Commission did not carry out any investigation as to doctors' actual prescribing practices and refer to their reply to the statement of objections.

46 In addition, the EFPIA complains that the Commission, contrary to the judgment in Case T-168/01 *GlaxoSmithKline Services* v *Commission* [2006] ECR II-2969, paragraph 276, omitted to check the nature and import of the evidence taken into consideration and that it drew inferences from documents submitted to it during the investigation without conducting any independent analysis. As regards its examination of doctors' prescribing practices, the Commission chose data selectively from the IMS Health report produced by the applicants, without rebutting the other data contained in that report showing that H2 blockers exercised competitive constraints over PPIs. The EFPIA maintains that the only evidence mentioned in the contested decision that was not supplied by the applicants comes from a correlation study supplied by the complainants, which the Commission itself recognised as suffering from methodological weaknesses.

47 The EFPIA submits that it is not sufficient to show that sales by value of PPIs increased and sales by value of H2 blockers decreased or stagnated in order to conclude that the latter no longer exert competitive pressure on PPIs. It points out, in that regard, that the volume of sales of H2 blockers in Germany and the United Kingdom exceeded that of sales of PPIs until 1997 and 1998 respectively, and in 2000 still represented 40% of combined PPI and H2 blocker sales in those countries. Moreover, the fact that Losec lost sales to its generic version and to other PPIs does not mean that H2 blockers did not exert competitive pressures on PPIs during the relevant period.

48 In the light of the foregoing, the applicants and the EFPIA therefore submit that the Commission's conclusion that PPIs and H2 blockers were in different product markets from 1993 onwards is wrong.

(b) Arguments of the Commission

49 The Commission observes, first, that the applicants focus exclusively on prescription practices, without addressing the aspect of the contested decision concerning the question of how H2 blockers failed to exercise any significant competitive constraint on Losec during the relevant period, and in particular on the setting of its price. In its view, a ground of annulment as partial as that cannot succeed.

50 It then makes three points of clarification regarding the applicants' claims. First, it states that the examination does not relate to the question of whether an innovative new product such as Losec forms a separate product market at the time of its introduction on the market, or to that of whether Losec was dominant in a separate PPI market shortly after its launch. Losec was launched on the market in the late 1980s, that is four to five years before the year adopted by the Commission as the starting point for the market definition (1993). Studies demonstrating the efficacy of Losec relative to existing treatments were carried out between its launch date and the beginning of the relevant period and were communicated to medical practitioners. Consequently, the significant sales of PPIs in 1993 and 1994 show that, at the beginning of the relevant period, the message of the therapeutic superiority of PPIs was already reaching doctors and that the effect of 'inertia' had largely been overcome.

51 Secondly, the Commission points out that the combined sales of PPIs and H2 blockers underwent a considerable expansion in the countries concerned, increasing from a value of approximately United States Dollars (USD) 644 million in 1993 to approximately USD 1.43 billion in 1999. The IMS Health data show that PPIs accounted for the bulk of that expansion. They were used in the treatment of conditions for which H2 blockers were not previously regarded as appropriate or effective. Sales of the latter tended to decline in absolute value terms, before stabilising or increasing very moderately relative to their 1993 levels, then decreasing considerably from 1997

onwards. According to the Commission, the temporary stabilisation and increase in sales of H2 blockers coincided with a partial shift to treatment areas where they were less exposed to competition from PPIs. The reaction of the producers of H2 blockers in the face of the threat from PPIs was to reposition their products towards the treatment of milder gastrointestinal conditions, and even to convert them into over-the-counter drugs. It necessarily follows from the considerable expansion of combined sales during the relevant period, which was largely captured by PPIs, that PPIs did not only replace sales of H2 blockers. That is supported by recitals 382 and 386 of the contested decision, in which it is observed that PPIs were deemed to be the only effective remedy for a large number of conditions. The Commission points out, however, that it does not contend that the growth in PPI sales over that period was exclusively at the expense of H2 blockers.

52 Moreover, those two products were prescribed by medical practitioners sequentially at the different stages of a single course of treatment, depending on whether a step-down or step-up of that treatment was required. Consequently, PPIs and H2 blockers should not be considered as substitutes, but as part of a hierarchy of medicines. The Commission observes, in that regard, that the applicants do not dispute that the therapeutic superiority of PPIs over H2 blockers results in the two products serving different types of demand. There is comprehensive evidence on actual prescriptions by doctors, demonstrating that PPIs progressively extended to the entire relevant disease spectrum (recitals 380 to 399 of the contested decision). The Commission adds that it is not necessary to quantify the prevalence of step-up and step-down treatment strategies, as these are only part of the explanation of the extraordinary sales expansion, which necessarily implies that PPIs were prescribed in circumstances in which H2 blockers had not traditionally been used.

53 In reply to the EFPIA's arguments, the Commission submits that the clear therapeutic superiority of PPIs over H2 blockers exceeds the quality that might be attributed to the best product in a given class of treatments. It is clear from AZ's explanations in its 1996 annual report and from its publications (recitals 37 and 38 of the contested decision) that from the end of the 1970s it considered omeprazole to be a superior pharmaceutical product. The Commission points out that the Court has acknowledged that two products with similar functions and whose substitutability is asymmetrical, the relationship between them being characterised by migration from one product to the other, do not belong to the same product market, even if the migration is not complete by the end of the relevant period (Case T-340/03 *France Télécom* v *Commission* [2007] ECR II-107, paragraphs 88 and 89).

54 The Commission further disputes the EFPIA's assertion that it did not analyse the factors that determine doctors' prescribing practice. It states that in the contested decision, it relies on IMS Health data on prescriptions, both in aggregated form in respect of each country and year and in disaggregated form detailing prescriptions across the disease spectrum. It identified the prescribing patterns throughout the relevant period, as well as the therapeutic factors influencing the prescribing choices (recitals 386 to 399 of the contested decision).

55 Thirdly, the Commission draws attention to three points in the consumption trends, which are key elements in its analysis. Firstly, the annual percentage of sales of either H2 blockers or PPIs as a proportion of the combined sales of those products does not convey either the market expansion dominated by PPIs or the repositioning of H2 blockers. Secondly, the increase in the absolute value of sales of PPIs between 1991 and 2000 was dramatic. Thirdly, the 'inertia' of medical practitioners contributed to the gradual character of the market process.

56 As regards the 'inertia' characterising prescribing practice, the Commission contends that it is an exogenous characteristic of the market, unrelated to competition on the merits, which autonomously dampens demand for a new product. Thus, 'inertia' on the part of prescribing doctors cannot be regarded as a competitive constraint imposed by H2 blockers, akin to brand loyalty generated by past reputation or advertising. In the Commission's view, producers of H2 blockers had few resources available for appreciably increasing that 'inertia'. Moreover, there is nothing to indicate that, once the effect of 'inertia' had been overcome, H2 blockers offered sufficient advantage to reverse the process of one-way substitution.

57 As regards the applicants' argument that the Commission contradicts itself by taking the view that 'inertia' is a relevant factor in the determination of dominance, the Commission contends that 'inertia' may mitigate the constraints imposed on an incumbent firm by new products by creating a barrier to entry and expansion for products challenging the putatively dominant product. It points out, in that regard, that the purpose of market definition in this case is to determine the competitive constraints on PPIs, and not the competitive constraints on H2 blockers. In addition, the Commission points out that, in any event, the market definition is based on an overall assessment of all relevant factors and cannot be called into question on the assumption — which it disputes — that 'inertia' could be regarded as a competitive advantage specifically attributable to H2 blockers.

58 As regards the competitive constraints on PPIs, the Commission maintains that it is evident from the consumption data that 'inertia' neither prevented the growth of PPIs nor permitted H2 blockers to reverse the process of substitution by PPIs. It therefore infers from this that 'inertia' protected sales of H2 blockers from an even more rapid decline. Moreover, the fact that PPI producers succeeded in negotiating and applying prices which were higher than those of H2 blockers shows that national health systems had accepted that PPIs represented an innovation which was not comparable to H2 blockers.

59 The Commission makes it clear that it does not maintain that PPIs have been part of a market distinct from that of H2 blockers since 1993. It did not in fact exclude, in recital 504 of the contested decision, the possibility that a distinct PPI market may have existed before that date. However, it points out that it was unnecessary to examine previous years, because the abusive behaviour had begun in 1993.

60 The Commission submits that the evidence to which the applicants refer in support of their argument relates to uncontested factual premises and cannot help them. Thus, the IMS Health report attests to the gradual process by which PPIs displaced H2 blockers, a fact which was taken into account in the contested decision. At the very most, AZ's expert medical testimony explains the origins of the 'inertia' phenomenon, but does not explain how H2 blockers exercised a competitive constraint over PPIs. The Lexecon report does not address either the considerable lapse of time between the first marketing of Losec and 1993 or the broad acknowledgement of the superiority of PPIs over H2 blockers. Nor does it explain how 'inertia' could be attributable to the competitive constraints exercised by H2 blockers over PPIs. Finally, AZ's internal documents mentioning the resilience of H2 blockers concern an undisputed fact. However, those documents do not demonstrate that H2 blockers exercised significant competitive constraints over PPIs.

(c) Findings of the Court

61 The dispute between the parties regarding the definition of the relevant product market centres on the competitive interaction between two pharmaceutical products, PPIs and H2 blockers. It is appropriate first of all to present those products succinctly.

62 It is apparent from recital 34 of the contested decision that histamine receptor antagonists (also known as 'antihistamines' or 'H2 blockers') and PPIs are pharmaceutical products for the treatment of gastrointestinal acid-related conditions which proactively inhibit acid secretion into the stomach. Acid is pumped into the stomach by a specific enzyme ('the proton pump') inside the parietal cells along the stomach's wall. While H2 blockers only block one of the stimulants of the proton pump, namely the histamine receptors in the parietal cells, PPIs operate on the proton pump itself. In the contested decision, the Commission thus found that H2 blockers only operated indirectly on the proton pump, whereas PPIs had the ability to operate directly on the proton pump.

63 Next, it should be noted that it is common ground that the therapeutic strength of PPIs is significantly greater than that of H2 blockers. The parties also agree that sales of PPIs increased significantly and that sales of H2 blockers fell significantly. As the Commission observes, it is apparent from tables 9 to 15 in the Annex to the contested decision that combined sales of PPIs and H2 blockers, measured in value terms, underwent considerable expansion in Germany, Belgium, Denmark, Norway, the Netherlands, the United Kingdom and Sweden between 1991 and 2000, with sales growth of PPIs accounting for the bulk of that expansion. During that same period, sales of H2 blockers, also measured in value terms, declined considerably. Similarly, it is clear from tables 17 to 23 in that annex that the combined number of PPI and H2 blocker treatments increased considerably between 1991 and 1999 or 2000 in those countries. Within that trend, the number of PPI treatments increased strongly and, according to the country in question, the number of H2 blocker treatments declined significantly or stagnated. The accuracy of the data in those tables is not disputed.

64 The first plea essentially alleges a manifest error of assessment as to the relevance of the gradual nature of the increase in use of PPIs at the expense of H2 blockers. Essentially, that plea hinges on reasoning in two stages. In the first place, even if their therapeutic strength was lesser, H2 blockers constituted therapeutic substitutes for PPIs and, at the end of the relevant period (1991-2000), were being sold in significant quantities for the treatment of gastrointestinal conditions identical to those for which PPIs were prescribed. Consequently, in the second place, since sales of PPIs increased at the expense of H2 blockers in a gradual manner, H2 blockers must have exercised a significant competitive constraint over PPIs.

65 In the light of those arguments, it is necessary to examine the lawfulness of the contested decision as regards, first, the therapeutic use of PPIs and H2 blockers, and then, second, the relevance of the gradual nature of substitution of PPIs for H2 blockers for the purposes of assessing the competitive constraint that H2 blockers are alleged to have exercised over PPIs.

The differentiated therapeutic use of PPIs and H2 blockers

66 In recitals 381 to 386 of the contested decision, the Commission took the view that the therapeutic superiority of PPIs over H2 blockers pointed to the existence of a product market composed solely of PPIs. It thus found that there was a significant patient population suffering from gastrointestinal acid-related conditions for which only PPIs were an appropriate remedy. According to the Commission, doctors increasingly considered that PPIs constituted the most effective and appropriate remedy.

67 In support of their challenge to the Commission's view that the therapeutic superiority of PPIs constitutes a factor supporting a market definition comprising only PPIs, the applicants claim that PPIs and H2 blockers were used for the same therapeutic purposes, since H2 blockers were to a significant extent prescribed for the same conditions as PPIs. The applicants rely in this respect on written statements from medical experts that they submitted during the administrative procedure in reply to the statement of objections.

68 Having conducted an examination of the statements of the medical experts which were brought to its attention, the Court finds that those statements agree on the following points:

— H2 blockers and PPIs belong to a continuum of therapies aimed at suppressing acids;

— since their entry on the market, PPIs were perceived by the medical community as more powerful medicines than H2 blockers;

— PPIs were suspected of having carcinogenic effects and were prescribed only very gradually by doctors; specialists were prepared to prescribe PPIs before primary care doctors, who remained very cautious in this respect, were prepared to do so;

— H2 blockers and PPIs were prescribed as part of the step-up or step-down in treatments; the 'step-down' approach, which was generally preferred by doctors, consisted in prescribing at the beginning of treatment PPIs in sufficient doses to control symptoms, then in prescribing milder pharmaceutical products, such as H2 blockers or other products (for example antacids); the 'step-up' approach consisted in administering relatively mild products initially (H2 blockers or other products) and subsequently PPIs when the products initially prescribed were not sufficient to treat the condition;

— in certain countries, including Germany, the high cost of PPIs might have been a relevant factor in the prescription of PPIs and in the choice between the 'step-up' or 'step-down' approach;

— PPIs were generally administered initially to treat the severe forms of gastro-intestinal conditions; however, their use seems to have expanded to the less severe forms of the conditions.

69 It is therefore apparent from the statements of the medical experts that, between 1991 and 2000, PPIs and H2 blockers were administered to treat the same conditions. However, it is also apparent from those statements that PPIs were generally prescribed to treat the severe forms of the conditions while H2 blockers were generally prescribed more to treat their mild or less serious forms.

70 In their statements, the medical experts sometimes stated that H2 blockers and PPIs were alternative first-line treatments, according to whether a 'step-up' or 'step-down' approach was adopted. However, the fact that PPIs were prescribed at the start of treatment or at a later stage, according to whether a 'step-down' or 'step-up' approach

was chosen, does not change the finding that PPIs and H2 blockers were prescribed in different situations, in the context of a gradation of treatments.

71 The fact that H2 blockers were prescribed to treat the same conditions as PPIs, or constituted, just as much as PPIs, first-line treatments, is of limited relevance, since it does not make it possible to determine whether, in the light of the therapeutic use of PPIs, which were used above all to treat the severe forms of the conditions, H2 blockers exercised a significant competitive constraint over them. It is absolutely clear from the abovementioned statements that, once it was necessary to control symptoms of a certain degree of severity, H2 blockers were replaced by PPIs, whether at the beginning of the treatment, when a 'step-down' approach was adopted, or at the end of it, when a 'step-up' approach was chosen.

72 It is therefore apparent from the statements of the medical experts submitted by the applicants during the administrative procedure that, although they were prescribed to treat the same conditions, PPIs and H2 blockers were used differently. While PPIs were essentially prescribed to treat the severe forms of gastrointestinal acid-related conditions, H2 blockers were prescribed to treat the less severe, or mild, forms of those conditions. It should also be noted, as the Commission observed at the hearing, that that fact was put forward by the applicants themselves in reply to the statement of objections (point 4.41(ii)(b) of the reply to the statement of objections).

73 The Commission was therefore right to find, in recital 389 of the contested decision, that the fact, put forward by the applicants during the administrative procedure, that PPIs tended to be used only to treat the more severe forms of the conditions supported the conclusion that there was a relevant product market comprising PPIs only.

74 The applicants cannot claim that the differentiated use of PPIs and of H2 blockers, according to the step-up or step-down in treatment, constitutes a new element which cannot be taken into account in the review of the lawfulness of the contested decision. It is apparent from the contested decision that the Commission did in fact take account of the differentiation in the therapeutic use of those products, in response, indeed, to the arguments put forward by the applicants, as is evident from recitals 389, 490 and 502 of the contested decision.

75 In this respect, it should also be noted that, on the basis of AZ's internal documents, the Commission found, in recitals 384 and 490 of the contested decision, that the first PPI placed on the market, Losec, prompted the H2 blocker firms to turn their attention towards treatment of the mild forms of the conditions, which have traditionally been treated by antacids and alginates, and even to make their products available on a non-prescription basis.

76 Moreover, the fact, alleged by the applicants, which rely in this respect on the IMS Health report, that major gastrointestinal conditions still gave rise at the end of the relevant period and in most of the countries to a significant proportion of H2 blocker prescriptions, does not invalidate the conclusion that the therapeutic use of H2 blockers and PPIs was differentiated. Similarly, the assertion that H2 blockers were, to a small extent (the IMS Health report states 10%), prescribed to treat the severe forms of the conditions corroborates the view — which stems from the evidence submitted

by the applicants themselves — that the severe forms of gastrointestinal acid-related conditions gave rise, overwhelmingly, to the prescription of PPIs.

77 The applicants and the EFPIA further claim that the Commission did not carry out any investigation as to doctors' actual prescribing practices and that the Commission chose data selectively from the IMS Health report without rebutting the other data contained in that report.

78 First of all, it should be recalled that it is important that the Commission bases its assessment on all the relevant data that must be taken into consideration in a specific case (see, to that effect, in relation to control of concentrations, *Commission* v *Tetra Laval*, paragraph 33 above, paragraph 39). That implies inter alia that the Commission is required to examine with particular attention the relevant arguments and evidence submitted to it by the undertakings involved in the administrative procedure (see, to that effect and by analogy, *GlaxoSmithKline Services* v *Commission*, paragraph 46 above, paragraph 276).

79 However, it cannot be inferred from this that the Commission must rely solely on the evidence that it has gathered as a result of its own investigations. It is permissible for the Commission to rely on evidence submitted by the parties to the administrative procedure, provided that that evidence is reliable and relevant, the onus being on the Commission, if necessary, to supplement it with other evidence where the information submitted by the parties to the administrative procedure proves to be insufficient or defective.

80 In this case, whilst it is true that the Commission did not undertake its own research into the therapeutic use of PPIs and H2 blockers by the medical community, the applicants produced several statements by medical experts which, as was observed in paragraphs 68 and 69 above, contained consistent evidence and also confirmed the relevant information in AZ's internal documents, to which reference is made in recital 502 of the contested decision. The Court therefore considers that the Commission was entitled, on that point, to take account of that information without carrying out its own investigations.

81 Next, as regards the alleged selective use of the data in the IMS Health report and the absence of any rebuttal of the other data in that report, and in so far as, by that argument, the EFPIA seeks to call in question the adequacy of the statement of reasons for the contested decision, it should be pointed out that the Commission is obliged to set out the reasons for not using certain data in a study only to the extent that the parties to the administrative procedure have put forward arguments during that procedure that were specifically based on those data and where it is apparent that those data are relevant. The Commission cannot in any event be required to set out systematically the reasons why it does not use or rejects certain data from a study, since it is sufficient that it states the reasons on which its decision is based, mentioning the facts and points of law which provide the legal basis for the measure and the considerations which have led it to adopt its decision. That applies all the more given that it is settled case-law that the Commission is not required to discuss all the issues of fact and of law which have been raised by the interested party during the administrative proceedings (Joined Cases 43/82 and 63/82 *VBVB and VBBB* v *Commission* [1984] ECR 19, paragraph 22; Joined Cases 142/84 and 156/84 *BAT and Reynolds* v *Commission* [1987] ECR 4487, paragraph 72; and Case T-2/93 *Air France* v *Commission* [1994] ECR II-323, paragraph 92).

82 Moreover, in so far as the EFPIA complains that the Commission failed to take into consideration certain elements of the IMS Health report, it must be stated that the EFPIA does not specify what those elements are, and the mere reference to the general conclusions of the IMS Health report is in this respect manifestly insufficient to identify any error by the Commission.

The relevance of the gradual nature of substitution of PPIs for H2 blockers

83 It should be noted, first of all, that it is common ground that the 'inertia' which characterised doctors' prescribing practices stems from their caution with regard to PPIs, in respect of which they were concerned about possible side effects. As the applicants claim, it is clear from the Lexecon report that doctors generally need time to get to know a new medicine and to be prepared to prescribe it. Similarly, it is apparent from the statements of the medical experts submitted by the applicants that prescribing doctors were concerned about the possible carcinogenic effects of PPIs.

84 The Court observes, next, that tables 17 to 23 in the Annex to the contested decision show that the number of PPI treatments prescribed increased gradually between 1991 and 2000 and overtook the number of H2 blocker treatments prescribed in Sweden in 1994, in Norway and Belgium in 1996, in Germany and Denmark in 1997, and in the Netherlands and the United Kingdom in 1998. Moreover, tables 9 to 15 in the Annex to the contested decision show that sales of PPIs, estimated in value terms, also increased gradually and overtook sales of H2 blockers in Sweden in 1992, in Belgium in 1994, in Denmark, Norway, the Netherlands and the United Kingdom in 1995 and in Germany in 1996.

85 The question whether during the relevant period H2 blockers exercised a significant competitive constraint over PPIs is a complex one which, as stated at paragraph 25 of the Notice on market definition, can be determined on the basis of a range of evidence consisting of various items, often of an empirical nature, the Commission having to take into account all relevant available information. In the present case, the applicants allege a manifest error of assessment by the Commission and focus, in the context of this plea, on a single aspect of the analysis carried out by the Commission in order to define the relevant market, namely they argue that the gradual nature of the increase in sales of PPIs at the expense of H2 blockers constitutes a decisive factor showing that, during the relevant period, H2 blockers must have exercised a significant competitive constraint over PPIs.

86 In order to evaluate the merits of the applicants' arguments, both in principle and in the specific circumstances of this case, it is necessary to place them in the theoretical framework adopted by the Commission in the Notice on market definition for the purposes of determining competitive constraints, in the light of which the Commission aims to assess the various available items of evidence in each specific case.

87 In paragraphs 15 to 19 of the Notice on market definition, the Commission states that it seeks to assess demand substitutability in the light of a theoretical approach which presupposes a small (in the range 5% to 10%) but permanent relative price increase in the product on the basis of which the relevant market is defined, and to evaluate whether that hypothetical increase could be applied profitably by the hypothetical monopolist of the relevant product. According to that economic test, as set out in paragraph 17 of the Notice on market definition, if substitution were enough to make such a price increase unprofitable because of the resulting loss of sales, substitutes must be regarded as exercising a significant competitive constraint over the relevant product.

88 As regards the specific case of the launch of a new product, and as is apparent inter alia from paragraph 45 of the Commission Notice establishing Guidelines on the applicability of Article 81 [EC] to horizontal cooperation agreements (OJ 2001 C 3, p. 2), it is often the case that the sales development of a new product substituting, even partly, for an existing product takes a certain amount of time, and accordingly, that those sales develop gradually.

89 In accordance with the theoretical framework (noted in paragraph 87 above) with which the Commission aims to assess the available items of evidence in order to assess whether an existing product exercises a significant competitive constraint over a new product, it is necessary to consider whether, account being taken at the same time of the gradual growth in sales of the new product, a small increase in the price of the new product would lead to a shift in demand towards the existing product in such a way that that price increase would not be profitable, in view of the income which would have been generated had that increase not taken place. It should be pointed out that the gradual nature of the growth in sales of the new product would not necessarily disappear if that price increase were profitable and, consequently, if it were concluded that the existing product does not exercise a significant competitive constraint over the new product.

90 Consequently, the Court finds that the Commission was entitled to take the view that, in principle, the gradual nature of the increase in sales of a new product substituting for an existing product cannot, in itself, suffice to conclude that the existing product exercises a significant competitive constraint over the new one.

91 Even if that conclusion is founded on reasoning which relies on an economic approach based on the observation of the reaction of demand to relative price changes, it is also applicable to the present case and is not invalidated by the specific features,

alleged by the applicants, which characterise pharmaceutical product markets, namely, in particular, that prescribing doctors and patients display only limited sensitivity to price changes. Whatever the actual applicability of the theoretical approach set out in paragraph 87 above to pharmaceutical product markets, and without needing to adopt a position in this respect, the Court notes that the assertion that prescribing doctors and patients are not sensitive to relative price changes does not affect the validity of the view that, in principle, the gradual nature of the increase in sales of a new product substituting for an existing product is not sufficient to conclude that the existing product necessarily exercises a significant competitive constraint over the new one.

92 In the present case, it is common ground that sales of PPIs increased gradually on account of the caution displayed by doctors towards a medicine whose properties were not yet entirely known to them and of their concerns about its possible side effects. However, the applicants adduce no evidence permitting the inference that that gradual increase in sales of PPIs was caused by a significant competitive constraint exercised by H2 blockers. They merely postulate a presumption of a causal link between the gradual nature of the increase in sales of PPIs and a competitive constraint exercised by H2 blockers over PPIs.

93 As was explained above, there is no such presumption in principle. Moreover, no element specific to this case gives grounds for the view that there is such a causal link in the present case. The applicants adduce no evidence to show that the caution displayed by doctors or their concerns in relation to PPIs influenced the ability of H2 blockers to exercise a significant competitive constraint over PPIs and, accordingly, the capacity of undertakings marketing PPIs to behave independently of H2 blockers.

94 It should be noted, in this respect, that it is common ground that the degree of 'inertia' of prescribing doctors influenced directly the level of income generated by PPIs and H2 blockers, since that 'inertia' slowed down sales of PPIs and, accordingly, the process of substitution of PPIs for H2 blockers. However, that fact alone does not show that H2 blockers exercised a significant competitive constraint over PPIs.

95 At the hearing, the applicants asserted that it was not possible to take the view that H2 blockers did not exercise any significant competitive constraint over PPIs in 1993, given that PPIs were still entering only tentatively into the market of H2 blockers, as evidenced by the difference between the still modest sales of PPIs and the much higher sales of H2 blockers in Germany, Belgium, Denmark, Norway, the Netherlands and the United Kingdom.

96 The Court points out, however, that the fact that sales of PPIs were much lower than those of H2 blockers in 1993 does not permit the conclusion that the latter exercised a significant competitive constraint over PPIs during that year. Likewise, the fact that, at a certain point in time, sales of PPIs overtook sales of H2 blockers is not in itself capable of showing that H2 blockers no longer exercised a significant competitive constraint over PPIs at that specific point. None the less, the finding of a trend of asymmetrical substitution characterised by the growth in sales of PPIs and the decrease or stagnation in sales of H2 blockers, in conjunction with the finding of a repositioning in the use of H2 blockers towards the treatment of the milder forms of the conditions, which have traditionally been treated by antacids and alginates, on account of the fact that PPIs were becoming increasingly dominant (see recitals 384 and 490 of the contested decision), supports the view that H2 blockers did not exercise any significant competitive constraint over PPIs.

97 Moreover, the fact that PPIs exercised a considerable competitive constraint over H2 blockers and, consequently, that PPIs belonged to the H2 blocker market between 1991 and 2000 is irrelevant in the context of this case, since it does not mean that H2 blockers exercised a significant competitive constraint over PPIs and, therefore, that H2 blockers belonged to the PPI market. The definition of the relevant market consists, in the present case, only in identifying the significant competitive constraints on PPIs during the relevant period and is therefore not concerned with the competitive constraints that PPIs might have exercised over other products. As the Commission rightly observed in recital 493 of the contested decision, it is clear from paragraph 3 of the Notice on market definition that the concept of relevant market is different from other definitions of market often used in other contexts, such as the area where the companies sell their products or, more broadly, the industry or sector to which the companies belong. Thus, the fact that H2 blockers were Losec's primary competitive focus does not mean that H2 blockers exercised a significant competitive constraint over Losec.

98 The applicants further claim that 'inertia' on the part of prescribing doctors depends on how good the pre-existing medicine is and what advantages the new product has. In this respect, it may be accepted that the quality of the pre-existing product may influence the degree of 'inertia' of prescribing doctors, in so far as, where there are doubts about the side effects of the new product, those doctors may consider it more prudent to continue prescribing the pre-existing product if its therapeutic efficacy is deemed sufficient. In the present case, the Court none the less points out that it is evident from the material in the file, and in particular from the Lexecon report and the statements of the medical experts submitted by the applicants themselves, that the 'inertia' characterising prescribing practices stems primarily from the caution that normally characterises doctors' attitudes towards a new product with whose properties they are not yet very familiar and, more specifically, from their significant concerns as to the possible carcinogenic side effects of PPIs.

99 The applicants cannot therefore claim that the 'inertia' characterising doctors' prescribing practices is, as a whole, attributable to the therapeutic quality of H2 blockers.

100 To the extent that the applicants seek to claim that the quality of H2 blockers significantly influenced the degree of 'inertia' characterising doctors' prescribing practices, the Court notes that they adduce no evidence to that effect, whereas the material in the file tends to indicate that that was not the case. It is not disputed that the therapeutic power of PPIs is much greater than that of H2 blockers. As the Commission found in recital 382 of the contested decision, PPIs were thus deemed to provide the only effective remedy to treat a number of gastrointestinal acid-related conditions, and more specifically the severe forms of those conditions. The fact that PPIs and H2 blockers were prescribed sequentially in the context of a single course of treatment, depending on whether that treatment was being stepped down or stepped up, does not affect that finding. On the contrary, it tends to confirm it.

101 Moreover, as the Commission observes, it is apparent from tables 17 to 23 in the Annex to the contested decision that the number of PPI treatments in 2000 was much higher than the number of H2 blocker treatments in 1991 in most of the relevant countries. Thus, the number of PPI treatments in 2000 is considerably higher than the number of H2 blocker treatments in 1991 or 1992 in Denmark, Norway, the Netherlands and in Sweden, and, to a significant extent, in Germany. It is only in Belgium and the United Kingdom that the numerical superiority of PPI treatments in 2000 over H2 blocker treatments in 1991 was less pronounced.

102 The fact that PPIs were deemed to be the only effective treatment for the severe forms of gastrointestinal conditions, that PPIs and H2 blockers therefore had different therapeutic uses and that the growth in PPIs was in many cases very largely not at the expense of H2 blockers supports the argument that the 'inertia' of doctors depended more, as the Lexecon report concluded, on the accumulation and dissemination of information on the properties of PPIs than on the quality of H2 blockers.

103 The applicants submit that the finding that the number of PPI treatments in 2000 was appreciably higher than the number of H2 blocker treatments in 1991 or in 1992 cannot be taken into consideration in the review of the lawfulness of the contested decision, since that fact was not expressly referred to in that decision. However, the Court points out that that finding was made on the basis of the tables annexed to the contested decision. It cannot therefore be considered to constitute a new element which cannot be taken into consideration, at the stage of the review of the lawfulness of the contested decision, for the purposes of responding to an objection against the Commission's reasoned assessment that the gradual nature of the increase of PPIs does not necessarily show that H2 blockers exercised a significant competitive constraint over PPIs.

104 The EFPIA also claims that it is not sufficient to show that sales by value of PPIs increased and sales by value of H2 blockers decreased or stagnated in order to conclude that the latter no longer exercise any competitive constraint over PPIs. However, and as is apparent from the examination of the second plea, the Court points out that the Commission's analysis does not rely on that finding alone, the Commission having, on the contrary, based its definition of the relevant product market on a series of factors, namely therapeutic uses, price indicators and the 'natural events' observed in Germany and the United Kingdom, and those factors were indeed contested one by one by the applicants and the EFPIA.

105 Lastly, it is necessary to reject the applicants' argument alleging that the Commission lacked consistency in so far as, in the contested decision, on the one hand, it rejected the relevance of the phenomenon of 'inertia' characterising prescribing practices in the context of its analysis of the market definition, and, on the other hand, accepted the relevance of that phenomenon of 'inertia' in the context of the assessment of AZ's dominant position. In this respect, the Court notes that, as the Commission observes, 'inertia' is a factor which is liable to reinforce the market position of an incumbent product by creating barriers to entry or expansion for competing products newly introduced on the market. That circumstance is not however at odds with the view that the 'inertia' of prescribing doctors does not permit the inference that H2 blockers exercised a significant competitive constraint over PPIs.

106 It follows from all the foregoing that the Commission did not commit a manifest error of assessment in rejecting the argument that the gradual nature of the increase in sales of PPIs at the expense of H2 blockers meant that H2 blockers exercised a significant competitive constraint over PPIs and that H2 blockers had, for that reason, to be included in the relevant product market.

107 The Court therefore dismisses the applicants' first plea in law with regard to the definition of the relevant market.

3. *The second plea in law, alleging various inconsistencies and errors of assessment*

(a) Arguments of the applicants and of the EFPIA

108 The applicants and the EFPIA submit, in the first place, that the Commission did not take sufficient account of the therapeutic use of the products under consideration for the purpose of defining the market. They take issue, first of all, with the Commission's assertion, in recital 373 of the contested decision, that it attributed significant weight in its previous decisions to differences between medicines' modes of action. The previous decisions adopted by the Commission on the basis of Council Regulation (EEC) No 4064/89 of 21 December 1989 on the control of concentrations between undertakings (OJ 1989 L 395, p. 1) to which the Commission refers in that regard, namely its decisions declaring compatible with the common market the concentrations of 26 February 1999 (Case COMP/M.1403 — Astra/Zeneca), of 17 May 1999 (Case COMP/M.1397 — Sanofi/Synthelabo), and of 27 February 2003 (Case COMP/M.2922 — Pfizer/Pharmacia), do not reflect that assertion, since the Commission took into account differences between medicines' modes of action where those modes of actions gave rise to different therapeutic uses, and rejected the relevance of the lack of similarities between modes of action where the medicines in question retained a similar therapeutic use.

109 The EFPIA adds that, in its previous decisions, the Commission normally takes, as the starting point of its analysis for defining the market, the therapeutic use of the product concerned, which led it to take account of the third level of the Anatomical Therapeutic Chemical Classification System ('ATC'), which generally groups medicines together in terms of their therapeutic indications.

110 The applicants and the EFPIA submit, next, that the Commission's approach is flawed in so far as it relies excessively on a description of the therapeutic characteristics of the products, which are irrelevant for the purposes of market definition, rather than assessing how those characteristics impacted on the choices made by decision-makers in the period between 1993 and 2000. The substitutability of prescription medicines depends not on their physical, technical or chemical properties but on their functional substitutability as viewed by those supervising their consumption, namely medical practitioners (Commission Decision 97/469/EC of 17 July 1996 in a proceeding pursuant to Regulation No 4064/89 (Case IV/M.737 — Ciba-Geigy/Sandoz) (OJ 1997 L 201, p. 1, recital 21)). The EFPIA claims that the technical superiority of a product in a given pharmaceutical category does not shield it from competitive constraints from the other products (Commission Decisions of 27 May 2005 (Case COMP/M.3751 — Novartis/Hexal) and of 22 May 2000 (Case COMP/M.1878 — Pfizer/Warner-Lambert)). When doctors prescribe a medicine, they base their decision on medical grounds such as active principle, tolerance, toxicity, and side effects of the medicine. However, the Commission did not single out any one of those medical grounds as being decisive in seeking to establish substitutability of medicines.

111 The EFPIA thus complains that the Commission failed to analyse the key factors influencing the behaviour of prescribing doctors, and at the same time failed to refute the evidence submitted by the applicants showing that doctors saw PPIs and H2 blockers as having the same therapeutic use. The Commission is therefore inconsistent in relation to its previous decisions and erred in fact and in law by using mode of action as a key characteristic of PPIs for the purposes of the defining the relevant market.

112 The applicants point out, in the second place, that the Commission's analysis relies on sales trends, absolute price differences and a correlation study. However, price-related indicators are inappropriate for competition analysis purposes where competition on the market in question is not based on price. On the other hand, non-price factors play a key role. In addition, the Commission relied excessively on the correlation

study submitted by the complainants, in order to prove the absence of significant competitive interaction between PPIs and H2 blockers, even though it questioned the reliability of that study because of methodological weaknesses. The applicants refer in particular to recitals 368, 411, 416, 436, 440, 447 and 451 of the contested decision.

113 The applicants and the EFPIA submit that the Commission should not have relied on the differences between the absolute prices of PPIs and those of H2 blockers in order to conclude that there was an absence of competitive interaction between those products. Firstly, the applicants state that the Commission accepted, in particular in recitals 362 and 363 of the contested decision, that prices were not determined by normal competitive interaction and that the decision-maker (doctor) and price regulation played key roles. In that regard, the EFPIA states that the setting by the public authorities of a higher price for PPIs than for H2 blockers simply reflects the authorities' perception of the value to public health, and the contribution to innovation, of the product concerned compared with existing products. Thus, a product with a high degree of innovation receives a higher price than existing products with the same therapeutic use. The gap between the price of the new product and those of existing products is even likely to increase, since the downward pressure exerted by the government on the price of prescription drugs targets older or off-patent products more aggressively. Manufacturers are therefore not free to set the prices of their products themselves. In addition, the price-setting process has limited impact on the consumption process, since doctors are not very price-sensitive and focus more on the therapeutic efficacy of products.

114 Secondly, the applicants point out that market definition involves an assessment of how consumers respond to changes in relative prices. Absolute price levels are therefore irrelevant so far as competitive interaction is concerned. Thirdly, the

Commission's assertion that Losec is more costly than H2 blocker alternatives is inconsistent with the consideration that PPIs are more cost-effective than H2 blockers. The Commission did not take account of the fact, despite having accepted it in recitals 38, 382 and 385 of the contested decision, that PPIs enable patients to be treated more quickly and that, therefore, the overall cost of treatment with PPIs is lower, even though the cost of a daily PPI dose is higher than the cost of an equivalent daily H2 blocker dose.

115 The applicants therefore dispute that a measure based solely on volume is incapable of reflecting therapeutic differences between products. Such a measure reflects the required number of treatment days to treat a given condition and better translates the relative proportions of usage of two different drugs by patients at a given point in time, unlike a value-based measure.

116 In reply to the Commission's argument that the fact that AZ was given the opportunity to negotiate higher prices for PPIs indicates that PPIs are in a product market separate from that for H2 blockers, the applicants submit that the Commission did not carry out any investigation of the actual process by which PPI prices were agreed in individual Member States. They explain, in that regard, that AZ sought a price which was equal to twice the price of Zantac on a 'price per day' basis, on the grounds that the overall cost per treatment course would be the same, since such a price would reflect Losec's greater efficacy.

117 The applicants and the EFPIA claim, thirdly, that, in regard to Germany and the United Kingdom, the Commission placed excessive reliance on isolated 'natural events'. They submit that, when changes in a particular variable are affected by many factors simultaneously, econometric analysis serves to assess the effect of an individual

factor in isolation while taking into consideration the effect of all other factors. The Commission cannot therefore attribute all the effect to an individual factor, as it did by focusing on 'natural events'. Taking as a basis the Lexecon report, they submit that it was necessary to assess the simultaneous effect of the following factors: the price of Losec and competing products, the entry on the market of competing products, the number of presentation forms available for Losec and competing products, the promotional activity for all products on the market, the dates when new indications for Losec were approved and the time trend. The applicants add that the Lexecon report demonstrates that H2 blockers were in the same market as PPIs and maintain that they responded to the criticisms set out by the Commission in recitals 458 to 487 of the contested decision regarding the methodology used by that report.

118 The applicants state that, so far as Germany is concerned, the Commission analysed three events, namely the entry of the second PPI (pantoprazole) in 1994, the introduction of the generic H2 blocker ranitidine in 1995 and the introduction of generic omeprazole in 1999. As regards the first event, relating to the market entry of pantoprazole, the applicants submit that the apparent interaction between the prices of Losec and other PPIs and the apparent absence of interaction between the prices of PPIs and H2 blockers do not demonstrate that PPIs and H2 blockers were in separate product markets. They maintain that, when prescribing medicines, doctors are sensitive to their therapeutic properties and not so much to their prices. Therapeutic substitutability as perceived by prescribing doctors is therefore an essential aspect and the Commission was therefore not justified in focusing its analysis on price competition. The Lexecon report shows that, after the launch of pantoprazole, the decline in the market share of H2 blockers increased significantly, which indicates that pantoprazole had taken market share at the expense of H2 blockers and that those products were therefore in the same market.

119 As regards the second event studied by the Commission, relating to the market entry of the generic H2 blocker ranitidine in August 1995, the applicants again maintain that an analysis founded on relative prices is of limited value. Regardless of relative prices, prescribing doctors viewed H2 blockers and PPIs as therapeutic substitutes during the relevant period. It is apparent from figures 2 and 3 in the Lexecon report that the market share enjoyed by H2 blockers was in sharp decline prior to the introduction of ranitidine. The applicants and the EFPIA state that the introduction of that generic caused an increase in the market share, estimated by volume, of H2 blockers for a period and then slowed the rate of decline in their market share. Moreover, the market share of Losec suffered a significant drop as a result of the introduction of ranitidine and the rate of increase in the market share of other PPIs levelled off when that generic was introduced. In the view of the applicants and the EFPIA, those figures show that the introduction of ranitidine had an adverse effect on the market shares of Losec and other PPIs, which indicates that those products were in the same market.

120 The EFPIA adds that the Commission's explanation that the launch of ranitidine in Germany exerted strong pressure on the prices of other H2 blockers but did not affect the price of PPIs overlooks the fact that price setting results from government regulation and that the different pricing evolution of a cluster of products compared with other products reflects government policy, and that may vary from one Member State to another.

121 In reply to the Commission's argument in recital 424 of the contested decision that the introduction of ranitidine strongly influenced promotional activity in the H2 blocker segment, and not in the PPI segment, the applicants dispute that promotional activity in relation to PPIs did not increase when that generic was introduced. According to them, although it had been generally decreasing, the level of promotional activity both for Losec and for other PPIs (lansoprazole and pantoprazole) increased at the time of the introduction of the generic ranitidine. The applicants observe, furthermore, that one isolated incident in time in relation to promotional activity cannot

be claimed to represent a position that applied throughout the relevant period of the alleged abuses, between 1993 and 2000. In that regard, they state that promotional activity for H2 blockers increased significantly at the time of the market entry of the PPI lansoprazole in June 1993, but decreased at the time of the market entry of the PPI pantoprazole in September 1994. This suggests that promotional strategies did not respond solely to isolated events in the market. For a significant part of the relevant period, promotional activity for H2 blockers was significant in order to compete against the new PPI technology. The applicants further maintain that the events surrounding the introduction of the generic ranitidine in August 1995 were of limited evidential value for the purpose of identifying the relevant product markets during the period between 1993 and 2000. The Commission itself accepted that those events would corroborate the existence of a distinct PPI market in Germany only in respect of August 1995.

122 As regards the third event, relating to the launch of the generic omeprazole in Germany in April 1999, the applicants submit that the Commission's conclusion, set out in recital 425 of the contested decision, that the significant effect of the launch of the generic omeprazole on Losec's volume of sales and market share demonstrates that Losec was not constrained as much by H2 blockers, is unfounded. The applicants maintain that the fact that, in April 1999, Losec was constrained most by generic omeprazole does not mean that it was not also constrained by H2 blockers both at that point in time and during a previous or following period.

123 Regarding the United Kingdom, the applicants submit that it is not possible, on the basis of the general information set out in table 16 in the Annex to the contested decision, to justify the Commission's assertions, in recitals 452 to 456 of the contested decision, that sales of Losec remained unaffected and its price increased despite the

introduction of cheaper generic ranitidine in January 1997. Figure 7 in the Lexecon report shows that, at the time when generic ranitidine entered the United Kingdom market, total sales of Losec and other PPIs had dropped, whilst the trend of those sales was generally upward.

124 Finally, the applicants complain that the Commission's empirical assessment for the purposes of market definition was limited. The Commission's primary basis for its conclusions was a correlation analysis submitted by a complainant, which it acknowledged as being of limited use, and an anecdotal discussion of market characteristics. In contrast, the applicants submit that it was necessary to address the issue of market definition on the basis of four separate and complementary sources of evidence. Firstly, the expert medical evidence demonstrates that doctors had only gradually come to view the molecules in question as therapeutically substitutable products. Secondly, the internal strategy documents reflect the competitive relationship between H2 blockers, which were the incumbent therapy with which prescribers were satisfied, and omeprazole. Thirdly, the IMS report, which studied prescribing patterns over time, shows that PPIs and H2 blockers were prescribed for the same micro-diagnoses with very limited segmentation in usage patterns. According to the applicants, whilst the general trend in all countries was to prescribe relatively more PPIs over time, the relative decline in H2 blockers was only gradual. Fourthly, the applicants carried out an econometric analysis in respect of Germany and the United Kingdom, the results of which were consistent with those of the three other sources of evidence.

(b) Arguments of the Commission

125 The Commission challenges *seriatim* the arguments of the applicants and the EFPIA alleging inconsistencies and errors on its part. Thus, as regards, first of all, product characteristics, on which it is accused of having relied excessively, the Commission contends that it did not regard differences in the mode of action of medicinal products as a decisive or relevant factor in itself. The mode of action of PPIs was identified as determining the therapeutic effectiveness of PPIs relative to H2 blockers and served to explain prices and sales data. The Commission therefore submits that the applicants are not justified in asserting that it relied on a description of therapeutic characteristics, rather than assessing how those characteristics impact on the choices made by decision-makers.

126 As regards the EFPIA's argument alleging inconsistency between the contested decision and the Commission's previous practice, the Commission submits, firstly, that its previous practice does not constitute a benchmark for the lawfulness of a decision. Secondly, in any event, it denies that it contradicted itself. In this case, the Commission found that the third level of the ATC did not reflect market reality, since it listed in class A2B only peptic ulcer disease, which represented only a decreasing proportion of the gastrointestinal acid-related conditions for which PPIs were used, and excluded reflux disease and dyspepsia. The differences in physical, technical or chemical properties between PPIs and H2 blockers were therefore relevant, since the differences in modes of action between PPIs and H2 blockers explained the superior efficacy of the former, the significant expansion of their sales and the limited substitutability between those two products. The Commission also contends that the US anti-trust authorities have defined pharmaceutical product markets below the third level of the ATC, by reference to modes of action or to individual molecules.

127 Next, as regards the allegedly unjustified importance attributed to price-based results, the Commission maintains that, in relation to differentiated products, sales by value are the better indicator of the relative position and strength of different suppliers, since a purely volume-based measure is unable to reflect either differences in recovery times or the non-temporal therapeutic differences between products, such as higher success rates. In addition, value-based measurement of sales takes into account both volume, which tends to be lower per patient for PPIs than for H2 blockers, and price, which tends to be higher for PPIs, due to their efficacy. The Commission points out that those considerations are not affected by the relatively low degree of price sensitivity displayed by decision-makers on the demand side, in so far as, firstly, the measurement of sales patterns is a distinct issue from that of price elasticity, since sales patterns reflect non-price factors, in that they make it possible to assess the responses of the market to the varying merits of differentiated products, and, secondly, the price negotiation process is heavily influenced by differentiating factors between different medicines in terms of both their therapeutic value and their cost effectiveness. It further contends that, even if the volume-based sales data were to be taken into account, similar demand trends to those shown by the value-based data would appear from the volume data, although in a less pronounced fashion (recital 394 of the contested decision).

128 The Commission disputes the EFPIA's argument that it did not conduct an independent analysis of price and sales trends. It relied on the data contained in the IMS Health report and interpreted them differently from the applicants. It also rejects the claim that it made selective use of those data and contends that IMS Health's conclusion that PPIs and H2 blockers were prescribed for all the major micro-diagnoses during the relevant period was put back in its context, which was characterised by one-way substitution, expansion of overall sales and repositioning of H2 blockers towards milder gastrointestinal conditions.

129 With regard to the allegedly exaggerated significance attached to the Charles River associates (CRA) correlation study, the Commission points out that that study was considered, in recital 407 of the contested decision, to be a subsidiary source of evidence. It states that price correlations between products based, respectively, on the same active substance, on different active substances in the same class, and on different active substances in different classes are based not only on the CRA study, but also on the Lexecon report. Moreover, that reference is made in the discussion of the price-setting process and tends to confirm the Commission's finding that the therapeutic efficacy and cost effectiveness of different medicines are key factors in determining the relative bargaining position of firms engaged in price negotiations with national buying organisations. The Commission adds that the other references to the CRA correlation study were made prudently, in order to establish that, prima facie, there was no material substitution between PPIs and H2 blockers.

130 With regard to the allegedly unjustified importance attached to absolute price levels, the Commission states that the specific features of European pharmaceutical product markets do not lend themselves to an approach which consists in testing consumers' reactions to changes in relative prices. In the contested decision, the Commission made findings relating to prices in different competitive relationships. In the case of products based on the same active substance (AZ's omeprazole and generic omeprazole), price competition is intense. On the other hand, with regard to the relationship between different active substances entailing significant differences in terms of therapeutic efficacy (such as PPIs and H2 blockers), changes in relative prices have very limited relevance. Thus, in the light of the peculiarities of the sector, absolute price differences gave a significant indication of competitive constraints, since companies offering a superior class of products in terms of therapeutic efficacy are normally able to negotiate higher prices with buying organisations.

131 In that regard, the Commission disputes the EFPIA's approach of considering that prices do not represent a relevant parameter of competition since companies do not set prices as in normal markets and doctors are not very price-sensitive. It explains that the price reflects the interplay between various factors, such as the value added provided by new products, negotiations with buying organisations, commercial decisions by companies on pricing under systems that allow companies to price freely (such as reference-price systems), national rules on pharmacy substitution, or the entry of new products.

132 In the light of the fact that innovation is a key competitive factor in the pharmaceutical sector, the superior efficacy of a medicine resulting from innovation is generally reflected in the acceptance by buying organisations of higher prices than those negotiated for less innovative products already present on the market. In view of the fact that the pharmaceutical company is not obliged to launch its new product on the market of a given country, the securing of higher maximum prices or reimbursement levels than for existing products tends to confirm the therapeutic superiority of an innovative product and to indicate that incumbent products do not exert sufficient constraints to permit the buying organisation to hold prices at pre-existing levels. Similarly, the maintenance or increase over time of differentials in reimbursement levels, maximum prices agreed or prices actually applied in the market tend to confirm that the innovative product is not subject to significant constraints. According to the Commission, the presence or absence of competitive constraints from other products and the consequential effects on pricing negotiations are factors relevant to the commercial prospects of pharmaceutical companies and therefore constitute decisive factors in defining a product market.

133 The Commission asserts that supply and demand also play a role in the pricing process, in so far as the price is ordinarily a function of the buying organisation's willingness to pay, which will depend on its ability to pay and the value it places on the

medicine in terms of therapeutic efficacy and innovation, and the pharmaceutical company's willingness to supply. The fact that public policies vary according to the country or time in question does not negate the relevance of price, since it is not disputed that greater therapeutic efficacy relative to existing products is invariably a relevant factor in negotiations. It adds that the fact that the price of Losec was much more sensitive to the market entry of medicines based on similar or identical molecules than it was to inferior drugs such as H2 blockers, far from being due to the arbitrary exercise of regulatory power, corroborates that view.

134 The Commission disputes the EFPIA's assertion that manufacturers are not free to set the prices of their products and states that, of the countries taken into account, the United Kingdom uses free pricing, Belgium sets only maximum prices and five States apply reference price systems under which pharmaceutical firms are free to price above the reimbursement level. The Commission submits, moreover, that the fact that prices agreed with buying organisations were above the competitive level is supported by the fact that the price of Losec and other PPIs dropped significantly after the entry of generic omeprazole in Germany in 1999.

135 The Commission adds that although there is agreement that price does not greatly influence doctors' prescribing patterns, since doctors are primarily guided by therapeutic considerations, price greatly influences the revenues derived from consumption. Consequently, the constraints on the commercial behaviour of a producer of PPIs must be evaluated not only by reference to the question whether H2 blockers constrained sales, but also by reference to the question whether H2 blockers constrained prices.

136 As regards the applicant's argument to the effect that the overall cost of treatment with PPIs is lower due to the fact that the treatment is shorter, the Commission submits that this argument derives from a 'simplistic quantification' of the relative cost-effectiveness of PPIs and H2 blockers. It states, in that regard, that this argument takes into account only a single parameter, namely healing time, and does so in respect of only one of the conditions for which Losec was authorised, namely peptic ulcer. In addition, this argument leaves out of account the fact that PPIs are significantly superior to H2 blockers in terms of healing rates, symptom relief and prevention of relapse, and that PPIs and H2 blockers were considered to occupy different positions in the hierarchy of treatments. *[confidential]*

137 Moreover, the introduction of a superior new drug may lead to a considerable number of new sales in circumstances where previously available treatments were not used, and as a result of the use of the new drug in combination with the pre-existing product. In that regard, combined sales of H2 blockers and PPIs in the countries concerned increased by over 50% between 1993 and 1999, whilst there is no evidence that the corresponding medical conditions increased in similar proportion. It is therefore likely that the introduction of PPIs was accompanied by a rise in the absolute cost of treatment of gastrointestinal acid-related conditions.

138 Furthermore, the Commission points out that, during the oral procedure, the applicants did not contest that PPIs were more expensive than H2 blockers. In any event, there are no grounds for making the adjustment proposed by the applicants, since the therapeutic superiority of PPIs made it possible to secure higher absolute prices per unit, on the one hand, and led to doctors increasingly prescribing them, on the other. Consequently, to adjust prices on account of the therapeutic superiority of

PPIs would amount to disregarding the factor which put PPIs beyond the competitive reach of H2 blockers.

139 With regard to the allegedly incorrect interpretation of the importance of 'natural events', the Commission states that it is necessary that the event examined be an isolated one, examined against an otherwise fairly stable background. It submits that the applicants are wrong to maintain that the Commission relied on individual events observed in two countries in order to define the market between 1993 and 2000 in seven countries. The Commission's event analysis supplements and confirms findings relating to a wide range of factors, such as product characteristics, sales, substitution and price patterns during the years in question. The Commission further submits that, even seen in isolation, the 'natural events' identified in Germany and the United Kingdom in themselves constitute strong evidence that H2 blockers did not impose any significant competitive constraint on PPIs. The Commission adds that the Lexecon report failed to address a number of doubts regarding autocorrelation, the specification of the model that assumes that H2 blockers and PPIs form part of the same market, and the 'cellophane fallacy'. Moreover, the conclusions of the Lexecon report are not inconsistent with the existence of a separate market for PPIs in Germany and the United Kingdom, a finding which is not contested by the applicants. In response to the argument that it did not carry out its own econometric study, the Commission contends that its study relies on a number of factors contained in the file. It observes, however, that the specific features of the market make it difficult to apply standard econometric models of demand substitution.

140 The Commission also points out that the applicants do not identify the specific contemporaneous events which need to be taken into account in interpreting the events identified by the Commission in the United Kingdom and German markets. It denies, moreover, that its assessment is not based on detailed factual data, since that assessment is based inter alia on the IMS Health data concerning demand and prices for the

products concerned and on the data provided by AZ itself at the time of the response to the statement of objections.

141 The Commission then addresses in turn the 'natural events' analysed in the contested decision. As regards, first of all, the market entry of pantoprazole in Germany in 1994, it notes that the further decline in market share of H2 blockers after the launch of pantoprazole indicates that PPIs gained sales at the expense of H2 blockers and benefited from substantial expansion sales. In the Commission's view, whilst that development indicates that PPIs were a significant competitive constraint on H2 blockers at that time, it does not demonstrate that the reverse is also true.

142 As regards the market entry of the generic ranitidine in Germany in 1995, the Commission disputes that Losec sales suffered upon the introduction of that generic product, whilst sales of other PPIs stopped increasing for a while, and points out that the Lexecon figures are based on volume. It notes that the applicants do not explain why, in this case, sales by value are not a more appropriate indicator as regards differentiated products. In value terms, sales of PPIs, as a proportion of the combined sales of PPIs and H2 blockers, continued to increase from 32% in 1994 to 42% in 1995, to 57% in 1996 and to 67% in 1997 (table 16 annexed to the contested decision; the Commission also refers to the trend of sales of PPIs in absolute value terms, shown in table 11 of that annex). In any event, the annual sales figures by volume do not support the applicants' argument, since table 19 annexed to the contested decision shows that in Germany there was an unbroken decrease in annual volume sales of H2 blocker treatments between 1994 and 1997, and an unbroken rise in annual volume sales of PPIs during the same period. As regards the EFPIA's argument that the introduction of generic ranitidine in Germany in 1995 caused a fall in the market share, by volume, of

Losec, the Commission points out that the sole relevant comparison is that between H2 blockers and PPIs and not that between H2 blockers and Losec only.

143 The Commission submits that it is not possible to conclude, on the basis of figures 5 and 6 in the Lexecon report, that the number of promotional visits to doctors in relation to Losec was decreasing. It notes that figure 5 in that report indicates that the number of promotional visits to doctors in relation to H2 blockers more than doubled around the time of entry of generic ranitidine and thereafter fell back again to its previous leve1. The conclusion drawn by the Commission in recital 424 of the contested decision is therefore valid. Moreover, the Commission maintains that the analysis of 'natural events' focused on certain identifiable events which resulted in substantial, observable effects over a short period. Accordingly, the contested decision takes account only of the specific event of the entry of generic ranitidine in Germany, since that is the only event presenting a clear link with the number of promotional visits to doctors.

144 As regards the entry of generic omeprazole on the German market in 1999, the Commission argues that the impact of generic omeprazole on Losec sales and prices is to be interpreted in conjunction with the manifest lack of effect, on PPI prices and sales, of the entry of generic ranitidine. The argument that the identification of a product's closest substitute does not exclude the existence of other close substitutes does not enable the applicants to overturn the Commission's conclusion that, in Germany, H2 blockers did not exercise a sufficiently significant competitive constraint to be included in the same market as PPIs.

145 As regards the market entry of the generic ranitidine in the United Kingdom in 1997, the Commission states that table 16 annexed to the contested decision shows that PPI sales, expressed as a proportion of combined sales of PPIs and H2 blockers, continued to increase in the United Kingdom in 1997 and afterwards, despite the entry of generic H2 blockers on 1 January of that year. Tables 30 and 37 annexed to the contested decision show, furthermore, that Losec sales and prices increased in 1997. In

the Commission's view, even taking into account the data relating to sales in volume terms, it is not possible to deduce from figure 7 in the Lexecon report that Losec sales had dropped significantly at the time of entry of the generic ranitidine into the United Kingdom market, since the drop in Losec sales is not out of the ordinary compared with the general variations in sales by volume, measured on a monthly basis. In addition, sales of other PPIs, in volume terms, continued to progress without interruption.

146 The Commission submits that the applicants' claim that the empirical examination undertaken by it was too limited is unfounded and that the list of evidence adduced by them does not alter the considerations set out above. It also disputes the applicants' conclusion and submits that it is irrelevant that sales of H2 blockers were still significant at the end of the relevant period, since the existence of a separate market is not conditional on the fact that sales of a category of products have become very weak.

(c) Findings of the Court

147 The grounds of complaint set out by the applicants and the EFPIA can essentially be grouped together around three issues: failure to take sufficient account of therapeutic use, excessive attention paid to price indicators, and the excessive importance attached to 'natural events'. Those grounds of complaint will be examined in turn below.

The account taken of the therapeutic use of the relevant products

148 The applicants and the EFPIA claim in essence that the Commission relied excessively on a description of the therapeutic characteristics of the products, without taking into account the therapeutic uses of the relevant products, which, in their view, are identical.

149 The Court observes in this respect that, in recitals 373 to 379 of the contested decision, the Commission began its analysis of the market definition by stating, in the first place, that PPIs and H2 blockers displayed significant differences in terms of mode of action. The Commission thus noted that, on account of their unique mode of action, which was to act directly on the acid-producing proton pump, PPIs were therapeutically superior to H2 blockers. Although it regarded mode of action as the key product characteristic, it was careful to state, in recital 378 of the contested decision, that this factor alone did not suffice to establish a separate market.

150 In the second place, therefore, the Commission focused on the therapeutic uses of PPIs and H2 blockers. In recital 382 of the contested decision, it found that, in a number of cases involving peptic ulcer diseases, ulcers induced by non-steroidal anti-inflammatory medicine, Zollinger-Ellison-syndrome, gastrointestinal oesophageal reflux and dyspepsia, PPIs were deemed to provide the only effective remedy in terms of symptom relief, healing and long-term prevention of relapse. The Commission also found, in recitals 384 and 490 of the contested decision, that Losec put significant competitive pressure on H2 blockers, which forced H2 blocker firms to focus on milder downstream conditions for which antacids and alginates have traditionally

been used. It is inter alia for that reason that H2 blockers could be obtained over the counter during the relevant period.

151 That finding is to a large extent supported by the statements of the medical experts submitted by the applicants during the administrative procedure, from which it is apparent, as is mentioned in paragraph 68 above, that PPIs were generally used to treat the severe forms of the conditions while H2 blockers were reserved more for their milder forms. In recital 389 of the contested decision, the Commission thus found that the therapeutic superiority of PPIs had led to a hierarchical relationship between PPIs and H2 blockers, those products being used at different stages of the treatments, depending on whether those treatments were being stepped down or stepped up.

152 Consequently, it emerges unequivocally from the contested decision that the Commission did not confine itself to establishing the therapeutic characteristics of the products for the purposes of defining the relevant market. On the contrary, the mode of action of PPIs was considered an essential factor only in so far as it determined that PPIs were therapeutically superior to H2 blockers. That therapeutic superiority was then considered to be a factor determining the difference in the respective therapeutic uses of PPIs and H2 blockers and, accordingly, the relationship between those products in terms of functional substitutability.

153 Therefore, although, as is apparent from the Commission's previous decisions referred to in paragraph 108 above, the applicants are justified in observing that it is necessary to take account of differences between medicines' modes of action where they give rise to different therapeutic uses and to disregard them where the medicines in question have a similar therapeutic use, they cannot claim that the Commission did not take therapeutic use into consideration in the present case. It is apparent from the contested decision that the Commission took due account of those therapeutic uses in its analysis.

154 As regards the ground of complaint that the Commission departed from its previous practice of taking account of the third ATC level for the purpose of defining the market, the Court observes first of all that it is apparent from recital 371 of the contested decision that the ATC system classifies pharmaceutical products into different groups, according to the organs or systems on which they act and their chemical, pharmacological and therapeutic properties, and divides them into five different levels. The third ATC level groups pharmaceutical products according to their therapeutic indications, the fourth ATC level normally takes into consideration the mode of action and the fifth level defines the narrowest classes, including active substances taken individually. The Commission stated in the contested decision that, concerning market definition, the analysis generally started from the third ATC level. However, it added that the other ATC levels were also taken into consideration where it appears that sufficiently strong competitive constraints operate at other ATC levels and that, consequently, the third ATC level does not seem to allow a correct market definition.

155 It is apparent from recital 372 of the contested decision that, for the purposes of this case, the Commission did not take account of the third ATC level, since the A2B class comprised only drugs for treatment of peptic ulcer disease and did not include those for the treatment of two of the three main gastrointestinal acid-related conditions, namely gastrointestinal oesophageal reflux and dyspepsia. The EFPIA does not put forward any argument calling in question the merits of the Commission's assessment on that point. The Court also points out that the taking into account of the ATC level in which the medicines are placed constituted only a preliminary step in the Commission's analysis.

156 The complaint that the Commission wrongly attached excessive importance to the characteristics of the products and did not take account of their therapeutic use must therefore be rejected.

The importance attached to price indicators

157 The applicants and the EFPIA submit that the Commission committed manifest errors in the assessment of price-related factors for the purposes of defining the relevant market.

158 When assessing the arguments of the applicants and of the EFPIA, it is necessary to bear in mind the regulatory framework of the pharmaceuticals sector, as set out in the undisputed findings in the contested decision.

159 In the contested decision, the Commission found that, for publicly reimbursed medicines, prices were influenced by the public authorities according to two systems, which are sometimes combined in certain countries. In the first system, the public authorities negotiate a reimbursable price with the manufacturers or unilaterally set the reimbursable price on the basis of information provided by the manufacturers. The factors taken into account by the public authorities include the added therapeutic value, cost-effectiveness, prices for the same or similar products on the domestic or foreign markets, and the research and development costs borne by the manufacturers (recitals 118 and 120 of the contested decision). The Commission found, in this respect, that a firm's ability to obtain high prices is particularly strong to the extent that its product is necessary to adequately treat certain conditions (recital 365 of the contested decision).

160 In the second system, the reimbursable price is fixed according to a reference price, which is established for each group of products with a similar therapeutic effect on the basis of the relatively low price of one or more products within that group. The reference price constitutes the maximum reimbursement level for all products within

the reference category, manufacturers being free to set higher prices, in which case patients must bear the additional cost. In response to the questions put by the Court, the Commission confirmed that that system was normally applied only to products in respect of which a generic version existed. The system may also be accompanied by a substitution mechanism, which allows or obliges pharmacies to replace the product prescribed by the doctor with cheaper equivalent generics (recitals 118 and 119 of the contested decision).

161 Analysis of the prevailing systems in Germany, Belgium, Denmark, Norway, the Netherlands, the United Kingdom and Sweden led the Commission to take the view that the bargaining position of pharmaceutical companies depended significantly on the added value and efficacy of their products in relation to other products on the market. Breakthrough products which offer significant advantages over existing products are generally able to command a higher price from public authorities (recital 128 of the contested decision). The Commission observed that, in Germany and Denmark (since 1995), the Netherlands (until 1996), the United Kingdom and Sweden, manufacturers were allowed to set prices freely for their reimbursable products. However, manufacturers rarely price their products above the reimbursement level fixed by the public authorities, as demand becomes more elastic where patients are required to bear the amount exceeding the portion of the price which is reimbursed. Under the reference price system, a manufacturer of the original medicine that does not align its price downwards towards a reference price set following the market entry of a generic product may experience significant loss of market share (recital 129 of the contested decision).

162 In the present case, the Commission found that prices of PPIs were in general significantly higher than those of H2 blockers between 1991 and 2000 (recital 401 of the contested decision).

163 In the first place, the Court observes that it is apparent from the Commission's findings with regard to regulatory systems under which public authorities influence or determine prices that the price of a new pharmaceutical product depends to a large extent on the public authorities' perception of its relative therapeutic value in comparison with existing products. When a new product offers an added therapeutic value, the national body will tend to grant it a maximum reimbursement level or sale price, according to the system in force in the relevant State, which is significantly higher than those of existing pharmaceutical products with a lesser therapeutic value.

164 That consideration is moreover consistent with what the Commission found. In recital 369 of the contested decision, it observed that the therapeutic advantages and cost effectiveness of PPIs were key factors in the ability of pharmaceutical companies to negotiate relatively high prices with national authorities. Similarly, in recital 385 of the contested decision, it found that the fact that the price extracted by AZ for Losec was higher than the price of H2 blockers shows that public authorities perceived PPIs as therapeutically superior.

165 The Court therefore takes the view that the difference between the absolute prices of PPIs and H2 blockers reflects to a large extent the public authorities' perception of a factor which was already taken into consideration by the Commission for the purposes of market definition, namely the greater therapeutic efficacy of PPIs in comparison with H2 blockers.

166 In the second place, it should be noted, as is apparent from paragraph 39 of the Notice on market definition, that the similarity of price levels and/or their convergence may be relevant for the purposes of defining the relevant product market, since a

significant divergence in price between two products may arise where the cheaper product does not exercise any competitive constraint.

167 The applicants and the EFPIA claim that the gap between prices is irrelevant in the present case, given that prices are not the result of normal competitive interaction, but are strongly influenced by public authorities. In the light of that argument, it is necessary to examine whether the fact that competitive interactions on the basis of prices between H2 blockers and PPIs are determined by public authorities and the national regulatory systems in force makes the differences between the absolute prices of PPIs and H2 blockers wholly irrelevant.

168 In this respect, the Court observes that it is apparent from the Commission's findings regarding the national regulatory frameworks under which prices are set that, during the relevant period, companies were free to set their prices in Germany, Denmark, Norway, the Netherlands until 1996, in Sweden and, in so far as the profit frameworks agreed with the public authorities allowed it, in the United Kingdom. In Belgium, where a system of maximum prices was in force until 2001, and in the Netherlands, where a system of maximum wholesale prices was introduced in 1996, the freedom of pharmaceutical companies to set prices was limited. Furthermore, in the United Kingdom, the public authorities also set prices for reimbursable generic products (recitals 121 to 129 of the contested decision).

169 It follows from those observations that prices of pharmaceutical products could be set above the reimbursement levels agreed by the public authorities, which is where demand tends to become more elastic. However, nothing in the contested decision makes it possible to determine whether, and to what extent, prices of PPIs in the relevant countries were set above reimbursement levels.

170 It is therefore necessary to examine the merits of the applicants' argument that, in the present case, the differences between the prices of PPIs and H2 blockers are irrelevant by reference to two situations, namely, first, that in which prices of the pharmaceutical products were set by the public authorities and/or did not exceed the reimbursement levels set by the public authorities and, second, that in which prices of the pharmaceutical products exceeded the reimbursement levels set by the public authorities.

171 Thus, first, as regards the relevance of the prices of PPIs and H2 blockers in the situation where prices of pharmaceutical products were set by the public authorities and/or did not exceed reimbursement levels, the Court observes first of all that it is apparent from recital 130 of the contested decision that, when national authorities pursued policies aimed at limiting their health expenditure, the means used were generally aimed at encouraging doctors to prescribe generic pharmaceutical products instead of the original versions of those products. Moreover, the reference price system in force in most of the relevant countries, which was applied only if a generic version of a product existed, and the measures aimed at encouraging or even imposing substitution, at the pharmacy level, of original medicines by their generic versions, were such as to enable the generic products, once they had been introduced on the market, to exercise a significant competitive constraint over original PPIs, such as Losec.

172 However, there is nothing in the documents before the Court to show that the national regulatory systems exerted downward pressure on sales or prices of PPIs on account of the lower price of H2 blockers. It does not appear that the authorities generally promoted or imposed substitution of H2 blockers for PPIs at the stage when the medicines were dispensed in pharmacies. Moreover, it is apparent from the contested decision that, since the reference price system applied, in the relevant States, only to original pharmaceutical products and their generic versions, prices of PPIs or

the reimbursement levels granted to them were in no way dependent on the (lower) prices of H2 blockers.

173 It follows from the foregoing that, although the national regulatory systems to a certain extent prevented normal competitive interaction on prices between pharmaceutical products, the fact remains that they were capable of significantly influencing the income of the pharmaceutical undertakings by setting prices or reimbursement levels by reference to the prices of generic products and by promoting or imposing the substitution of original PPIs by their generic versions at the dispensing stage in pharmacies.

174 The fact that, in the present case, the regulatory systems did not influence the prices or the amount of sales of PPIs by reference to the lower prices of H2 blockers leads to the conclusion that the reimbursement levels granted to PPIs to a large extent prevented the lower prices of H2 blockers from exercising a competitive constraint over them. It should be recalled in this respect that the purpose of defining the relevant market is to determine the competitive constraints on the product on the basis of which the market is defined. The fact that the absence or insignificance of those competitive constraints is due to the regulatory framework which determines the conditions under, and the extent to, which competitive interactions between products take place does not affect the relevance, in the context of market definition, of the finding that those competitive constraints are non-existent or insignificant.

175 Where it is established that a group of products is not subject to a significant extent to competitive constraints from other products, so that that group may be considered to form a relevant product market, the type or nature of the factors that shield that group of products from any significant competitive constraint is of only limited relevance, since the finding of an absence of such competitive constraints leads to

the conclusion that an undertaking in a dominant position on the market thus defined would be able to affect the interests of consumers on that market by preventing, through abusive behaviour, the maintenance of effective competition.

176 Consequently, the Commission did not commit a manifest error of assessment in finding, in recital 364 of the contested decision, that the initial setting and maintenance of the price of a new category of products at a level significantly higher than that of other products used within the same therapeutic area reflects a low degree of competitive pressure from those other products.

177 Second, inasmuch as the price of PPIs could be higher than the reimbursement level set by the public authorities and the patient was thus required to bear that excess amount, there was liable to be demand elasticity, even if, as the applicants and the EFPIA assert, it is apparent from all the documents before the Court that such elasticity would in any case have been weak in view of the central role played by doctors in choosing the medicines prescribed and of the importance they attached to the therapeutic efficacy of the products when they did so.

178 It should be added, in this respect, that the fact — which has not been disputed — that patients and doctors display limited sensitivity to the cost of medicines, even where those costs exceed reimbursement levels, supports the view that H2 blockers did not exercise, by means of their lower prices, a significant competitive constraint over PPIs, and this could be reflected by a significant difference between the absolute prices of those products.

179 Nevertheless, for the purposes of assessing whether the lower prices of H2 blockers exercised a significant competitive constraint over PPIs, the question whether the price of PPIs exceeded the reimbursement level is of only limited relevance, since the main question is whether or not the non-reimbursed portion of the price of PPIs chargeable to patients is higher than the non-reimbursed portion of the price of H2 blockers that patients must bear.

180 If the non-reimbursed portion of the price of PPIs chargeable to patients were higher than the non-reimbursed portion of the price of H2 blockers that patients had to bear, the Court would have to find that H2 blockers did not exercise any significant competitive constraint over PPIs, since patients were prepared to bear an additional cost when purchasing PPIs.

181 Conversely, if the cost ultimately borne by patients when purchasing H2 blockers were higher than that which they bore when purchasing PPIs on account of the high reimbursement level of the latter, it would again be necessary to find, for the reasons set out in paragraphs 174 and 175 above, that the fact that the regulatory system shielded PPIs from the competitive constraint that H2 blockers were able to exercise by means of lower prices does not preclude a definition of the relevant product market which excludes H2 blockers, since this in fact supports such a market definition. In that situation, it would be necessary to find that, because of the high reimbursement level granted to PPIs, the regulatory system to a large extent prevents H2 blockers from exercising a significant competitive constraint over PPIs by means of prices. Such a finding is relevant for the purposes of assessing the competitive constraints on PPIs.

182 In any event, the Commission cannot maintain, as it does in recital 365 of the contested decision, that, in principle, the ability of an undertaking to maintain its prices above the reimbursement level, where demand tends to be more elastic, constitutes

in itself evidence of an absence of any significant competitive constraint, without examining the extent to which the price of other potentially substitutable products is reimbursed by the national health insurance system. The Commission has failed to establish, in the present case, that the non-reimbursed portion of the price borne by patients when purchasing H2 blockers was lower than that of PPIs. Nevertheless, for the reasons set out in the preceding paragraphs, that error does not affect the soundness of the conclusions of the Commission, which took the view that, where prices exceeded reimbursement levels, the fact that absolute prices of PPIs were higher than those of H2 blockers showed that H2 blockers did not exercise any significant competitive constraint over PPIs.

183 It follows from the foregoing that the specific features which characterise competitive mechanisms in the pharmaceutical sector do not negate the relevance of price-related factors in the assessment of competitive constraints, although those factors must be assessed in their specific context. In the pharmaceutical sector, competitive relationships respond to mechanisms which differ from those determining competitive interactions normally present in markets which are not so heavily regulated.

184 In the present case, the Commission found that the degree of price correlation between PPIs and H2 blockers tended to be low throughout the relevant period. By contrast, the degree of price correlation tended in general to be stronger between different active substances within the same class, such as omeprazole and the 'me-too' PPI products which entered the market after omeprazole. It found that the degree of price correlation was strongest between products containing the same active substance, such as original substances and their generic counterparts (recital 368 of the contested decision).

185 The Commission found that it was the price of generic versions of omeprazole which had had the strongest impact on demand for AZ's omeprazole. Moreover, the price of other PPI products was also capable of influencing, to some extent, demand for AZ's omeprazole. By contrast, the much lower price of H2 blockers between 1991 and 2000 did not, according to the Commission, exert any significant competitive constraint on the demand for omeprazole or other PPIs, in view of the upward trend for PPI sales and of the downward or stagnating trend for H2 blocker sales (recital 401 of the contested decision).

186 The Court takes the view that those findings relate to factors which are not irrelevant in the present case and that the Commission did not commit a manifest error of assessment in considering that those factors, together with the other factors taken into consideration in the contested decision, support the view that H2 blockers did not exercise any significant competitive constraint over PPIs.

187 The fact, relied upon by the applicants, that non-price factors play a significant role in competitive relationships between pharmaceutical products is in no way at odds with the aforementioned considerations. As was observed above, since doctors are primarily guided by the therapeutic effect of medicines when choosing what to prescribe, the prices of medicines whose therapeutic uses differ have limited impact on their level of consumption. In so far as they determine doctors' choices, non-price factors, such as therapeutic use, therefore also constitute, alongside price-based indicators, a relevant factor for the purposes of market definition; this was indeed duly taken into consideration by the Commission, as was noted in paragraphs 149 to 152 above.

188 As regards the applicants' argument that the Commission failed to take account of the overall cost of PPI treatment, which is shorter because of its superior efficacy, the

Court notes that the applicants are justified in claiming that the amount by which the total cost of PPI treatment exceeds the total cost of H2 blocker treatment is likely to be less than is indicated at first sight by just the difference between the cost for treatments of 28 days, presented in tables 1 to 7 in the Annex to the contested decision.

189 However, it should be observed that the length of treatment depends in any event considerably on the type of condition in question and is liable to vary from one patient to another. The Commission cannot be expected to take account of the specific actual duration of PPI and H2 blocker treatments, the setting of an average in this respect being moreover a potentially uncertain exercise, in view (i) of the fact that PPIs and H2 blockers were used in varying proportions in the context of a single course of treatment, depending on whether that treatment was being stepped up or stepped down, and (ii) of the fact that such an average would be liable to vary over time, depending on the acceptance rate of PPIs by prescribing doctors and on the development of medical knowledge and practices.

190 Since quantification of cost-effectiveness is likely to be particularly complex and uncertain, it cannot be considered that the Commission committed a manifest error of assessment in taking into account the price of the medicines for an identical period of treatment.

191 In addition, it is apparent in any event from the findings made in paragraphs 171 to 175, 177 and 178 above, that H2 blockers were not capable of exercising a significant competitive constraint over PPIs by means of lower prices, in view (i) of the limited sensitivity of doctors and patients to price differences on account of the importance of the role played by therapeutic efficacy in the choice of what to prescribe, and (ii) of the regulatory systems in force in the relevant States, which were not designed in

such a way as to enable the prices of H2 blockers to exert downward pressure on sales or prices of PPIs.

192 As regards the applicants' argument that the Commission attached excessive value to the CRA correlation study, the Court would point out, as the Commission contends, that that study was taken into consideration only on a subsidiary basis (recital 407 of the contested decision) and was relied upon to the extent that it tended to support the findings based on other indicia, such as the therapeutic differences between H2 blockers and PPIs and the price differences between those two products. Similarly, the references to that correlation study in recitals 411, 416, 436, 440, 447 and 451 of the contested decision cannot be regarded as being the primary basis for the Commission's findings, since those findings are based above all on sales trends, price differences and, in the case of Germany and the United Kingdom, on the observation of certain 'natural events'. The references to the correlation study are thus made incidentally in so far as they tend to substantiate prima facie the Commission's view that PPIs and H2 blockers were not competing on price. Such use of that correlation study, whose weaknesses the Commission alluded to, cannot constitute a manifest error of assessment.

193 The applicants also contest the merits of the Commission's use of value-based data rather than volume data. The Court would point out in this respect that the volume data set out in tables 17 to 23 of the contested decision come from the IMS Health report (recital 63 of the contested decision), from which it is apparent that those data correspond to measurement units based on the concept of 'treatment day'. As the Commission observed at the hearing, the superior efficacy of PPIs means that fewer treatment days are required to treat a condition when PPIs are used than when H2 blockers are used. On that point, the applicants themselves acknowledge that PPIs

treat conditions more rapidly than H2 blockers. Thus, volume-based calculations do not reflect differences in terms of healing times or success rates.

194 By contrast, as the Commission contends, sales by value take account both of the volume of treatment administered and of the therapeutic superiority of PPIs over H2 blockers. The fact that prices stem from regulatory mechanisms in which public authorities have a significant role does not alter that consideration, since, as was found above, those authorities attach great importance to the added therapeutic value of a product.

195 The Court therefore holds that the Commission did not commit a manifest error of assessment in finding that value-based data were better able to reflect the relative position of PPIs and H2 blockers.

196 The applicants complain lastly that the Commission did not carry out any investigation of the process by which PPI prices were agreed in individual Member States. On that point, the Court also takes the view that that lack of any investigation constitutes a lacuna, since price-based indicators constitute an important element of the Commission's definition of the relevant market in the present case. It was incumbent on the Commission to gather precise information on the manner in which prices are either influenced or set by the public authorities.

197 It is apparent however from recitals 116 to 132 of the contested decision that the Commission conducted a detailed study of the regulatory systems for setting prices or reimbursement levels of pharmaceutical products in the countries concerned. It follows from the foregoing that the Commission's findings make it possible to understand the mechanisms by which prices are influenced or determined by the public authorities, and the competitive constraints by means of prices which those regulatory

systems enable the pharmaceutical products in question in the present case to exercise over each other.

198 The Court notes, in this respect, that the Commission's findings have not been called in question by the applicants and the EFPIA. The fact, alleged by the applicants, that AZ sought a price for PPIs which was equal to twice the price of Zantac on a 'price per day' basis is not capable of calling in question the Commission's view that national bodies granted PPIs a higher price than that of H2 blockers in consideration of the added therapeutic value of PPIs. On the contrary, it tends to confirm it.

199 The Court therefore holds that, in the light of all the factors on which the Commission also based its assessment, that lacuna does not affect, in the present case, the validity of the conclusions that it drew from the gap in prices between PPIs and H2 blockers.

The 'natural events'

200 During the administrative procedure, the applicants produced an econometric study, the Lexecon report, which aimed to show that H2 blockers exercised a significant competitive constraint over PPIs in Germany and the United Kingdom. That study presents information on a series of 'natural' events that occurred on the German and United Kingdom markets, which the Commission took into consideration for the purposes of its analysis of the relevant product market, the Commission taking the

view, in recital 421 of the contested decision, that those events constituted important evidence.

201 As regards, in the first place, the three 'natural events' observed on the German market, it should be recalled that those events related to the market entry of the PPI pantoprazole in 1994, the introduction of the generic H2 blocker ranitidine in 1995 and the introduction of generic omeprazole in 1999.

202 As regards, first of all, the entry on the German market of pantoprazole in 1994, the Commission found, in recital 422 of the contested decision, that it was accompanied by a reduction in the price of Losec of 16%, but that it did not significantly affect the slowly falling trend in the price level of H2 blockers.

203 In this respect, it should be noted, once again, that the applicants' assertion that prescribing doctors are essentially guided by the therapeutic use of products does not make price-based indicators wholly irrelevant, since the latter may also be evidence of the competitive constraints on the relevant products. In the present case, and as the applicants stated during the administrative procedure (see recitals 427 and 428 of the contested decision), that event tends to show that price competition at the inter-molecular level existed in Germany only in so far as the relevant products had a very similar therapeutic profile, which appeared to be the case with omeprazole and pantoprazole, those products both being PPIs. By contrast, the market entry of pantoprazole does not appear to have significantly influenced the price of H2 blockers. As was held in paragraph 183 above, the fact that competitive interaction on the basis of prices is to a large extent influenced or determined by the regulatory system in force does not affect the relevance of price indicators in the assessment of competitive constraints.

204 Moreover, the applicants' submission that the decline in the market share of H2 blockers accelerated after the introduction of pantoprazole is not capable of showing that they exercised a competitive constraint over PPIs. On the contrary, that fact tends to confirm the Commission's findings that PPIs exercised a unilateral competitive constraint over H2 blockers.

205 As regards, next, the entry of the generic H2 blocker ranitidine on the German market in 1995, the Commission observed, in recitals 423 and 424 of the contested decision, that it was clear from the Lexecon study that, over a period starting just before the market entry of that substance and ending three months later, H2 blocker prices declined by roughly 40%, whereas prices of PPIs remained unaffected, and that total PPI sales continued to grow rapidly. Moreover, promotional activity, measured in visits by medical representatives, increased sharply in the H2 blocker segment shortly before the introduction of generic ranitidine and decreased sharply shortly after its introduction. By contrast, the market entry of generic ranitidine did not have any effect on promotional activities or sales of PPIs. The Commission thus inferred from this that intensification of competition between H2 blockers in terms of prices and promotional activity did not affect PPIs.

206 The applicants and the EFPIA assert that the introduction of the generic H2 blocker ranitidine positively affected sales in volume terms of H2 blockers and had a negative impact on sales in volume terms of PPIs. However, as the Commission observes, it is apparent from table 16 in the Annex to the contested decision that sales by value of PPIs, expressed as a proportion of combined sales of PPIs and H2 blockers, continued to increase between 1994 and 1997, from 32% in 1994 to 42% in 1995, to 57% in 1996 and to 67% in 1997. As was held in paragraph 195 above, where products are differentiated, the Commission is justified in attaching more importance to sales by value than sales by volume, which are the sales on which figures 2 and 3 in the Lexecon report are based.

207 In any event, table 19 in the Annex to the contested decision indicates that the amount of prescriptions in volume terms of PPIs increased steadily between 1994 and 1997, from over 2 million prescriptions in 1994 to more than 3.3 million prescriptions in 1997.

208 The applicants rely on figures 2 and 3 in the Lexecon report in submitting that the market shares of H2 blockers increased as a result of the introduction of generic ranitidine, while Losec's market share declined and the market share of other PPIs levelled off. The Court would however point out, as the Commission stated in recitals 462 and 463 of the contested decision, that those figures present the relative shares of sales in volume terms of PPIs and H2 blockers, expressed as a proportion of combined sales of PPIs and H2 blockers, that is to say in an assumed common market for H2 blockers and PPIs. In such a context, because of autocorrelation, an increase in sales of H2 blockers will inevitably adversely affect the market share of PPIs, even if the increase in sales of H2 blockers occurs in market segments that are uncontested by PPIs, such as those consisting of the mild forms of gastrointestinal conditions, where pharmaceutical products are therapeutically relatively weak. The Commission did not therefore commit a manifest error of assessment in taking the view that those data did not serve to establish that H2 blockers exercised a significant competitive constraint over PPIs.

209 Moreover, the fact, relied upon by the EFPIA, that the reference price system in force in Germany prevented the lower price of generic ranitidine from being able to constrain PPI prices does not alter the finding that PPIs were not significantly constrained by the lower prices of H2 blockers (see paragraphs 174 and 175 above).

210 As regards the observation of promotional activities, the applicants cannot seriously argue that promotional activity in respect of Losec and the other PPIs increased in reaction to the entry of ranitidine. It is apparent from figures 5 and 6 in the Lexecon report that variations in promotional activity in respect of PPIs were not particularly significant, unlike the clear and significant increase in promotional activity in respect of H2 blockers. On the basis of those observations, the Commission was accordingly justified in taking the view that the market introduction of ranitidine led to increased competition between H2 blockers through increased promotional activity, but that that intensification of competition did not involve PPIs, for which promotional activity remained stable. That event accordingly tends to show clearly the relationship between its separate elements, namely the market entry of ranitidine, the increased competition between H2 blockers, and the lack of any significant effect on promotional activity for PPIs. Although limited in time, that observation therefore supports the conclusion that H2 blockers did not exercise any significant competitive constraint over PPIs.

211 The Court would also point out that, although the applicants claim that promotional activity may vary according to other factors, they do not specify the factors which, in the present case, would tend to invalidate the conclusions which the Commission drew from the very marked increase in promotional activity in respect of H2 blockers following the market entry of generic ranitidine and the corresponding absence of any particular effect on promotional activity for PPIs.

212 As regards, lastly, the entry of generic omeprazole in Germany in 1999, the Commission observed, in recital 425 of the contested decision, that that event resulted in a decline in Losec's sales volume of around 60% and negatively affected the sales of the other PPIs.

213 The Commission rightly states that the very significant impact of the market entry of generic omeprazole both on sales of Losec and on its price must be viewed in conjunction with the absence of any effect of the introduction of the generic H2 blocker ranitidine on prices and sales of PPIs. Although the applicants claim that the Commission could not rule out that H2 blockers exercised a significant competitive constraint over Losec, they have failed to adduce evidence capable of overturning the Commission's findings.

214 As regards, in the second place, the entry of the generic H2 blocker ranitidine in the United Kingdom in 1997, the Commission observed that, despite that event, PPI sales in absolute terms as well as their share of overall PPI and H2 blocker sales in the United Kingdom continued to increase from 1997 onwards. Moreover, it found that the market entry of generic ranitidine did not influence the increase in price of Losec.

215 It is apparent from table 16 in the Annex to the contested decision that PPI sales, expressed as a proportion of combined sales of PPIs and H2 blockers, continued to increase after 1997, from 56% in 1996 to 60% in 1997, then to 65% in 1998 and 70% in 1999. Those data reveal, as the Commission observed in recital 454 of the contested decision, that the introduction in 1997 of ranitidine at a significantly lower price on the United Kingdom market did not exercise any significant competitive constraint over sales of PPIs. The Court would point out, moreover, that the decline in sales of PPIs, alleged by the applicants, is not clearly apparent from figure 7 in the Lexecon report. Although the rate of increase in Losec sales slowed slightly, sales of the other PPIs still increased on a sustained basis, thus permitting the inference that, on the whole, sales growth of PPIs was not affected by the market entry of generic ranitidine.

216 It is also apparent from that figure that the introduction of ranitidine did not exert downward pressure on the price of PPIs. On the contrary, that figure reveals a slight increase in those prices, until they declined in March 1998 by reason of the United Kingdom Pharmaceutical Price Regulation Scheme, which required profits from the sale of selected products to be brought within a determined ceiling (see page 21 of the Lexecon report). The applicants' arguments must therefore be rejected on that point also.

217 The applicants also submit that, as regards the events observed in Germany and the United Kingdom, the Commission wrongly attributed the changes observed to an individual factor, whereas those changes are affected by many factors simultaneously. In attempting to cast doubt on the Commission's conclusions, the applicants do not however explain, as regards the specific events examined above, the effect that the various factors on which they rely might have had in those specified cases, namely the price of Losec and competing products, the entry on the market of competing products, the number of presentation forms available for Losec and competing products, the promotional activity for all products in the market, the dates when new indications for Losec were approved and the time trend. In those circumstances, and in view of the fact that the Commission's conclusions find support in the information that it analysed, that complaint is not sufficient to identify a manifest error of assessment by the Commission.

218 Lastly, the applicants claim that the empirical evidence on which the Commission based its assessment is too limited to support the definition of the relevant product market.

219 It is apparent from the examination of all the pleas and arguments put forward by the applicants against the Commission's definition of the relevant market that the Commission based its assessment on the greater efficacy of PPIs, the differentiated

therapeutic use of PPIs and H2 blockers, the trend of asymmetrical substitution that characterised the growth in sales of PPIs and the corresponding decrease or the stagnation in sales of H2 blockers, price indicators, such as they resulted from the regulatory framework in force, and the 'natural events' observed in Germany and the United Kingdom.

220 Following an overall appraisal of the evidence on which the Commission based its assessment, and in the light of the grounds of complaint set out by the applicants and the EFPIA, the Court finds that that evidence, some of which was produced by the applicants themselves, constitutes, in the present case, a body of relevant data that is sufficient to establish to the requisite legal standard the conclusion that the Commission reached, namely that H2 blockers did not exercise a significant competitive constraint over PPIs during the period between 1993 and 2000.

221 The Court therefore finds that the applicants and the EFPIA have failed to establish that the Commission committed a manifest error of assessment in finding that the relevant product market was composed solely of PPIs in Germany, Belgium and Denmark between at least 1993 and 1999, in Norway, the Netherlands and the United Kingdom between at least 1993 and the end of 2000, and in Sweden.

222 In view of all the foregoing, the second plea, directed against the market definition, must be dismissed.

B — *Dominance*

1. *Arguments of the parties*

223 The applicants and the EFPIA submit that there are a number of specific features of competition in the pharmaceutical sector which it is essential to take into account. In that regard, the EFPIA states that dominance is defined as the ability to raise prices without fear of effective reprisals from customers or competitors. The applicants and the EFPIA point out that the pharmaceutical product markets in the relevant Member States are characterised by a high degree of public regulation, including, in particular, rules constraining pricing and reimbursement, which restrain prices. The fact that neither the key decision-makers (doctors) nor the ultimate consumers (patients) bear the bulk of the cost of prescription medicines has the effect that the decision-makers display limited price sensitivity when prescribing medicines. In addition, national markets are often dominated by an effective monopsony purchaser. Moreover, according to the EFPIA, output decisions are constrained by continuity of supply obligations and pharmaceutical companies have to invest regularly in order to maintain their market position (Opinion of Advocate General Jacobs in Case C-53/03 *Syfait and Others* [2005] ECR I-4609, point 81 et seq.; judgment in *GlaxoSmithKline Services* v *Commission*, paragraph 46 above, paragraphs 106, 125, 141, 259, 264, 271 and 300). Consequently, the pharmaceutical product markets in the EEA do not have normal conditions of competition.

224 With regard to the relevance attached to the possession of market shares, the EFPIA maintains that, in the absence of a thorough analysis of competitive conditions on

the market in question, high market shares are not sufficient to conclude that there is dominance. That is particularly the case in the pharmaceutical sector, which is characterised by strong competition by innovation, where substantial market shares are noticeably less meaningful than in other industry sectors, and do not communicate any useful information about the relevant factor of competition in this case, namely the degree of innovation.

225 Similarly, the applicants submit that the Commission relied excessively on factors relating to prices and market shares. They maintain that pharmaceutical companies cannot exercise market power in respect of price, even if they have high market shares. Prices in themselves are neither a reliable measure, nor the overriding factor, of competition. In view of the nature of the pharmaceutical product markets, exceptional circumstances are required in order for it to be possible for a pharmaceutical manufacturer to be dominant. The Commission does not demonstrate how, given the regulation in force on the relevant market, AZ could have hindered competition by behaving independently of its competitors, doctors and patients.

226 The EFPIA also disputes the allegation in recital 547 of the contested decision that AZ's market power is evidenced by the fact that its higher prices reflect its bargaining power vis-à-vis the national authorities to extract higher prices for Losec and Losec MUPS. Higher prices set by national regulatory authorities reflect the innovative value and cost benefits of the product and are merely the result of the Member States' policies with respect to national health schemes and stimulation of innovation. In addition, even assuming that the pharmaceutical companies sometimes have a power of negotiation, the prices for medicines fall structurally outside the play of supply and demand (*GlaxoSmithKline Services* v *Commission*, paragraph 46 above, paragraphs 140 and 141). Moreover, prices tend to decrease over time on account of the downward pressure exerted by public authorities, which have an interest in that.

Consequently, in the pharmaceutical sector, the level of prices and their development cannot be influenced by a dominant position.

227 In any event, the EFPIA maintains that there is a presumption that the price set by the public authorities reflects the competitive price and that the Commission has not demonstrated that this was not the case with respect to the relatively higher price obtained by AZ.

228 It also disputes the assertion in recital 554 of the contested decision that the influence on prices exercised by the health systems confers more market power on pharmaceutical companies than in a situation where the final consumer would bear the full cost of the medicines. The EFPIA contends that, since the public authorities bear the health costs, those authorities will see to it that the price is set at a competitive level from the start and will exert downward pressure on it. It is therefore wrong to assert that AZ had the ability to behave independently vis-à-vis the health systems to a significant extent (see recital 561 of the contested decision).

229 As regards the relevance to be attached to intellectual property rights, the EFPIA disputes the Commission's allegation in recital 517 of the contested decision that the intellectual property and other rights which AZ derives from 'pharmaceutical law for the protection of its technology' are one of the principal factors in determining dominance. That consideration is in conflict with the case-law, which has refused to accept the notion that the mere existence of intellectual property rights can give rise to market power (Case 238/87 *Volvo* [1988] ECR 6211; Joined Cases

C-241/91 P and C-242/91 P *RTE and ITP* v *Commission* [1995] ECR I-743, '*Magill*'; and Case C-418/01 *IMS Health* [2004] ECR I-5039).

230 The applicants maintain that the fact that AZ took legal action — the legitimacy of which the Commission does not dispute in recital 535 of the contested decision — to protect its intellectual property rights and that it concluded 'settlement agreements' is not relevant to a finding of dominance. They submit that the facts surrounding the litigation and the 'settlement agreements' analysed in recitals 515 to 540 of the contested decision were also irrelevant, and they refer, in that regard, to the response to the 'letter of facts', dated 21 January 2005. The applicants also point out that the Commission did not find that the terms of the 'settlement agreements' were abusive.

231 The EFPIA adds that the Commission's reasoning that the legal actions brought by AZ are relevant for assessing its dominance implies that a company that enters the market with an innovative product should refrain from enforcing the full scope of its intellectual property rights and from charging royalties to some of its competitors, in order not to risk being found dominant and, consequently, having its commercial policy become subject to restrictions. Such a position risks eliminating any incentive to create innovative products.

232 In relation to the question of the advantage enjoyed by the incumbent product or first mover, the applicants point out, in addition, that pantoprazole obtained a 20.66% market share in Germany in only its second year on the market (1995). They suggest that that is because Byk Gulden, the manufacturer of pantoprazole, was a German company. They also point out that AZ's intellectual property rights did not prevent lansoprazole and pantoprazole from entering the market in 1993 and 1994 respectively.

233 The EFPIA further disputes that AZ's incumbency on the PPI market is, in general, such as to confer competitive advantages, since such advantages are, in its view, irrelevant for determining dominance. The success of a pharmaceutical product is by definition short-lived, since it is vulnerable to the entry of other innovative products and also to the entry of generic products, as the Commission recognises in recital 562 of the contested decision. Moreover, licensing agreements and disclosure of the information provided for the purpose of obtaining marketing authorisations facilitate rivalry by competitors.

234 As regards the analysis of AZ's financial strength, resources and specialisation, the EFPIA complains that the Commission compares figures relating to sales, earnings after tax, total assets, return on equity, research and development resources and marketing resources, without drawing from them any conclusions as to the competitive strength of AZ's competitors with respect to PPIs.

235 In any event, the applicants submit that the Commission's finding that there was dominance in Germany between 1995 and 1997 is erroneous. In that regard the applicants claim that the three factors on which the Commission relies, namely market shares, prices and promotional activity, do not support the finding that there was dominance. First, as regards market shares, the applicants point out that table 26 in the Annex to the contested decision shows that, although AZ had the largest market share between 1995 and 1997, the market shares of its competitors were also significant. Furthermore, that table shows that AZ's market share declined from 82.57% to 64.94% between 1994 and 1995, whilst the market share of pantoprazole increased from 5.34% in 1994 to 20.66% in 1995. In 1996 and 1997, AZ's market share continued to decline, whilst the market shares of lansoprazole and pantoprazole increased.

236 Next, as regards the pricing information set out in table 33 in the Annex to the contested decision, the applicants maintain that, during the period between 1995 and 1997, the prices of Antra 20 mg capsules (omeprazole), Agopton 30 mg capsules (lansoprazole) and Rifun 40 mg tablets (pantoprazole) were the same, which indicates that AZ was not able to maintain higher prices than its competitors.

237 Finally, as regards the information on promotional activities in Germany, the applicants refer to figure 6 in the Lexecon Report. That figure shows that promotional activities for pantoprazole were greater than for Losec, whilst promotional activities for lansoprazole were equivalent to those for Losec. In the light of table 26 in the Annex to the contested decision, the applicants submit that the greater promotional activity for pantoprazole enabled it to win and maintain a significant market share whilst Losec's market share decreased. This indicates the ability of a new market entrant to compete effectively with Losec by virtue of the promotional activities of which it was the subject.

238 The Commission contests the merits of the arguments put forward by the applicants and the EFPIA.

2. *Findings of the Court*

239 It should be noted at the outset that it is settled case-law that a dominant position under Article 82 EC concerns a position of economic strength held by an undertaking which enables it to prevent effective competition from being maintained on the relevant market by giving it the power to behave to an appreciable extent independently

of its competitors, its customers and, ultimately, consumers. In general the existence of a dominant position derives from a combination of various factors which, taken separately, are not necessarily decisive (Case 27/76 *United Brands and United Brands Continentaal* v *Commission* [1978] ECR 207, paragraphs 65 and 66, and Case 85/76 *Hoffmann-La Roche* v *Commission* [1979] ECR 461, paragraphs 38 and 39).

240 In the present case, the Commission found, in recital 601 of the contested decision, that AZ held a dominant position within the meaning of Article 82 EC on the PPI market in Germany from 1993 until the end of 1997, in Belgium from 1993 until the end of 2000, in Denmark from 1993 until the end of 1999, in the Netherlands from 1993 until the end of 2000, in the United Kingdom from 1993 until the end of 1999 and in Sweden from 1993 until the end of 2000. As regards Norway, the Commission found that, for the purposes of Article 54 of the EEA Agreement, AZ's dominant position lasted from 1 January 1994, the date of the entry into force of that agreement, until the end of 2000.

241 The applicants and the EFPIA challenge the Commission's assessment of AZ's dominant position by calling in question, in substance, the relevance of five factors taken into consideration in the contested decision, namely market shares, the level of prices, the existence and use of intellectual property rights, first-mover status and AZ's financial strength. The applicants also challenge the merits of the Commission's findings on AZ's dominant position in Germany. Those complaints will be examined in turn below.

(a) AZ's market share

242 As regards, first of all, the relevance attached to the possession of substantial market shares for the purposes of determining whether AZ held a dominant position, it should be borne in mind that, although the importance of market shares may vary from one market to another, the possession over time of a very large market share is in itself, save in exceptional circumstances, evidence of the existence of a dominant position (*Hoffmann-La Roche* v *Commission,* paragraph 239 above, paragraph 41; Case T-30/89 *Hilti* v *Commission* [1991] ECR II-1439, paragraph 91; and Joined Cases T-24/93 to T-26/93 and T-28/93 *Compagnie maritime belge transports and Others* v *Commission* [1996] ECR II-1201, paragraph 76).

243 In this respect, it has been held that market shares of more than 50% constitute very large market shares (Case C-62/86 *AKZO* v *Commission* [1991] ECR I-3359, paragraph 60) and that a market share of between 70% and 80% is in itself a clear indication of the existence of a dominant position (*Hilti* v *Commission*, paragraph 242 above, paragraph 92, and Joined Cases T-191/98, T-212/98 to T-214/98 *Atlantic Container Line and Others* v *Commission* [2003] ECR II-3275, paragraph 907).

244 In the present case, it should be noted, in the first place, that the Commission did not base its examination exclusively on AZ's market share, but took care to conduct an in-depth analysis of competitive conditions by taking into consideration various factors relating, principally, to the importance of intellectual property rights and other rights of a regulatory nature, to the advantages associated with first-mover status, to the relevance of price as a parameter of competition, to the relevance of the presence of monopsony purchasers and of regulated price systems, and to the relevance of research and development investment, promotional activities and financial resources.

245 The Court none the less points out, in the second place, that the Commission could not disregard the importance that had to be attached to AZ's generally very large market share throughout the entire relevant period in all the countries concerned. It is apparent from the Commission's findings, which have not been challenged by the applicants or the EFPIA, that AZ was always the leading player on the PPI market.

246 In the contested decision, the Commission found that, in Germany, AZ held a market share of 96% in 1993 and nearly 83% in 1994 (table 26 in the Annex to the contested decision states 82.57%), while Takeda and Byk Gulden held market shares in 1994 of 12% and 5% respectively. AZ's market share was more than twice that of Byk Gulden between 1995 and 1997, the latter accounting for between one fifth and one quarter of the market, while Takeda held 12% of the market in 1994 and 17% in 1997. The market shares of AZ, Byk Gulden and Takeda fell considerably following the introduction of generic omeprazole during 1999 (recitals 582 and 583 of the contested decision).

247 As regards Belgium, the Commission found that AZ's market share was 100% prior to 1993, remained above 90% between 1994 and 1996, fell slightly below 90% in 1997, decreasing to 81% in 1998 and 68% in 2000. Its main competitors, Takeda and Byk Gulden, had market shares in 2000 of 27% and 5% respectively (recital 570 of the contested decision).

248 As regards Denmark, table 25 in the Annex to the contested decision states that AZ held 100% and 97.47% of the market in 1993 and 1994 respectively. The Commission found that, from 1995 to 1997, Losec accounted for between 85% and 75% of market share. That share increased in 1998 and then stabilised at slightly below 75% in 1999, despite the fact that its price exceeded that of lansoprazole and pantoprazole by approximately 13% (recitals 577 to 579 of the contested decision).

249 As regards Norway, the Commission found that omeprazole sales accounted for between 100% and 74% of the market between 1993 and 2000. In 1998, AZ's market share fell to 45% on account of parallel imports. However, the parallel imports disappeared the following year, in 1999, and AZ recovered a market share of almost 75% (recital 590 of the contested decision).

250 As regards the Netherlands, the Commission found that omeprazole sales accounted for between 100% and 86% of the market between 1993 and 2000. Until 1998, a significant part of those sales was attributable to parallel traders. However, no single parallel trader was able to challenge the superiority of AZ's market share, which, in 1996, fell to its lowest level, at less than 59% (recitals 586 and 587 of the contested decision).

251 As regards Sweden, the Commission found that omeprazole sales accounted for nine tenths of PPI sales between 1993 and 1999 and eight tenths of sales in 2000. While all those sales were attributable to AZ until 1996, parallel imports as a proportion of those sales increased, bringing down AZ's market share to 44% in 1998. However, subsequent, according to the Commission, to deregistration of the marketing authorisations, AZ's market share again increased, reaching slightly below 65%. By contrast, the market shares of Byk Gulden and Eisai did not exceed 2.4% and 0.8% respectively, and that of Takeda did not exceed 7%, except in 2000, when Takeda secured 15% of market share at the expense of parallel traders (recitals 594 to 597 of the contested decision).

252 Lastly, as regards the United Kingdom, the Commission found that AZ's market share varied between 100% and 88% from 1993 to 1996. Subsequently, AZ's market share remained twice as high as Takeda's, the two undertakings holding market shares of 78% and 20% in 1997, of 68% and 29% in 1998, and of 63% and 31% in 1999, respectively.

In 2000, AZ's market share fell to 57%, whilst Takeda's rose to 33% (recital 599 of the contested decision).

253 In the light of those findings, which have not been challenged by the applicants and the EFPIA, the Commission was entitled to take the view that AZ's possession of a particularly high market share and, in any event, a share which was much higher than those of its competitors, was an entirely relevant indicator of its market power, which was out of all comparison to those of the other market players.

254 The fact, relied upon by the EFPIA, that innovation is an essential parameter of competition in the pharmaceutical sector does not call in question the relevance that must be attached to AZ's very high market share, as assessed in its context. In this respect, it is apparent from the contested decision that AZ's privileged position stems precisely from an innovative breakthrough by it, which enabled it to develop a new market and to have the advantageous status of first mover on that market as a result of marketing the first PPI. Furthermore, the applicants and the EFPIA do not explain how the specific features of the pharmaceutical sector are capable of negating the relevance attached to market shares.

(b) Price levels

255 The applicants and the EFPIA dispute that the higher prices charged by AZ for Losec amounted to evidence of the existence of AZ's market power.

256 As regards the EFPIA's argument that prices are the result of or are strongly influenced by decisions of public authorities, the Court would point out that it is apparent from the contested decision, which has not been challenged by the applicants and the EFPIA on that point, that pharmaceutical undertakings which offer for the first time products with a high added therapeutic value as a result of their innovativeness are able to extract from public authorities higher prices or reimbursement levels than those of existing products. In this respect, it has been observed that national authorities which set reimbursement levels or prices of medicines are encouraged, on account of their public interest mission, to ensure the inclusion in their health systems of products which contribute significantly to the improvement of public health.

257 Since prices or reimbursement levels of medicines are necessarily set by public authorities as a result of a dialogue with pharmaceutical undertakings, at the very least in so far as the latter must provide them with relevant information for this purpose, the Commission was entitled to take the view that pharmaceutical undertakings had bargaining power vis-à-vis the national authorities, which varied according to the added therapeutic value that their products offer in comparison with pre-existing products. Furthermore, it is also apparent from the contested decision, which has not been challenged on that point, that, in certain cases, it may be in the strategic interest of pharmaceutical undertakings not to market their products on certain markets, where the prices which national authorities are prepared to pay do not meet their expectations (see recitals 557 and 559 of the contested decision).

258 The EFPIA emphasises that pricing decisions are adopted unilaterally by public authorities. It recognises however that prices or reimbursement levels of medicines are set according to their innovative value and, consequently, that a product offering a significant added therapeutic value will be granted a price or reimbursement level higher than that of products not offering such therapeutic value. It is therefore common ground that, although the price or reimbursement level stems from a decision adopted by the public authorities, the ability of a pharmaceutical undertaking

to obtain a high price or reimbursement level depends on the innovative value of the product.

259 In the present case, the Court observes that, as the first undertaking to offer a PPI, namely omeprazole, whose therapeutic value was much higher than that of the existing products on the market, AZ was able to obtain a higher price from public authorities. By contrast, such higher prices were not so easy to obtain for pharmaceutical undertakings marketing other PPIs, the 'me-too' products, such as lansoprazole, pantoprazole and rabeprazole. The applicants themselves explained to the Commission that reimbursement bodies tended to view 'me-too' products, product line extensions and new formulations of existing products more sceptically since such products offered only limited added therapeutic value (recital 550 of the contested decision).

260 The Court therefore takes the view that AZ's ability to obtain higher prices or reimbursement levels reflects the advantages that it derived from its first-mover status on a market which it pioneered. That first-mover status is an important factor in AZ's leading competitive position, which the Commission took into account in recitals 541 to 543 of the contested decision. It is that first-mover status which is in part the cause of the undisputed strength of AZ's omeprazole in terms of market share, in comparison with competitors which marketed other PPIs.

261 Furthermore, as the Commission claimed in reply to the questions put by the Court, the fact that AZ was able to maintain a much higher market share than those of its

competitors while charging prices higher than those charged for other PPIs is a relevant factor showing that AZ's behaviour was not, to an appreciable extent, subject to competitive constraints from its competitors, its customers and, ultimately, consumers. The fact that the higher prices charged by AZ are due in part to the setting of high reimbursement thresholds does not affect that finding.

262 In this respect, the Court would point out that the Commission is justified in finding, in recital 554 of the contested decision, that the health systems which characterise markets for pharmaceutical products tend to reinforce the market power of pharmaceutical companies, since costs of medicines are fully or largely covered by social security systems, which to a significant extent makes demand inelastic. That is more particularly the case where a pharmaceutical undertaking, which is the first to offer a new product with an added therapeutic value in relation to existing products, is able to obtain a higher reimbursement level than that which will subsequently be granted to 'me-too' products. Vis-à-vis undertakings which enjoy first-mover status, the reimbursements paid by social security systems are set at relatively high levels in comparison with 'me-too' products and enable the pharmaceutical company which enjoys such status to set its price at a high level without having to worry about patients and doctors switching to other less costly products.

263 Similarly to what was observed in the context of the definition of the relevant market, in paragraph 174 above, it matters little that the ability of AZ to maintain a particularly high market share while charging significantly higher prices is made possible or favoured by social security systems, that circumstance having no bearing on the finding that AZ was able to maintain higher revenues than those of its competitors without the various players in the pharmaceutical product markets, namely patients, prescribing doctors, national social security systems and AZ's competitors, being able

to challenge that privileged position during the periods selected by the Commission for the purposes of determining dominance.

264 Furthermore, the general ability of AZ to maintain its prices at a level higher than those of its competitors, while retaining a much higher market share, must be assessed in the light of the fact that public authorities were making efforts to reduce health expenditure in order to compensate for the limited sensitivity of prescribing doctors and patients to the high prices of medicines (recital 555 of the contested decision) and the fact that new entrants in Germany and the United Kingdom were incurring proportionately higher promotional expenses (recitals 585 and 600 of the contested decision).

265 The EFPIA claims none the less that the prices set by public authorities are presumed to be set at a competitive level. The Court observes however that, since prices are influenced by decisions of public authorities as regards reimbursement levels or maximum prices, those prices are not the result of normal market forces. It is not therefore possible to argue that the level of a price set in such a context is competitive, since it has been set in the absence of competitive mechanisms for ascertaining where such a competitive level lies. In any event, the Court would point out that the purpose of analysis of a dominant position is to determine whether an undertaking is able to behave, to an appreciable extent, independently on the market. The Commission's findings in relation to AZ's prices show that, to an appreciable extent, it enjoyed such independence, given its ability to maintain a far higher market share than those of its competitors.

266 The applicants claim that the heavy regulation on pharmaceutical product markets in any event prevents a pharmaceutical company from being able to exercise market power in respect of price or from being able to hinder competition by behaving

independently of its competitors, doctors and patients, even where it holds a significant market share. On that point, the Court would point out, as was found above, that the ability of AZ to maintain higher prices than those of its competitors, while retaining a much higher market share, shows that it was able to exercise market power in respect of price, since neither competing producers, nor social security systems, which bore the cost of the medicines, nor indeed patients, were able to force AZ to bring its prices into line with those of competing products. In this respect, it should be recalled that, apart from in Belgium and, from 1996, in the Netherlands, pharmaceutical undertakings were able to set their prices freely.

267 Next, it must in any event be pointed out that a finding of market power, that is to say the ability of an undertaking to behave to an appreciable extent independently of its competitors, its customers and, ultimately, consumers, in the sense that it is in particular able to maintain prices at a higher level while retaining a much higher market share than those of its competitors, is not conditional on the ability of the undertaking to make use of that market power in such as way as to prevent effective competition from being maintained. As far as concerns practices intended to exclude or reduce competition, in order to be classified as an abuse of a dominant position, behaviour does not necessarily have to result from, or be made possible by, the economic strength of the undertaking, since no causal link is required between the dominant position and the abuse of that position (see, to that effect, Case 6/72 *Europemballage and Continental Can* v *Commission* [1973] ECR 215, paragraph 27, and *Hoffmann-La Roche* v *Commission*, paragraph 239 above, paragraph 91).

268 Furthermore, the applicants cannot merely assert that AZ was not able to act independently of the other players on the pharmaceutical products market. In this respect, as regards the Commission's statement in recital 561 of the contested decision — which is disputed by the EFPIA — that AZ had the ability to behave independently vis-à-vis the health systems to a significant extent, the Court would point out that it

was in AZ's interest to ensure that generic products could not enter the market, since they were able to exert strong downward pressure on the price of Losec and undermine the launch of the next generation of AZ's products at an advantageous price for AZ (see in particular recitals 298 to 301 and 551 of the contested decision). The Commission observed that, as was apparent from the practices to which it objected, AZ was, as holder of the first marketing authorisations, alone in being able to apply an exclusionary strategy against competing generic products (recitals 527 and 528 of the contested decision) and to do so even though it was in the interest of national health systems for prices of pharmaceutical products to come down. In view of the contrast between the position of the public authorities, which were incapable of influencing the entry of cheaper generic products, and that of AZ, which was able to influence the entry of those generics by making use of the regulatory system, the Commission was entitled to find that AZ was able to behave independently vis-à-vis the health systems to a significant extent.

269 In the light of the foregoing, the Court therefore finds that the Commission did not commit a manifest error of assessment by taking into account price-based indicators for the purpose of assessing AZ's competitive position on the market.

(c) The existence and use of intellectual property rights

270 As regards the grounds of complaint regarding the relevance attached to intellectual property rights and rights conferred by pharmaceutical regulation, the Court would point out, first of all, that it cannot be argued that intellectual property rights do not constitute a relevant factor for the purposes of determining the existence of a dominant position. Although the mere possession of intellectual property rights cannot

be considered to confer such a position, their possession is none the less capable, in certain circumstances, of creating a dominant position, in particular by enabling an undertaking to prevent effective competition on the market (see, to that effect, *Magill*, paragraph 229 above, paragraphs 46 and 47).

271 In the present case, the applicants and the EFPIA do not call in question the Commission's finding that, as the first PPI to be introduced on the market, Losec enjoyed particularly strong patent protection, on the basis of which AZ brought a series of legal actions which enabled it to impose significant constraints on its competitors Takeda, Byk Gulden and Eisai and to dictate to a large extent market-entry terms to them. *[confidential]* Similarly, Eisai was forced to pay compensation to AZ for sales of rabeprazole and to give it access to certain technologies which could be used for future formulations of omeprazole (see recitals 88 to 96 and 521 to 524 of the contested decision).

272 The fact, noted by the applicants, that the patent proceedings brought by AZ and the ensuing amicable settlements were in no way unlawful does not affect the Commission's finding that the patent protection enjoyed by Losec enabled AZ to exert significant pressure on its competitors, which was, in itself, a relevant indicator of its dominant position. Thus, contrary to what the applicants seem to suggest, it is in no way necessary that the terms of the 'settlement agreements' be abusive in order to find that they constitute evidence of a dominant position. As the Commission observes, the applicants' argument stems from confusion between the notions of dominance and abuse.

273 Lastly, the Court must reject the assertion that the taking into account of intellectual property rights and of their exercise, even if not abusive, in order to establish the existence of a dominant position is liable to reduce any incentive to create innovative products. The Court would point out that innovation is in any event rewarded by the exclusivity that intellectual property rights confer on the author of the innovation. To the extent that, as in the present case, the possession and exercise of those intellectual property rights may be relevant evidence of the dominant position, it should be recalled that such a position is not prohibited *per se*; only the abuse of such a position is so proscribed. In this respect, where the holder of the intellectual property right is regarded as enjoying a dominant position, the requirement that use of that right be non-abusive cannot be regarded as insufficient reward in the light of the incentives for innovation.

274 In addition, as regards the applicants' argument that lansoprazole and pantoprazole entered the German market in 1993 and 1994 respectively, the Court observes that, to be a relevant factor, the existence of solid protection by means of intellectual property rights does not necessarily have to be such as to exclude all competition on the market.

275 The Court therefore finds that the Commission did not commit a manifest error of assessment in taking into consideration the existence and use of AZ's intellectual property rights when assessing its competitive position on the market.

(d) AZ's first-mover status

276 In recitals 541 to 543 of the contested decision, the Commission outlined the competitive advantages which could be derived from first-mover status and incumbency on the PPI market.

277 The applicants dispute however the relevance of AZ's first-mover status, in the light, in particular, of the fact that pantoprazole had acquired a 20.66% market share in 1995 in Germany after only two years of presence on the market.

278 The Court observes, first of all, that the Commission based its assessment of AZ's dominant position on a series of factors, foremost of which was its much higher market share than those of its competitors. Next, in view (i) of the specific features of the markets for pharmaceutical products, which are characterised by 'inertia' on the part of prescribing doctors, and (ii) of the difficulties encountered by pharmaceutical undertakings to enter a market which increase in line with the number of competitors and products already on that market, difficulties that are demonstrated by a study of the Organisation for Economic Co-operation and Development (OECD) which was taken into account by the Commission, the latter was entitled to take the view that first-mover status was an appreciable competitive advantage. That competitive advantage is also borne out by AZ's internal documents, which show that Losec enjoyed a solid brand image and reputation on account of its status of 'first product on the market', and had the most experience behind it.

279 None the less, the Commission did not state that the competitive advantages related to AZ's extended presence on the PPI market precluded competitor sales growth in all circumstances. Thus, the fact that pantoprazole was able to obtain a 20.66% market

share in Germany cannot call in question the competitive advantages that AZ derived from its first-mover status, either on the German market or on the other relevant geographic markets, where AZ's position was sometimes overwhelmingly strong. The Court also observes that pantoprazole was not able to challenge Losec's status as the largest selling PPI in Germany.

280 Similarly, the fact that generic products were in a position to undermine AZ's dominant position does not call in question the fact that its first-mover status conferred on it appreciable competitive advantages. The Court would also point out that, during the periods selected by the Commission during which AZ was in a dominant position, generic products had not undermined AZ's dominant position on the relevant geographic markets.

281 As regards, next, the EFPIA's argument that the vulnerability of a pharmaceutical product to the entry of innovative products negates the relevance of first-mover status, suffice it to note, as the Commission observes, that neither the applicants nor the EFPIA make any mention of the market entry of innovative products which challenged AZ's dominant position on the PPI market.

282 Lastly, the fact that AZ concluded licensing agreements with certain competitors cannot negate the relevance of its incumbency on the market in the present case. Moreover, as the Commission observes, the regulatory framework does not at all facilitate the market entry of manufacturers of generic products seeking to market their products, since data communicated by manufacturers of original products for the purpose of obtaining marketing authorisations are protected for a period of between 6 and 10 years (see Point 8(a)(iii) of the third paragraph of Article 4 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 proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 24, as amended at the material time)), so that, during that period, manufacturers of generic products who wish to obtain marketing authorisations may not refer to those data and must carry out their own tests.

283 The Court therefore finds that the Commission did not commit a manifest error of assessment in also taking into account, in its overall assessment, AZ's first-mover status on the PPI market.

(e) AZ's financial strength

284 In recitals 78 to 86 and 566 of the contested decision, the Commission found, on the basis of precise and undisputed information taken from the annual reports of the undertakings in question, that during the period between 1993 and 2000 AZ's resources and performances outclassed those of its competitors Takeda and Byk Gulden, inter alia as regards its general financial solidity, research and development resources and marketing resources. As regards, more specifically, AZ's turnover, which was much higher than Takeda's and Byk Gulden's, the Commission found that it was derived almost exclusively from the sale of pharmaceutical products, whereas a third of Takeda's and Byk Gulden's turnover came from non-pharmaceutical sales. The remainder of Byk Gulden's turnover was derived mainly from the sale of chemicals, vitamins and agro products (recital 78 of the contested decision).

285 Those findings thus clearly suggest that AZ's superiority in terms of financial resources is derived almost exclusively from its pharmaceutical business, on which it also focuses almost all its resources, whereas its competitors, Takeda and Byk Gulden, have more limited resources which they do not devote exclusively to their businesses in the pharmaceutical sector. Furthermore, the superiority in terms of the financial and human resources devoted by AZ to research and development and to its sales force is also a relevant factor for assessing the position of that undertaking relative to its competitors on the market.

286 Although they are not sufficient in themselves to warrant the conclusion that AZ was in a dominant position during the relevant period, those findings none the less constitute a series of relevant indicia which permit the inference that AZ had superior resources to those of its competitors such as to reinforce its market position in relation to them. The EFPIA's assertion that the Commission failed to draw conclusions as to the competitive strength of AZ's competitors with respect to PPIs must therefore be rejected, since those conclusions follow in the present case from the abovementioned findings.

(f) AZ's dominant position in Germany

287 As regards the Commission's finding that AZ held a dominant position in Germany between 1993 and the end of 1997, the applicants contest that such a position existed between 1995 and 1997.

288 The Court notes that AZ's market share in Germany declined during the period selected, from 96.09% in 1993 to 82.57% in 1994, to 64.94% in 1995, to 58.27% in 1996

and to 53.99% in 1997 (table 26 in the Annex to the contested decision). Although those data show an uninterrupted downward trend in AZ's market share, it was still very significant in 1997 (53.99%). A dominant position may be presumed from market shares above 50% (see, to that effect, *AKZO* v *Commission*, paragraph 243 above, paragraph 60).

289 Moreover, as the Commission observes, between 1995 and 1997, AZ's market share remained far above those of its closest competitors. AZ's three most significant competitors on the German market, namely Takeda, Byk Gulden and Schwartz Pharma, held respective market shares of 12.38%, 10.88% and 9.77% in 1995, of 12.57%, 11.50% and 10.01% in 1996, and of 14.10%, 12.91% and 10.64% in 1997 (table 26 in the Annex to the contested decision).

290 It should moreover be noted that AZ's market share fell below 50% only in 1999, that is two years after the last year selected for the purpose of assessing the dominant position, its market share tumbling to 35.31% that year, in particular on account of the market entry of generic omeprazole.

291 The Court also observes, as the Commission states, that AZ's sales revenues continued to increase, although to a lesser extent than the Commission contends, those revenues rising from more than USD 116 million in 1994 (when it held a market share of 82.57%) to more than USD 141 million in 1997 (when it held a market share of no more than 53.99%). In comparison, Takeda's revenues ranged from between USD 17 million in 1994 and USD 37 million in 1997, while Byk Gulden's and Schwartz Pharma's respective revenues increased from more than USD 4 million and more than USD 3 million in 1994 to more than USD 33 million and to nearly USD 28 million in

1997 (table 26 in the Annex to the contested decision). AZ's revenues therefore remained much higher than those of its competitors.

292 Thus, although AZ's competitive position was slightly weaker in Germany than in the other countries examined, the Court finds, in the light of the foregoing, that the Commission did not commit a manifest error of assessment in finding that AZ still enjoyed a dominant position there between 1995 and 1997.

293 The fact that the prices charged by AZ were not significantly higher than those of its competitors and that promotional activities for pantoprazole and lansoprazole were equivalent to, or greater than, those for Losec, does not affect that conclusion, since the evidence on which the Commission relied is sufficient, in the present case, to enable it to consider, without committing a manifest error of assessment, that AZ still held a dominant position in Germany between 1995 and 1997.

294 Consequently, in view of all the foregoing considerations and of the arguments advanced by the parties, the Court finds that the Commission did not commit a manifest error of assessment in reaching the conclusion that AZ held a dominant position within the meaning of Article 82 EC and Article 54 of the EEA Agreement on the PPI market in Germany from 1993 until the end of 1997, in Belgium from 1993 until the end of 2000, in Denmark from 1993 until the end of 1999, in Norway from 1994 until the end of 2000, in the Netherlands from 1993 until the end of 2000, in the United Kingdom from 1993 until the end of 1999 and in Sweden from 1993 until the end of 2000.

C — *The first abuse of a dominant position, relating to supplementary protection certificates*

1. *Regulatory framework and behaviour objected to*

295 Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1) provides for the creation of a supplementary protection certificate ('the SPC'), the purpose of which is to extend the duration of the exclusive right guaranteed by a patent and, therefore, to confer an additional protection period. The SPC is designed to compensate for the reduction in the period of effective protection conferred by the patent, corresponding to the period between the filing of a patent application in respect of a medicinal product and the granting of authorisation to place that product on the market.

296 Regulation No 1768/92 in the version in force at the material time, provides, in Article 13, as follows:

'1. The certificate shall take effect at the end of the lawful term of the basic patent 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.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.'

297 Article 3 of Regulation No 1768/92, which specifies the conditions for obtaining an SPC, provides:

'A certificate shall be granted if, in the Member State in which the application … is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product.'

298 Article 8(1) of Regulation No 1768/92, which specifies the items which must appear in an application for a certificate, provides:

'1. The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:

...

(iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3(b) 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;

(b) a copy of the authorization to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 4a of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC;

(c) if the authorization referred to in (b) is not the first authorization for placing the product on the market as a medicinal product in the Community, 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.'

299 Article 19(1) of Regulation No 1768/92 relating to transitional provisions states:

'1. Any 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.

In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988.

In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982.'

300 Decision of the EEA Joint Committee No 7/94 of 21 March 1994 amending Protocol 47 and certain Annexes to the EEA Agreement (OJ 1994 L 160, p. 1) incorporated, in Annex 15 thereto, Regulation No 1768/92 into Annex XVII (Intellectual property) to the EEA Agreement. For the purposes of Article 3(b) of Regulation No 1768/92, an authorisation to place the product on the market granted in accordance with the national legislation of the State of the European Free Trade Association (EFTA) is treated as an authorisation to place a product on the market granted in accordance with Directive 65/65. Furthermore, Finland and Norway are amongst the countries for which no SPC can be granted if the first authorisation to place a product on the market in the EEA is prior to 1 January 1988. As regards Austria, the first authorisation to place a product on the market in the EEA cannot be prior to 1 January 1982.

As regards Sweden, an SPC cannot be granted if the first authorisation to place a product on the market in the EEA is prior to 1 January 1985.

301 Under Article 19(2) of Regulation No 1768/92, the time-limit for filing applications for SPCs under the transitional arrangements was 2 July 1993. Under Article 3 of Decision of the EEA Joint Committee No 7/94 the time-limit for filing SPC applications in Austria, Finland, Norway and Sweden was 1 January 1995.

302 The Court of Justice, hearing a reference for a preliminary ruling stemming from proceedings between AZ and Ratiopharm in Germany, was required, in Case C-127/00 *Hässle* [2003] ECR I-14781, first, to rule on the compatibility of the transitional arrangements implemented by Article 19 of Regulation No 1768/92 with the principle of equal treatment and, second, to interpret the concept of first authorisation to place a product on the market in Article 19(1) of that regulation.

303 As regards the compatibility of the transitional arrangements implemented by Article 19 of Regulation No 1768/92 with the principle of equal treatment, the Court of Justice held that the setting of different reference dates for different Member States was justified by legitimate objectives concerning national public-health policies and, in particular the financial stability of the health systems. According to the Court of Justice, the differences between the relevant dates resulted from the assessment made by each Member State in the light of its health system, the organisation and financing of which varied from one Member State to the next. It was therefore held that the transitional arrangements of Regulation No 1768/92 did not infringe the principle of equal treatment (*Hässle*, paragraph 302 above, paragraphs 38 to 42).

304 As regards the concept of first authorisation to place a product on the market in Article 19(1) of Regulation No 1768/92, the Court held that it referred solely to the first authorisation to place a product on the market in accordance with Directive 65/65, granted in any of the Member States, and did not refer to authorisations required under legislation on pricing of or reimbursement for medicinal products (*Hässle*, paragraph 302 above, paragraph 79). Henceforth, in so far as reference is made specifically to the concept of authorisation to place a product on the market, as interpreted by the Court of Justice in *Hässle*, paragraph 302 above, the expression 'technical authorisation' will be used.

305 The first abuse of a dominant position identified by the Commission consists of the submission, as part of an overall SPC strategy designed to keep manufacturers of generic products away from the relevant market, of a pattern of deliberately misleading representations to patent agents, national patent offices and national courts in order to acquire or preserve SPCs for omeprazole to which AZ was not entitled or to which it was entitled for a shorter duration (see recitals 144 and 626 of the contested decision).

306 The Commission distinguished two stages in the conduct of that first abuse. The first concerns AZ's misleading representations on 7 June 1993, when it sent instructions to the patent agents through whom SPC applications were filed in seven Member States, amongst them Germany, Belgium, Denmark, the Netherlands and the United Kingdom (see recital 628 of the contested decision).

307 The second stage consists, first, of misleading representations made in 1993 and in 1994 to patent offices in reply to their questions on the SPC applications filed by AZ, second, of misleading representations made in December 1994 during the second round of SPC applications in three EEA Member States, namely Austria, Finland and Norway, and, third, of misleading representations made subsequently to other patent

offices, as well as before national courts, in the context of proceedings brought by competing generic manufacturers with a view to invalidating the SPCs in those States (see recital 629 of the contested decision).

2. *First plea in law, alleging an error of law*

(a) Arguments of the applicants

Applicable legal principles

308 The applicants observe that there is no 'precedent' establishing that Article 82 EC applies to applications for acquiring or extending an intellectual property right and propose that this question be addressed in the light of three principles.

309 First, neither a mere intention fraudulently to obtain a patent or SPC, nor an application for a patent or SPC, even if made fraudulently, nor the grant of a patent or SPC, which is incapable of immediate enforcement, can amount to an abuse of a dominant position. The applicants maintain, in that regard, that abuse of a dominant position is

an objective concept that does not depend upon intention to cause harm to competition but upon an objective ascertainment of that effect in fact (*Hoffmann-La Roche* v *Commission*, paragraph 239 above, paragraph 91, and Case T-128/98 *Aéroports de Paris* v *Commission* [2000] ECR II-3929, paragraphs 172 and 173). Accordingly, an intention to restrict competition is not sufficient to prove the requisite effect on competition, since the conduct intended to have that effect must have been engaged in. It follows that conduct that has not actually been implemented or is not capable of having the effect of a restriction on competition does not constitute an abuse. The applicants submit, in particular, that evidence of 'subjective intention' to commit an abuse and evidence of conduct preparatory to an abuse, conduct which is not, in itself, capable of restricting competition, are not sufficient to establish the existence of an abuse within the meaning of Article 82 EC.

310 Second, in the absence of additional elements, the mere acquisition of an exclusive right is not an abuse of a dominant position (Case T-51/89 *Tetra Pak* v *Commission* [1990] ECR II-309, paragraphs 23 and 24). The applicants point out that the judgment in *Tetra Pak* v *Commission* concerns a specific case relating to the acquisition of an intellectual property right in circumstances where that right is akin to a business. In their submission, the acquisition of an exclusive patent licence constitutes an abuse of a dominant position where (i) that acquisition has the effect of strengthening the undertaking's dominance, (ii) very little competition is to be found and (iii) the acquisition of the right has the effect of precluding all competition in the relevant market.

311 Third, an abuse of a dominant position can only exist where the fraudulently obtained patent is enforced and that enforcement meets the conditions set out in Case T-111/96 *ITT Promedia* v *Commission* [1998] ECR II-2937. In that judgment, the Court held that the fact of bringing legal proceedings may constitute an abuse of a

dominant position within the meaning of Article 82 EC only in exceptional circumstances, namely where (i) the action cannot reasonably be considered as an attempt to establish the rights of the undertaking concerned and would therefore serve only to 'harass' the opposite party and (ii) the action is conceived in the framework of a plan whose goal is to eliminate competition. Those two conditions should be construed and applied strictly, in a manner which does not defeat the application of the general principle of access to the courts.

312 Consequently, the enforcement of a patent can amount to an abuse of a dominant position only when the undertaking has wilfully acquired or enforced the patent knowing that it is invalid. The applicants add that, although in certain circumstances it is possible for the mere maintenance or defence of a patent, without its active enforcement, to amount to an abuse of a dominant position, such abuse can take place only when the patent's period of protection commences. Allowing, for the purpose of finding an abuse of a dominant position, anything less strict than fraud and knowledge of the invalidity of the patent would result in a 'freeze' on patent applications in the European Community, since undertakings would fear that inadvertent error or negligence in patent enforcement could result in the imposition of fines by the Commission.

313 Patent protection is central to the encouragement of innovation in economically viable conditions and it is therefore necessary to recognise a public policy imperative that undertakings should not be unduly deterred from registering patents in the pharmaceutical sector under the SPC scheme.

314 In their reply, the applicants claim that it is necessary that the patent should have been enforced or threatened to have been enforced after the SPC was granted, and they maintain, alternatively, that the SPC should at least have been acquired and that its existence must have been capable of influencing the conduct of competitors. Moreover, deliberate and intentional fraud on the patent offices must be proved by means of clear and convincing evidence; mere negligence or inconsistency on the part of the applicant is insufficient.

315 The applicants add that the national laws and rules governing application for, and correction of, patents and SPCs provide for procedures enabling the courts or the patent offices to rectify, or even withdraw, the registration where errors have been made, whether inadvertently or fraudulently. In that regard, the patent offices and competing undertakings may challenge the patents or SPCs and, in certain circumstances, sue for damages. Consequently, it is not appropriate, in the applicants' submission, to use the competition rules to make remedies possible or impose punishments following acquisitions of patents and SPCs, by virtue of the fact that they are potentially anticompetitive, where such applications do not have any actual effect on competition. The role of competition rules is not to police patent applications, and the rules applicable to patent applications and SPCs are normally sufficient to preclude any anticompetitive effect. Accordingly, the applicants submit that, in order to be able to intervene, the Commission must demonstrate the anticompetitive effects.

316 In support of their argument, the applicants refer to United States law. In their submission, in the first place, under that law, an antitrust action is justified where the patent was procured by knowingly and wilfully misrepresenting facts to the patent office. In that regard, neither gross negligence nor recklessness, nor the existence of inequitable conduct are sufficient, proof of fraud being required. Wilful misrepresentation

amounting to intentional fraud is therefore an essential requirement for liability to be incurred, so that clear and convincing evidence of specific intent is required. Non-disclosure can support an allegation of fraud only in exceptional circumstances, where the intent to deceive and the reliance of the patent office which was induced, by virtue of that omission, to grant the patent are clearly established.

317 In the second place, in United States law, actual enforcement of the patent is necessary for application of the antitrust rules, mere acquisition of a patent being insufficient, since the immediate cause of the anticompetitive effect must be the conduct of the patent owner and not the action of the public agency. Further, just as in Community law, an action can be regarded as 'sham' only where the legal action is objectively baseless in the sense that no litigant could reasonably expect success on the merits.

318 Finally, the applicants submit that the performance of an act which is capable of restricting competition only if other contingent acts are also carried out cannot constitute an abuse of a dominant position. For the finding of an abuse of a dominant position, there must be a real probability that the act will result in a restriction of competition and a direct causal relationship between the act and the harm to competition. Thus acts that are purely internal to the undertaking concerned, such as a communication within the group, and external acts that are merely preparatory to a potential abuse of a dominant position but which are incapable of having an effect on competitors or competition, cannot be considered to be abusive. The applicants therefore dispute the Commission's assertion that the illegal nature of the behaviour cannot depend on the contingencies of the behaviour of a third party. They argue, by way of example, that a proposal for an agreement that would violate Article 81(1) EC would result in an infringement of the competition rules only if the parties reach agreement in that regard.

The errors of law allegedly made by the Commission

319 The applicants submit that the Commission erred in alleging that AZ's dealings with its patent attorneys revealed fraudulent conduct from 7 June 1993, when AZ communicated instructions to them (recital 774 of the contested decision). The Commission places the commencement of the abuse of a dominant position at a point in time even before the SPC was applied for. Since neither AZ nor its attorneys had yet contacted the patent offices and since AZ had not yet obtained a right or enforced a right, its conduct could not have had any effect on competition. The applicants add that it should not be considered that that conduct commenced in 1993, since the basic patents did not expire until five years later, in April 1999. The effect of that conduct on competition was therefore only very remote, especially as AZ had not yet exercised its rights conferred by those SPCs, for example, in response to a request for a licence. They submit that the Commission cannot justify that date by the fact this was the first act forming part of a chain of acts which was aimed at excluding competitors, since that reasoning would lead to the undertaking's liability being incurred in the absence of any direct effect on competition, in an excessively wide range of circumstances.

320 As regards the countries in which no SPCs were granted, namely Denmark and the United Kingdom, the applicants submit that the Commission erred in law in considering that AZ committed an abuse of a dominant position in those countries. In so far as the patent offices of those countries rejected AZ's applications and no SPCs were therefore granted, its conduct could not have had any effect on competition in those markets. Consequently, the applicants dispute the Commission's arguments in recitals 763 to 765 of the contested decision and state that it is necessary for the conduct to be capable of having an effect on competition. A mere application for an SPC is in itself not capable of having any actual effect on competition. At the very most, there were acts preparatory to an abuse, or an attempted abuse. In addition, the applicants maintain that the Commission conceded that the abuses ceased in June 1994 in the case of the United Kingdom and in November 1994 in the case of Denmark, that is to

say, long before the substance patents expired in April 1999 and therefore long before any grant of an SPC could have been capable of affecting competition. Moreover, no deterrent effect on the entry of competitors in the relevant market could have arisen in those countries.

321 In that regard, the applicants dispute the Commission's assertion in recital 762 of the contested decision that the grant of SPCs delays the preparations of generic producers which often take several years, and draw attention to the absence of evidence regarding the period needed for those preparations. In the applicants' submission, no deterrent effect arises before the commencement of the extended patent term, or until a time sufficiently close to the date on which that extended term is due to come into force, such that its prospective existence may influence competitors' behaviour. The Commission cannot therefore assert that five to six years prior to the expiration of the basic patent, a deterrent effect on the entry of competitors in the relevant market was capable of arising. Moreover, on the basis of the evidence adduced by the complainants, it was conceded, during the oral procedure, that generic medicines had not been affected by SPCs until after the expiry of the substance patent.

322 In response to recital 758 of the contested decision, in which the Commission asserts that where an undertaking actually implements a practice, the aim of which is to keep competitors away from the market, the fact that it does not achieve that aim is not enough to avoid the practice being characterised as an abuse of a dominant position, the applicants maintain that the acts implemented must themselves be capable of having that effect. Since the substance patents still had five years to run, the mere application for SPCs could not conceivably have been capable of having such a far-off effect. In addition, even if AZ had succeeded in obtaining SPCs in Denmark and the United Kingdom, it is necessary, in order for competition law to be applicable, for AZ to seek to enforce its rights. Consequently, AZ's attempts to obtain SPCs in Denmark and the United Kingdom are not abusive and, even if it is decided otherwise, the

duration of the alleged infringements is far too long because it has as its starting point preparatory acts which were not abusive in themselves.

323 As regards the countries in which SPCs were granted, the applicants maintain that, contrary to what the Commission contends, the judgment in *Tetra Pak* v *Commission*, paragraph 310 above, makes it clear that the mere acquisition of intellectual property rights does not in itself constitute an abuse of a dominant position. Paragraph 139 of the judgment in *ITT Promedia* v *Commission*, paragraph 311 above, which refers to the abovementioned judgment, adds nothing to the *Tetra Pak* judgment.

324 Moreover, those judgments are to be distinguished from the present case, in so far as they were considering the acquisition by a company in a dominant position of intellectual property rights belonging to another person. There is no 'precedent' which makes it possible to state that the acquisition of a patent or an SPC for a company's own inventions is abusive, nor any basis for that view. In the applicants' submission, something more is required, namely the elimination of all competition (*Tetra Pak* v *Commission*, paragraph 310 above) or the exercise of the SPC (United States case-law). However, it is clear that the grant of the SPCs did not have the effect of eliminating all competition, since, as the Commission itself has acknowledged, subsequent to the grant of the SPCs, competition increased and AZ lost market shares.

325 The applicants submit that, prior to the expiry of the substance patents in Belgium, Denmark, Germany, the Netherlands, Norway and the United Kingdom in April 1999, the grant of the SPCs was not capable of having any further restrictive effect on

competition, since the market entry of generics was in any event precluded as a result of the existence of the basic patents.

326 As regards Germany, the Commission conceded that AZ did not have a dominant position after the end of 1997, a time long before the SPCs came into effect. Moreover, in recital 766 of the contested decision, the Commission acknowledges that the SPC granted in Germany had been revoked prior to the expiry of the basic patent, which makes it impossible for AZ's conduct to have had any restrictive effect on competition. Furthermore, it is not at all proven that the brief existence of the SPC in Germany, which was revoked in June 1997, that is, two years before its planned entry into force in April 1999, was capable of deterring competitors from preparing their market entry on that latter date.

327 The applicants maintain that, as regards the countries for which the dates of 1 January 1985 and 1 January 1982 are laid down by Article 19 of Regulation No 1768/92 as the dates after which the first authorisation to place a product on the market in the Community must have been obtained in order for that product to be granted an SPC, the only effect of the alleged abuse was to extend the duration of the SPCs by 7 months. In Belgium and the Netherlands, the extra time gained as a result of the grant of the SPCs started in April 2002 and finished in September and October 2002 respectively. It was therefore only during that period that the conduct at issue would have been capable of producing an anticompetitive effect. However, on the Commission's definition of the relevant product market, AZ's dominance in those countries ceased at the end of 2000. Accordingly, AZ was not in a dominant position at the time when its conduct was capable of producing an effect. Nor can any deterrent effect on competitors' entering the market be identified in 2002.

328 Norway is the only country in which AZ could have been dominant at a point in time when its conduct was capable of having an effect on competition. However, the SPC in that country was revoked by the District Court of Oslo in June 1999, two months after the basic patent had expired in April 1999. In the applicants' submission, no competition could have been excluded by reason of the SPC, since AZ had a formulation patent that did not expire until well after the first abuse of a dominant position alleged had terminated.

(b) Arguments of the Commission

Applicable legal principles

329 The Commission contends that the use of public procedures and regulations may, in specific circumstances, constitute an abuse of a dominant position (Joined Cases C-395/96 P and C-396/96 P *Compagnie maritime belge transports and Others* v *Commission* [2000] ECR I-1365, paragraphs 82 to 88), in so far as such public regulations may impose potent entry barriers capable of preserving market power over extended periods of time. In the Commission's view, misrepresentations that distort national authorities' decision-making in ways that create or shield market power may inflict severe public harm.

330 In that context, the limited discretion of the national authorities in question as to the action to be taken in respect of the request is a relevant circumstance which must be taken into consideration (*Compagnie maritime belge and Others* v *Commission*,

paragraph 329 above, paragraph 82). Where the discretion of the administrative authority is limited, the cause of the anticompetitive effect resulting from a decision based on inaccurate information is not State action, but the misrepresentations.

331 The Commission observes that the fact that the effects on the market may be dependent on further action by public authorities does not exclude the existence of an abuse, since the abuse exists even if the public authority does not react as requested. The illegal nature of behaviour cannot depend on the contingencies of the behaviour of a third party. It is therefore irrelevant whether or not the public authority actually granted the SPC pursuant to AZ's misleading representations. The Commission adds that if the abuse could be found only in the Member States where a given behaviour was successful, the very same behaviour could constitute an infringement in some Member States but not in others, depending on how the public authority reacted. However, the scope of Article 82 EC covers behaviour which is aimed at or capable of achieving anticompetitive effects, regardless of its success.

332 From that point of view, it is the date of the implementation of the conduct capable of restricting competition which must be taken as the starting point of the abuse, even if a period of time elapses before that course of conduct produces the desired anticompetitive effects and the achievement of those effects is dependent on third party factors. Any other solution would, in the Commission's view, lead to the inference that the period in which the abuse occurred is a period in which the undertaking does not deploy any behaviour, but in which the effects are produced. Moreover, since the exclusion of the competitor is frequently the point in time when the abuse ends, there is no point, in the Commission's view, in being in a position to continue exclusionary behaviour only from the time when its aim has been achieved. The Commission therefore rejects the applicants' argument that there is no abuse until the SPC comes

into effect. The fact that the intended effect was supposed to occur at a later date does not alter the fact that the behaviour intended to achieve that effect was implemented.

333 The Commission adds that the distinction, advanced by the applicants, between internal and external acts is irrelevant since, depending on the circumstances, what may at first sight appear to be an internal act, when considered in isolation, may, when assessed in its context, be evidence of a Treaty infringement.

334 In reply to the arguments advanced by the applicants, the Commission points out, first, that, although abuse is an objective concept (*Hoffmann-La Roche*, paragraph 239 above), the establishment of which does not require the existence of intent, intent is nevertheless not irrelevant. It then explains that its case is not simply based on intent, but on a course of conduct executing that intent and aimed at excluding competitors. Intention is a relevant element in assessing whether behaviour is objectively capable of restricting competition, since, if an undertaking implements a strategy aimed at excluding competitors, or in the knowledge that it is liable to have such effect, its behaviour is capable of restricting competition. In any event, behaviour whose purpose or object is to restrict competition falls within the scope of Article 82 EC, regardless of whether the aim is achieved (Opinion of Advocate General Tizzano in Case C-551/03 P *General Motors* [2006] ECR I-3173, points 77 and 78, and Case T-203/01 *Michelin* v *Commission* [2003] ECR II-4071, paragraphs 241, 242 and 245). The Commission denies, furthermore, that the contested decision is based on mere intention on the part of the applicants, since that decision identified behaviour which was capable of excluding competitors.

335 It points out the concept of 'fraud' does not appear in the contested decision, which uses the expression 'misleading representations'. In order to be abusive, a representation does not necessarily have to contain false information, originating in a 'falsehood', since misleading information is also liable to induce public bodies to act in a way which is capable of excluding competition. In that regard, the Commission argues that a statement which may be true when considered in isolation remains misleading when it is not accompanied by material, qualifying facts.

336 The Commission submits that the applicants' argument that conduct that has not actually been implemented or is not capable of having the effect of a restriction on competition is not an abuse is irrelevant since its case is based on a course of conduct which was both intended to produce and capable of producing such a restriction. The Commission also states that the acquisition of an exclusive right may constitute an abuse (*Tetra Pak* v *Commission*, paragraph 310 above, paragraphs 23 and 24, and *ITT Promedia* v *Commission*, paragraph 311 above, paragraph 139). In its view, there is no reason to treat the acquisition of a licence to an industrial process differently from the acquisition of an SPC, since their effect on competition, namely the exclusion of competitors, is the same. In regard to the distinction which the applicants draw between the present case and the cases which gave rise to the judgments in *Tetra Pak* v *Commission*, paragraph 310 above, and *ITT Promedia* v *Commission*, paragraph 311 above, the Commission contends that the latter judgment does not concern the acquisition by a dominant company of intellectual property rights belonging to another. Moreover, the Commission disputes that the SPC was the applicant's before it was granted and submits that the 'something more' to which the applicants refer consists of the pattern of misleading representations. Furthermore, the case-law does not require the elimination of all competition for a finding of abuse. As recitals 758 to 770 of the contested decision show, it is sufficient that the entry of generic medicinal products is prevented or delayed in some markets.

337 The Commission points out, next, that this case only incidentally concerns court proceedings, since the matters at issue in this case are misleading representations to patent agents and patent offices. It refers, in this regard, to recitals 736 to 740 of the contested decision and asserts that AZ's submissions before the courts are the logical continuation of a proactive exclusionary strategy implemented as of 6 May 1993 at the latest and consisting of misleading representations. Accordingly, in so far as the competitors had to bear the costs and suffer the delays associated with legal proceedings, that was a consequence of the SPCs granted as a result of AZ's misleading representations, which obliged them to engage in extensive litigation.

338 The Commission denies that the contested decision is liable to have a deterrent effect on patent applications and states that the need to avoid discouraging parties from communicating with public authorities means that simple inaccuracies, negligent misstatements or the expression of debatable opinions must not be regarded as infringements of Article 82 EC. However, in the present case, the behaviour at issue does not consist of simple mistakes or isolated incidents of negligence, but is, on the contrary, characterised by continuity and consistency, indicating 'subjective intent' and full knowledge of the misleading character of the representations. The Commission maintains that such misuse of the patent system reduces the incentive to engage in further innovation, since it enables the company in a dominant position to rely on continued rents beyond the period envisaged by the legislator, and runs counter to the purposes of competition. It adds that this case does not concern a patent application, in which a government agency is required to assess numerous factors in order to determine the merits of the claimed invention, but the granting of an SPC under provisions which, at the material time, laid down only formal requirements and prescribed very little verification of the information.

339 With regard to the existence of specific patent remedies, the Commission points out that these have proved insufficient to deter misuses of the patent system by dominant

companies. In 1993, the applicants considered that the only risk incurred by their behaviour was a reduction of the duration of the SPC (recitals 200 and 745 of the contested decision). The Commission further disputes that the fact that Regulation No 1768/92 provides for specific remedies excludes the application of the competition rules and their own remedies. In its view, the concept of abusive conduct cannot be limited to conduct which does not violate other laws or for which no other remedy is available, since actual or foreseeable anticompetitive effects fall within the scope of competition law. Moreover, the scope of the 'remedy' provided for by that regulation would have been limited, since it would not have addressed the implementation of the exclusionary strategy in cases where that strategy did not result in the acquisition of an SPC, and would not have taken into account the anticompetitive object of the conduct where it is attributable to a dominant undertaking. Furthermore, competitors could not easily have challenged SPCs obtained by AZ since they did not have ready access to the relevant information concerning the date of technical authorisation in Luxembourg and the date of effective marketing in that country.

340 With regard to United States law, the Commission submits that it has limited relevance to the present case. In reply to the applicants' assertions, it states that there exists, in United States law, a '*Noerr-Pennington*' doctrine, according to which misrepresentations in a lobbying campaign in the political context are not subject to Sherman Act liability. However, it notes that the United States Supreme Court held that, when made in the adjudicatory process, such misrepresentations were not eligible for protection under that doctrine and could be subject to Sherman Act liability and, more specifically, that the enforcement of a patent procured by fraud on the Patent Office might be contrary to Section 2 of the Sherman Act. Moreover, many decisions of United States courts have recognised that misrepresentations may be caught by the Sherman Act. The Commission notes that that case-law also covers material omissions. In one of its judgments, the Federal Circuit even used the words 'inappropriate attempt to procure a patent' in place of 'fraudulent procurement' and

stated that fraud involved the 'intent to deceive', or at the very least a state of mind so reckless as to the consequences that it is held to be the equivalent of intent. Thus, contrary to the applicants' assertions, United States law does not require, for the purpose of establishing fraud, that the information is false.

341 The Commission acknowledges that certain courts have accepted that antitrust liability requires that measures are taken to enforce the patent. It points out, however, that other courts have held that the furnishing of false information is enough. Moreover, according to the Commission, although it has been considered in United States law that enforcing a fraudulently obtained patent may be abusive, that does not exclude the possibility that other types of behaviour may also be abusive.

342 It also submits that, in United States law, a further relevant point is whether the regulatory context surrounding the conduct at issue confers on the government agency a broad discretion or requires it to carry out only 'ministerial acts' involving minimal verification. It adds that, in contrast to European competition law, which applies regardless of the actual effects of the behaviour, United States case-law is based on liability in tort for fraud. However, this requires reliance by the authorities on a representation in order to establish a causal link between the misrepresentation and the harm.

343 It disputes, moreover, that the standard of proof required in antitrust cases based on misrepresentations is higher than the normal standard of proof. It makes the point, in that regard, that 'circumstantial evidence' was considered sufficient in the judgment of the Federal Circuit, mentioned in paragraph 340 above, since the court did not consider that intent needed to be proved by direct evidence. The Commission adds

that the contested decision is based on a wide and consistent body of evidence covering an extended period of time and bringing to light a consistent course of conduct.

The errors of law allegedly made by the Commission

344 The Commission contends that the sending of instructions on 7 June 1993 cannot be seen as a mere preparatory act, having regard to the context, nature and content of the instructions and applications. As regards, first, the regulatory context, the Commission points out that, under Article 10(5) of Regulation No 1768/92, Member States were not required to verify the date of the first authorisation to place the product on the market in the Community and that, in practice, they carried out limited verification in that regard. It maintains that, contrary to what is applicable in the context of a patent application, it was not the task of the patent offices to carry out a substantive assessment, since they were only obliged to consider a number of formal factual requirements in order to decide on the extension of a patent whose merits had already been assessed in connection with the patent application. Thus, the competent patent authorities had, in this case, only limited scope for assessment. Moreover, only AZ had knowledge of certain facts, such as the date as of which Losec was launched in Luxembourg, and this considerably limited the role of third parties in the process.

345 In the Commission's view, any misleading representation does not necessarily infringe Article 82 EC, since some representations can have only limited consequences for the granting of an SPC. In order to constitute an abuse of a dominant position, the

misleading representation must play a determining role in the decision. In the present case, it is reasonable to assume that, if the applicants had not made those representations, they would not have obtained an SPC in the countries in respect of which the first authorisation to place a product on the market in the Community must be after 1 January 1988, namely Germany, Denmark, Finland and Norway, or would have obtained them for a shorter period in the countries in respect of which the first authorisation to place a product on the market in the Community must be after 1 January 1982, namely Austria, Belgium and Italy, or after 1 January 1985, namely Ireland, the Netherlands, Luxembourg, the United Kingdom and Sweden. The Commission adds that the applicants' SPC applications gave no grounds for assuming that they were not based on the interpretation generally accepted at the time, which took into account the first technical authorisation date. Furthermore, the interpretation relying on the 'effective marketing theory' enabled AZ to deceive the public authorities, since it alone held the crucial information, thereby imposing on it an even greater burden to make representations which were not misleading.

346 Since protection of substances by an SPC has a practically total exclusionary effect on competing generic versions, the date of expiry of a substance patent or an SPC affects the preparations being made by generic manufacturers wishing to launch generic versions, who often strive to be ready to launch their products on the very day the patent or SPC expires. Business decisions by pharmaceutical companies are adopted well before the expiry of the substance patent, as is apparent from the interest expressed by Ratiopharm in AZ's SPC in Germany and the Netherlands in 1996 and 1997. It is therefore incorrect, in the Commission's view, to consider that there can be no abuse until the SPC comes into force. Moreover, the abuse also affected competitors in that it obliged them to incur considerable expenses in order to attempt to have certain of the SPCs revoked.

347 In the light of the foregoing, the Commission submits that the arguments advanced by the applicants are unfounded. As regards, first, the argument that there is no abuse of a dominant position prior to the actual application for an SPC, the Commission considers that the start of the abuse is the point in time when the applicant first adopts the behaviour objected to. Implementation of the strategy started with the instructions to the patent attorneys on 7 June 1993, which competitors had no way of knowing. The fact that this first act, which is part of a course of conduct, does not suffice, in itself, to achieve the desired effect and that acts by others have to occur for AZ to succeed in its strategy is irrelevant to the finding of an infringement of Article 82 EC, for the reasons set out in paragraph 331 above.

348 The Commission adds that, in the specific context in which the SPC applications were made, there was a high probability that the patent offices would accept the dates provided by AZ without verifying them. Consequently, the fact, to which attention is drawn by the applicants, that certain authorities, unlike others, were in the end not misled by AZ's representations is also irrelevant. The capacity of AZ's behaviour to restrict competition was the same in all the countries in question and is demonstrated by the fact that SPCs were granted in most of those countries. The fact that no SPCs were granted in Denmark and the United Kingdom simply shows that the effects depended on the behaviour of third parties. However, the patent offices in those latter countries might have been misled in the same way as other offices were.

349 The Commission disputes that the complainants acknowledged at the hearing that generic medicinal products had felt no effect of an SPC until after the expiry of the substance patent and submits that this is not at all apparent from the document cited by the applicants. On the contrary, the complainants stated that 'the very knowledge that Astra would benefit from a period of protection covered by the SPC ha[d] a "chilling" effect on those preparing to enter the market'. The Commission again adds

that competitors were affected by the fact that they incurred considerable expenses in order to attempt to have the SPCs revoked (recitals 760 and 762 of the contested decision).

350 Moreover, the Commission disputes that an abuse of a dominant position can be identified only when measures to enforce intellectual property rights are taken. The acquisition of an intellectual property right may be an abuse in itself, since other undertakings are expected to respect the exclusive rights associated with it. In the alternative, the Commission submits that the advertisement placed by AZ in a pharmaceutical journal, by which it made known its intention to 'ensur[e] that these intellectual property rights are respected and … take legal action against infringers thereof' is sufficient proof of enforcement in this case. Moreover, AZ brought actions for infringement in Germany on the basis of the SPC, which forced its competitors to incur considerable costs in attempting to have AZ's SPC revoked (see recitals 760 and 766 of the contested decision). The Commission contends that those measures are part of an overall strategy of exclusion, which started with the misleading representations in 1993.

351 With regard to the situations where AZ was able to prolong the period for which the SPCs were granted, the Commission agrees that the exclusionary effect is shorter in duration. However, that fact does not affect the finding that there was abuse. Moreover, the fact that the effects of the abusive behaviour occur at a time when the company is no longer dominant is equally incapable of affecting the legal assessment of the behaviour implemented when the company was in that dominant position, which is the only relevant circumstance. The Commission adds that there was a strong interrelationship between the components of the abuse, since impacts on the competitive situation in one country could potentially spill over into another country. The fact that AZ's misleading representations continued to produce effects until they were corrected and, moreover, were liable to have effects in other countries means that, in so far as it concerned Belgium, Germany, the Netherlands and Norway, the abuse of a dominant position cannot be limited to the last misleading representation in respect of those countries. In addition, the Commission submits that, taking into account

the level of sales of Losec at the time of expiry of the basic patent, the actual supplementary protection in Belgium, the Netherlands and Norway related to considerable interests.

(c) Findings of the Court

The classification of the behaviour in question as an abuse of a dominant position

352 According to settled case-law, an abuse is an objective concept referring 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 already weakened and which, through recourse to methods different from those governing normal competition in products or services on the basis of traders' performance, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition (*Hoffmann-La Roche* v *Commission*, paragraph 239 above, paragraph 91; *AKZO* v *Commission*, paragraph 243 above, paragraph 69; Case T-228/97 *Irish Sugar* v *Commission* [1999] ECR II-2969, paragraph 111; and *Michelin* v *Commission*, paragraph 334 above, paragraph 54).

353 In this respect, it should be borne in mind that Article 82 EC is aimed both at practices which may cause damage to consumers directly and at those which are detrimental to them through their impact on an effective competition structure (*Europemballage and Continental Can* v *Commission*, paragraph 267 above, paragraph 26).

354 It follows that Article 82 EC prohibits a dominant undertaking from eliminating a competitor and thereby strengthening its position by using methods other than those which come within the scope of competition on the merits (*AKZO* v *Commission*, paragraph 243 above, paragraph 70, and *Irish Sugar* v *Commission*, paragraph 352 above, paragraph 111). It is also apparent from the case-law that an abuse of a dominant position does not necessarily have to consist in the use of the economic power conferred by a dominant position (see, to that effect, *Europemballage and Continental Can* v *Commission*, paragraph 267 above, paragraph 27, and *Hoffmann-La Roche* v *Commission,* paragraph 239 above, paragraph 91).

355 In the present case, the Court observes that the submission to the public authorities of misleading information liable to lead them into error and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, constitutes a practice falling outside the scope of competition on the merits which may be particularly restrictive of competition. Such conduct is not in keeping with the special responsibility of an undertaking in a dominant position not to impair, by conduct falling outside the scope of competition on the merits, genuine undistorted competition in the common market (see, to that effect, *Nederlandsche Banden-Industrie-Michelin* v *Commission*, paragraph 30 above, paragraph 57).

356 It follows from the objective nature of the concept of abuse (*Hoffmann-La Roche* v *Commission*, paragraph 239 above, paragraph 91) that the misleading nature of representations made to public authorities must be assessed on the basis of objective factors and that proof of the deliberate nature of the conduct and of the bad faith of

the undertaking in a dominant position is not required for the purposes of identifying an abuse of a dominant position.

357 The Court would point out that the question whether representations made to public authorities for the purposes of improperly obtaining exclusive rights are misleading must be assessed *in concreto* and that assessment may vary according to the specific circumstances of each case. In particular, it is necessary to examine whether, in the light of the context in which the practice in question has been implemented, that practice was such as to lead the public authorities wrongly to create regulatory obstacles to competition, for example by the unlawful grant of exclusive rights to the dominant undertaking. In this respect, as the Commission asserts, the limited discretion of public authorities or the absence of any obligation on their part to verify the accuracy or veracity of the information provided may be relevant factors to be taken into consideration for the purposes of determining whether the practice in question is liable to raise regulatory obstacles to competition.

358 Moreover, in so far as an undertaking in a dominant position is granted an unlawful exclusive right as a result of an error by it in a communication with public authorities, its special responsibility not to impair, by methods falling outside the scope of competition on the merits, genuine undistorted competition in the common market requires it, at the very least, to inform the public authorities of this so as enable them to rectify those irregularities.

359 The Court would also point out, in the light of the applicants' arguments set out in paragraphs 309, 312 and 314 above, that, although proof of the deliberate nature of conduct liable to deceive the public authorities is not necessary for the purposes of identifying an abuse of a dominant position, intention none the less also constitutes a relevant factor which may, should the case arise, be taken into consideration by the Commission. The fact, relied upon by the applicants, that the concept of abuse of a dominant position is an objective concept and implies no intention to cause harm (see, to that effect, *Aéroports de Paris* v *Commission*, paragraph 309 above, paragraph 173) does not lead to the conclusion that the intention to resort to practices falling outside the scope of competition on the merits is in all events irrelevant, since that intention

can still be taken into account to support the conclusion that the undertaking concerned abused a dominant position, even if that conclusion should primarily be based on an objective finding that the abusive conduct actually took place.

360 Lastly, the mere fact that certain public authorities did not let themselves be misled and detected the inaccuracies in the information provided in support of the applications for exclusive rights, or that competitors obtained, subsequent to the unlawful grant of the exclusive rights, the revocation of those rights, is not a sufficient ground to consider that the misleading representations were not in any event capable of succeeding. As the Commission rightly observes, where it is established that behaviour is objectively of such a nature as to restrict competition, the question whether it is abusive in nature cannot depend on the contingencies of the reactions of third parties.

361 Consequently, the Commission applied Article 82 EC correctly in taking the view that the submission to the patent offices of objectively misleading representations by an undertaking in a dominant position which are of such a nature as to lead those offices to grant it SPCs to which it is not entitled or to which it is entitled for a shorter period, thus resulting in a restriction or elimination of competition, constituted an abuse of that position. The question whether those representations were objectively misleading must be assessed in the light of the specific circumstances and context of each individual case. In this case, the factual assessment made by the Commission in this respect is the subject of the second plea.

362 The Court rejects the applicants' argument that a finding of an abuse of a dominant position requires that an exclusive right obtained as a result of misleading representations has been enforced. When granted by a public authority, an intellectual property

right is normally assumed to be valid and an undertaking's ownership of that right is assumed to be lawful. The mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since public regulations require them to respect that exclusive right. Furthermore, to the extent that the applicants argue that an intellectual property right must have been exercised in legal proceedings, that argument would tend to make the application of Article 82 EC conditional on the contravention by competitors of the public regulations by their infringing the exclusive right of an undertaking; that argument must be rejected. Moreover, third parties seldom have information enabling them to know whether an exclusive right has been unlawfully granted.

363 Consequently, the applicants' arguments, based on the application of the criteria used by the Commission in *ITT Promedia* v *Commission*, paragraph 311 above, must also be rejected as irrelevant, since those criteria relate to a possibly abusive exercise of the right to bring legal proceedings against a competitor.

364 Moreover, it is not the case that the unlawful acquisition of an exclusive right constitutes an abuse of a dominant position only where it would have the effect of eliminating all competition. The fact that the behaviour in question concerns the acquisition of an intellectual property right does not justify such a condition.

365 In this respect, the applicants cannot rely on the judgment in *Tetra Pak* v *Commission*, paragraph 310 above, in order to submit that elimination of all competition would be necessary. The Court observes, first of all, that the present case and the judgment in *Tetra Pak* v *Commission*, paragraph 310 above, concern different situations. Whereas the present situation concerns acts liable to induce public authorities to grant an intellectual property right to which the undertaking in a dominant position is not entitled or to which it is entitled for a shorter duration, the judgment in *Tetra Pak* v *Commission*, paragraph 310 above, relates to the acquisition by an undertaking in a dominant position of a company holding an exclusive patent licence which constituted the only means of competing effectively with the undertaking in the dominant

position (paragraphs 1 and 23 of that judgment). Next, it is not all apparent from that judgment that Article 82 EC requires the elimination of all competition in order to be applied. In that judgment, the Court merely approved the Commission's assessment that, in the case before it, Article 82 EC did not allow the undertaking in a dominant position, by acquiring an exclusive licence, to strengthen its '[already] very considerable' dominance and to prevent or considerably delay 'the entry of a new competitor into a market where very little if any competition [was] found' (paragraph 23 of that judgment).

366 Furthermore, the Court rejects the applicants' argument that the existence of specific remedies which make it possible to rectify, or even annul, patents and SPCs granted unlawfully justifies application of the competition rules only where an anticompetitive effect is demonstrated. Where behaviour falls within the scope of the competition rules, those rules apply irrespective of whether that behaviour may also be caught by other rules, of national origin or otherwise, which pursue separate objectives. Similarly, the existence of remedies specific to the patent system is not capable of altering the conditions of application of the prohibitions laid down in competition law and, in particular, of requiring, in cases of behaviour such as that at issue in the present case, proof of the anticompetitive effects produced by such behaviour.

367 Nor can the applicants object that a finding of an abuse of a dominant position in cases where misleading representations have been made to patent offices for the purposes of obtaining intellectual property rights to which an undertaking is not entitled, or to which it is entitled for a shorter period, would result in a 'freeze' on patent applications and would run counter to the public interest in encouraging innovation. It is quite clear that, where established, such behaviour is indeed contrary to the public interest, as weighed up and applied by the legislator. As the Commission observes,

such misuse of the patent system potentially reduces the incentive to engage in innovation, since it enables the company in a dominant position to maintain its exclusivity beyond the period envisaged by the legislator.

368 Lastly, with respect to the applicants' arguments based on United States law, suffice it to note that the position adopted by the latter cannot take precedence over that adopted by European Union law (*Atlantic Container Line and Others* v *Commission*, paragraph 243 above, paragraph 1407).

The start of the alleged abusive practice

369 As regards the date on which the abuse of a dominant position — if established — is deemed to have started, the Commission took the view that, in the case of Germany, Belgium, Denmark, the Netherlands and the United Kingdom, that abuse started to be implemented on 7 June 1993, when the final instructions for the SPC applications in respect of omeprazole were sent to the patent attorneys in those countries (see recitals 179, 651 and 774 of the contested decision). As the applicants observe, the Commission thus puts the commencement of the alleged abuse of a dominant position at a point in time even before the SPC applications were filed with the patent offices.

370 The Court considers however that instructions sent to patent attorneys to file SPC applications cannot be regarded as equivalent to the filing of SPC applications themselves before patent offices. The desired outcome of the alleged misleading nature of the representations, namely the grant of the SPC, can arise only from the time

that the SPC applications are filed before the patent offices, and not when the patent attorneys, who in this case have only an intermediary role, receive the instructions regarding those applications.

371 The Court also notes that the Commission's position as regards the date on which the alleged first abuse started in Germany, Belgium, Denmark, the Netherlands and the United Kingdom is not consistent with its approach as regards Norway. The Commission found that, in Norway, the alleged first abuse started on 21 December 1994, namely when the patent attorney transmitted the SPC application to the Norwegian patent office (see recitals 234 and 774 of the contested decision).

372 The applicants are therefore justified in claiming that the Commission erred in law in considering that the alleged first abuse of a dominant position committed by AZ in Germany, Belgium, Denmark, the Netherlands and the United Kingdom started on 7 June 1993, when instructions were transmitted to the patent attorneys to file the SPC applications before the patent offices.

373 That error is not however capable of affecting the lawfulness of the contested decision as regards the existence of the alleged abusive practice from the time when the SPC applications were transmitted to the national patent offices. In this respect, according to recital 185 of the contested decision, the SPC applications were transmitted to the patent offices in Germany, Belgium, Denmark, the Netherlands and the United Kingdom between 12 and 30 June 1993. The consequences of that error for the amount of the fines will, where appropriate, be assessed below, in the part dealing with the applicants' plea on that point.

The anticompetitive nature of the behaviour objected to and its effects on competition

374 The applicants dispute that AZ's misleading representations before the patent offices were of an anticompetitive nature and claim that they were not capable in themselves of restricting competition.

375 The Court would point out, first of all, that, as was observed in paragraph 355 above, the acquisition, by means of conduct liable to mislead the public authorities, of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, constitutes a practice falling outside the scope of competition on the merits which may be particularly restrictive of competition. The assessment of whether representations made to public authorities for the purposes of improperly obtaining exclusive rights are objectively misleading must be undertaken with due regard to the specific features of the case.

376 The applicants claim that an abuse of a dominant position can be identified only where the behaviour in question has a direct effect on competition and that, in this case, the unlawful SPC applications had only remote effects on competition. In this respect, the Court would point out that it is not at all apparent from the case-law that, in order to constitute an abuse of a dominant position, behaviour must have a direct effect on competition. In a situation such as that of the present case, where the practices in question — if they are established — cannot, in any way, be regarded as being covered by normal competition between products on the basis of an undertaking's performance, it is sufficient for it to be established that, in view of the economic or regulatory context of which those practices form part, they are capable of restricting competition. Thus, the ability of the practice in question to restrict competition may be indirect, provided that it is shown to the requisite legal standard that it is actually liable to restrict competition.

377 Moreover, and as the Commission observes, in order to achieve its aim, conduct aimed at excluding competitors frequently requires cooperation from third parties, whether from public authorities or market players, since, in practice, such conduct is rarely capable of having a direct effect on the competitive position of competitors. Thus, the success of a practice of excluding competitors by setting up barriers to entry of a regulatory nature through unlawfully obtaining exclusive rights necessarily depends on the reaction of public authorities, or even that of national courts if proceedings have been brought by competitors in order to have those rights invalidated. None the less, representations designed to obtain exclusive rights unlawfully constitute an abuse only if it is established that, in view of the objective context in which they are made, those representations are actually liable to lead the public authorities to grant the exclusive right applied for.

378 The applicants dispute that a finding of an abuse of a dominant position in Germany, Belgium, Denmark, Norway, the Netherlands and the United Kingdom can be made and rely, in this respect, on arguments of a factual nature designed to persuade the Court that the acquisition of SPCs was not capable of having a restrictive effect on competition. In so far as those arguments are essentially factual in nature, the Court will examine them in paragraphs 601 to 607 below, in the context of the examination of the second plea, which is devoted to review of the Commission's assessment of the facts constituting the first abuse of a dominant position.

379 In so far as those arguments concern questions of principle, the applicants cannot rely on the fact that in Belgium and the Netherlands AZ was no longer in a dominant position at the time when the SPCs conferred supplementary protection. The fact that AZ was no longer in a dominant position at the time when its abusive behaviour was able to produce its effects does not alter the legal classification to be attached to its acts, since those acts were committed at a time when AZ was under a special responsibility not to allow its behaviour to impair genuine undistorted competition on the common market.

380 Lastly, the fact, relied upon by the applicants on several occasions, that the effect on competition of the misleading representations and the resulting grant of the SPCs would be felt only several years later, when the basic patents expired, does not cause the behaviour in question — if it is established — to lose its abusive character, in view of the exclusionary effect on competitors that may be expected when those SPCs are granted and are not subsequently revoked. Furthermore, as regards the objection to recital 762 of the contested decision, in which the Commission relies on the fact that the mere existence of the SPCs delays the preparations of generic producers, it follows from the foregoing that, even assuming that there is no such effect or it is on a lesser scale, objectively misleading representations whose object it is to obtain unlawful SPCs are in themselves — if they are established — liable to restrict competition.

381 In view of all the foregoing, the Court upholds the first plea in so far as it alleges an error of law by the Commission in its assessment of the date when the alleged first abuse of a dominant position started in Germany, Belgium, Denmark, the Netherlands and the United Kingdom. In those countries, the alleged first abuse did not start when AZ sent its instructions to the patent attorneys, but when the SPC applications were transmitted to the national patent offices. In those circumstances, and in the light of recital 185 of the contested decision, the Court finds that the first abuse of a dominant position — if it is established — started on 30 June 1993 at the latest.

382 However, the Court dismisses the first plea as to the remainder.

3. *The second plea in law, alleging failure to prove the abuse of a dominant position*

(a) Arguments of the applicants

The allegation of fraud

383 The applicants submit that the Commission's allegations relating to a strategy of making deliberate misrepresentations must be proved by evidence of the 'clearest nature'. Under the principle of the presumption of innocence, those allegations cannot be based on surmise and inference from circumstances which do not of themselves necessarily lead to a finding of fraud. In that regard, the applicants refer to United Kingdom and United States law and point out, in particular, that, contrary to what the Commission claims, the judgment of the Federal Circuit, referred to in paragraph 340 above, also requires 'clear and convincing' evidence of specific intent, evidence demonstrating gross negligence being insufficient. The applicants thus cast doubt on the relevance of the case-law relating to cartels. In the context of cartels, it is possible to infer intent or the existence of an agreement from the holding of meetings between competitors. However, in the context of relatively routine acts of patent prosecution, evidence which may seem to support the existence of fraud could equally well be consistent with gross negligence or inadvertence.

384 However, the Commission based its arguments on evidence which does not meet the required standard. In that regard, the applicants maintain that a series of insufficiently founded allegations, tenuous inferences and insinuations does not amount, even taken together, to clear and convincing proof. The Commission made selective references to documentary evidence, sometimes taking them out of context, and gave biased interpretations of them. Nor did it ever meet either AZ's employees or the authors of the documents on which it relies, and conducted no enquiries of experts, of the relevant patent offices or of patent attorneys.

385 It is insufficient for a finding of abuse merely to show that AZ did not proactively disclose the legal interpretation on the basis of which it was making its patent extension applications. That is, in any event, insufficient to demonstrate the intentional nature of an abuse of this type if, on the one hand, the interpretation of the regulatory context was held reasonably and in good faith and, on the other, that interpretation was revealed in response to a request for information on the part of the public authority. Consequently, the fact alleged by the Commission that the head of the patent department knew that the representations were incomplete or not wholly transparent is clearly inadequate for a finding of an abuse of this nature.

386 The applicants argue that AZ had interpreted 'first authorisation to place the product on the market' in Article 19 of Regulation No 1768/92 as meaning the date of completion, in any one Member State, of all the administrative steps which are necessary to make the launch of the product possible in that Member State. AZ thus considered that there was a first authorisation only when the national authority had approved the price of the product, so that the product could actually be marketed. Henceforth, the concept of authorisation to place a product on the market, as interpreted by AZ in the present case, will be referred to as 'effective marketing authorisation'.

387 The applicants submit that this interpretation was adopted in good faith and cannot be considered to be unreasonable, having regard to the imprecision of the legislation in question. AZ consulted two lawyers, whose opinions supported its interpretation of Regulation No 1768/92. [*confidential*]

[*confidential*]

389 In the applicants' submission, the fact that those distinguished lawyers adopted the same interpretation of Regulation No 1768/92 as AZ is a significant consideration in support of the claim that AZ's interpretation was reasonably held and, therefore, bona fide. They deny, moreover, that AZ brought pressure to bear on its corporate lawyers and refer, in this respect, to a witness statement from a lawyer.

390 The applicants add that the reasonableness and bona fides of that interpretation of Regulation No 1768/92 are supported by the fact that the Bundesgerichtshof (Federal Court of Justice, Germany) considered that that regulation was sufficiently imprecise for questions to be referred to the Court of Justice for a preliminary ruling on the interpretation and validity of that regulation.

391 They further assert that AZ's interpretation of Regulation No 1768/92 is consistent with its purpose, namely to make up for the reduction in the period of economic exploitation of the patent. Taking the example of France, they state that the French technical authorisation, which was the first technical authorisation granted in the Community, was granted in April 1987, whereas the price was not approved until two and a half years later, in November 1989, the date from which it was possible to market omeprazole in France. In support of their assertions, the applicants produce

10 witness statements from current and former AZ employees and 10 witness statements from patent attorneys and lawyers.

392 The applicants therefore submit that the Commission is wrong to assert, in recital 666 of the contested decision, that AZ had knowingly made false representations, since those representations were, on the contrary, made in good faith. They also complain that, in recitals 151 and 152 of the contested decision, the Commission described Article 8 of Regulation No 1768/92 while inserting, in that description, matters relating to the interpretation of that provision, so as to create the impression that the regulation in question clearly indicated that the date of technical authorisation was the same as that of the marketing authorisation.

393 The applicants submit that the Commission was not entitled to maintain that the national patent offices did not verify the information submitted by SPC applicants in relation to the dates of first marketing authorisations. The Commission took as its basis the practice in only two States, namely Finland and Norway, and the evidence dates from mid-1994, that is, well after the initial applications for SPCs were made, in June 1993. Moreover, the Commission does not allege abuse of a dominant position in Finland. In addition, no evidence was adduced of lack of verification in other Member States, in particular Germany and Denmark, at the time that the first applications were filed, in June 1993. The Commission did not even approach the national authorities in question in order to prove this point. Indeed, the Commission's assertion is invalidated by the fact that AZ's applications were challenged by many authorities. The applicants add that it does not necessarily follow from the fact that, under Article 10(5) of Regulation No 1768/92, Member States were not required to verify the first marketing authorisation date in the Community that they would not carry out such verification.

394 Nor has the Commission shown that AZ knew about the alleged absence of verification. The applicants maintain that AZ expected to have to discuss the basis of its applications with its patent attorneys and to defend its interpretation of Regulation No 1768/92 before the patent offices. In that regard, the applicants refer to the evidence given by the head of the patent department at the oral procedure before the Commission, and to the statements of patent attorneys.

The first stage of the abuse

395 The applicants state that the Commission is correct to find that the three memoranda of 16 March 1993 show that AZ had noticed that the first technical authorisation date in the Community for omeprazole, felodipine and omeprazole sodium appeared to be before 1 January 1988. They also admit that the immediate reaction of certain AZ staff had been to believe that AZ could not obtain SPCs in Germany and Denmark. However, they state that AZ was aware of a school of thought that considered that the date of the first marketing authorisation was the effective marketing authorisation date (see the third memorandum of 16 March 1993). Accordingly, the Commission is wrong to assert that AZ knew that the technical authorisation date was necessarily the determinative date for the application and that AZ could not obtain SPCs in the countries in respect of which the first authorisation to place a product on the market in the Community must be after 1 January 1988. On this point, the applicants refer to paragraphs 6 and 7 of the witness statement of Ms D.

396 As regards the information collected by AZ from its local marketing companies, the selectivity of which is criticised by the Commission in recital 636 of the contested decision, in so far as that information concerned only the 'problem products' and

focused only on the cases where technical authorisations had been issued before 1 January 1988, the applicants state that AZ only needed information regarding the products and countries in relation to which the effective marketing authorisation date might matter, since the question of whether SPCs could be issued did not arise for the other products whose technical authorisation dates were subsequent to 1988. They explain that AZ had limited resources and that the different record-keeping methods in the marketing companies made it difficult to check the correct dates of effective marketing authorisations. Making sensible use of limited resources, AZ therefore chose to request only information regarding the products whose authorisation dates were potentially problematic. The applicants add that, although AZ's approach may be characterised as inconsistent, it is not evidence either of an intention to mislead or of a deliberate fraud.

397 The applicants observe that the Commission failed to note that the letter of 17 December 1987, relating to the price approval for omeprazole in Luxembourg and mentioned in recital 637 of the contested decision, had been stamped by Astra Belgium on 31 December 1987. Furthermore, the letter from the marketing company confirmed that this was during the office's Christmas closure, so that it would have been impossible for Astra to act on that letter before Monday 4 January 1988. Accordingly, that letter of 17 December 1987 provided Astra with the information that the first effective marketing authorisation date for omeprazole capsules in the Community was bound to be after 1 January 1988 in Luxembourg, that is, after the relevant cut-off date for Germany and Denmark.

398 The applicants claim that it is clear from the words 'will argue before', contained in the memorandum of 29 March 1993, that AZ anticipated that the basis of the applications made to the German and Danish patent offices might be the subject of some controversy, and that it was preparing to defend its interpretation of Regulation No 1768/92

before the patent offices. They therefore deny both that AZ anticipated that the patent offices would merely rubber stamp its applications and accept the dates shown on the applications without verification and that AZ sought to conceal the basis for its applications. In that regard, the applicants refer to page 83 of the transcript of the oral procedure before the Commission.

399 The applicants reiterate their arguments set out in paragraphs 393 and 394 above and submit that the Commission cannot allege that AZ was seeking to conceal the legal basis of the dates it had submitted, since the contention that the degree of verification was, by and large, limited is insufficient in that regard. Furthermore, the fact that AZ intended to discuss authorisation dates with its patent attorneys and the patent offices is supported by the fact, accepted by the Commission itself, that the patent attorneys for the United Kingdom and Ireland were informed of the interpretation of Regulation No 1768/92. Similarly, the Luxembourg and French patent attorneys were also informed.

400 The applicants dispute the Commission's allegation that the memorandum of 29 March 1993, paragraph 398 above, contains a proposal by Mr H. to be proactive and to draw AZ's theory to the attention of patent offices, and point out that the Commission does not adduce any evidence in that regard. They claim that that memorandum merely shows that Astra had anticipated that it would find it necessary to present and defend its interpretation of Regulation No 1768/92. The applicants add that the Commission's dismissal of the statement on oath of the head of the patent department that he had many conversations with the patent attorneys reverses the burden of proof and is incompatible with the principle of the presumption of innocence.

401 Moreover, it is clear from the memorandum of 30 March 1993, to which the Commission refers in recitals 639 to 641 of the contested decision, that Hässle had considered that the effective marketing authorisation date was the decisive date for the purposes of Article 19(1) of Regulation No 1768/92. Hässle informed AZ's patent department that the date of publication of the official price was the effective marketing authorisation date for Luxembourg and that this date could not have been before 2 January 1988. Finally, Hässle proposed to obtain the effective marketing authorisation dates for all other countries.

402 The applicants state that, by memorandum of 7 April 1993, headed 'Re: Submission of SPC application', Hässle forwarded to the patent department further information from the Belgian and French marketing companies, among which was a document described as listing the authorised products in Luxembourg and dated March 1988. That document ('the Luxembourg list') contained a page of a list which included, among other products, Losec capsules and injectable products and was dated 21 March 1988. On 6 May 1993, Hässle decided on the instructions to be sent to patent attorneys for the SPC applications for omeprazole, as evidenced by the memorandum of 29 March 1993. The applicants deny that those instructions were misleading and maintain that the annotations that were made to the memorandum of 29 March 1993 simply implemented the approach adopted by Astra and Hässle of indicating on SPC applications the effective marketing authorisation dates in Luxembourg and France. Those amendments were made on the basis of materials gathered by the patent department, from which it was clear that Luxembourg had been the first Member State to grant effective marketing authorisation, on 21 March 1988, and that the marketing authorisations in the other Member States were granted at a later date, so that there was no need to make any further investigations. In support of their claims, the applicants refer to paragraphs 10 to 12 of the witness statement of Dr V., President of Astra Hässle at the material time.

403 The applicants submit that the Commission's accusations in recitals 643 and 665 of the contested decision are unwarranted and result from a subjective interpretation of the relevant documents. They deny that AZ sought to conceal the dates of the technical authorisations granted in France and Luxembourg, since the company simply considered that the relevant date was that of the effective marketing authorisation.

404 The applicants argue that the fact that AZ stipulated in its instructions that the March 1988 date be used for all applications filed in all countries demonstrates the absence of intention to mislead the national patent offices. In their submission, if AZ had intended to mislead those authorities, it would only have used the March 1988 date for the applications filed in Denmark and Germany. Moreover, the allegation that AZ concealed the nature of the Luxembourg authorisation is unjustified, since it is clear from the face of the Luxembourg list attached to the SPC applications that that document was not a technical authorisation.

405 The applicants claim that the insertion of the technical authorisation number for Luxembourg resulted from an error by AZ and was made by the Luxembourg patent office. They state that the head of Astra's patent department appeared at the oral hearing and testified to the bona fides of AZ.

406 With regard to the use of the Luxembourg law relating to technical authorisation under the 'Legal Provision' section of the instructions of 7 June 1993, the applicants maintain that AZ inserted that provision on the advice of the patent attorneys in Luxembourg. They refer, in that regard, to the witness statement of the Luxembourg patent attorney.

407 As regards the inconsistency stemming from the fact that the final instructions from Astra's patent department used three different types of authorisation dates when filing the SPC applications for different products, the applicants again maintain that this is due to the limited resources and time constraints which affected AZ. The technical authorisation dates relating to products other than omeprazole and omeprazole sodium were in or after 1988. Consequently, the effective marketing authorisation dates in the Community were necessarily later. By using the technical authorisation dates, Astra was assured that, in any event, an SPC would be granted, albeit of a shorter duration than that to which it believed it was entitled. As regards felodipine, the technical authorisation date was 29 December 1987, which would have precluded obtaining an SPC in Denmark or Germany. AZ therefore inserted the date of first publication of the technical authorisation.

408 The applicants deny that AZ knew that the date on the Luxembourg list was wrong. Hässle's memorandum of 30 March 1993 noted that the decisive date was that of publication of the price of the product and confirmed that, in Luxembourg, the price of a product had to be officially published before the product could be sold in pharmacies. On 7 April 1993, in the memorandum headed 'Re: Submission of SPC Applications', Hässle provided the patent department with further information which it had received from AZ's Belgian marketing company, and which included the Luxembourg list dated March 1988. The Belgian marketing company identified that list as a copy of an official paper listing the authorised products in Luxembourg. The applicants submit that Hässle could reasonably conclude that the information provided by the Belgian marketing company concerned the date of publication of the price of the product in Luxembourg.

409 Since the cover sheet of the Luxembourg list was dated March 1988 and the date on the relevant page of the list was 21 March 1988, it was reasonable to infer that 21 March 1988 was the effective marketing authorisation date. Accordingly, the Commission's finding that, even on its effective marketing interpretation of Regulation No 1768/92, AZ could not reasonably rely on the Luxembourg list is manifestly incorrect. In support of their assertions, the applicants refer to paragraphs 8 to 11 of the witness statement of Ms C. As regards the fact, relied on by the Commission, that Ms D. did not know about the 'effective marketing theory', the applicants maintain that it cannot constitute evidence of a deliberate attempt to use a wrong date.

410 The applicants add that the Commission is wrong to maintain that the legal advice provided by one of the law firms consulted did not deal with the Luxembourg list and was therefore irrelevant. [*confidential*] Finally, while the applicants accept that there were inconsistencies in the instructions of 7 June 1993 and regret that they occurred, they firmly deny that those inconsistencies were part of a strategy designed to hide the basis of the SPC applications and the interpretation of Regulation No 1768/92, and submit that there is no proper basis or evidence for the Commission to sustain that allegation.

411 The applicants further dispute the Commission's assertion that the explanation of the head of the patent department in paragraph 34 of his witness statement as to the reason why the French marketing authorisation date was used in the instructions to patent attorneys conflicts with the explanations provided by AZ in paragraph 6.84 of its reply to the statement of objections.

412 In reply to the Commission's objections relating to the fact that the Danish marketing authorisation date was not used in the SPC application for felodipine, the applicants maintain that the document on which the Commission bases its assertion that AZ knew the effective marketing date for that product as early as 30 March 1993, namely a fax of that date from Hässle to the patent attorneys at Astra, shows that the situation in relation to felodipine in Denmark was not straightforward and that Astra was still considering what position to adopt. They explain that felodipine was a product in relation to which the authorisation date was likely to pose a problem, since the technical authorisation date was too early for an SPC to be obtained. It was therefore important for AZ to establish the legally relevant date.

413 The applicants claim that the Danish effective marketing date was not used in the SPC application for felodipine because it was irrelevant, since it was neither the first Danish authorisation under Directive 65/65 nor the first authorisation in the Community. They dispute that the head of the patent department maintained at the oral procedure before the Commission that he would have liked to use the effective marketing dates for all products, since he in fact maintained that he 'would have liked to have had all eight applications to be based on the efficient, the first proper full market approval process with price and everything'. They maintain, finally, that the Danish patent attorney and the Danish patent office were informed of the basis upon which AZ had made its SPC application for felodipine, as was indicated in the reply to the statement of objections.

414 In general, the applicants deny that AZ relied on its interpretation of the regulatory framework a posteriori in order to justify the use of the March 1988 date, and refer, in that regard, to Hässle's memorandum of 30 March 1993. They submit that the Commission is inconsistent when it asserts that AZ developed its interpretation of Regulation No 1768/92 after making the SPC applications and in the context of the litigation

ensuing after the grant of the SPCs. It is clear from recitals 239 to 245 and 705 of the contested decision that, between March and June 1994, AZ sought legal advice on the interpretation of that regulation. Moreover, the Commission itself admitted, in recital 697 of the contested decision, that, by September 1993, AZ had decided to defend its 'effective marketing theory' before the United Kingdom patent office in order to obtain an SPC. The applicants also point out that, in recital 222 of the contested decision, the Commission noted that the litigation in the *Ratiopharm* case in Germany, which was regarded as the first court proceedings in which AZ had defended its SPC strategy, commenced from 18 June 1996. In support of their claims, the applicants refer to the witness statement of Mr W.

The second stage of the abuse

— The nature of the allegations relating to the second stage of the abuse of a dominant position

415 The applicants maintain that the Commission divides the second stage of the abuse into three elements. First, the Commission considered that AZ had sought to conceal from certain patent offices the earlier technical marketing authorisation date in

France of 15 April 1987, and that it thereby sought to gain an extra period of seven months of SPC protection. However, that allegation is unrelated to those concerning the first stage of the abuse, which do not concern the use of the technical marketing authorisation date in Luxembourg, or any attempt to obtain an SPC on that basis.

416 Secondly, according to the Commission, AZ left the patent attorneys and patent offices in the dark as to its strategy based on the effective marketing date. In the applicants' submission, the allegation of a failure to explain is different from the allegation of a supposed deliberate use of inconsistent dates in order to mislead the authorities. There is much evidence to show that AZ explained its 'effective marketing theory' both to its patent attorneys and to patent offices. To the extent that there is any failure to explain, it is not at all demonstrated that it is deliberate.

417 Thirdly, according to the Commission, although, according to its own claims, AZ relied on the Luxembourg list in its SPC applications, it was aware of a mounting body of evidence that Losec was marketed in Luxembourg before 21 March 1988. The applicants submit, however, that this allegation is groundless and that AZ was reasonably entitled to consider that 21 March 1988 was the first effective marketing date in Luxembourg.

418 The applicants maintain that the elements on which the Commission relies are omissions and not fraudulent misrepresentations. The fact that AZ failed to make full, frank and meticulous disclosure of all the facts to its patent attorneys and the patent offices cannot constitute an abuse of a dominant position.

— The instructions to the patent attorneys

419 The applicants state that, prior to sending the standard form instructions to the external patent attorneys on 7 June 1993, the AZ patent department, in view of the limited time available for it to act, made limited amendments only to the dates of the authorisations obtained in France and Luxembourg. In the applicants' submission, although those amendments created an apparent inconsistency in the information given with the instructions to the patent attorneys, that inconsistency did not relate to any information directly relevant to the various applications being filed.

420 The Commission is wrong in alleging that AZ did not explain either to the patent attorneys or to the patent offices its strategy based on the 'effective marketing theory'. Because of the formal nature of the instructions, AZ would not have been expected to explain its interpretation in detail, which was in line with its normal practice. In the applicants' submission, it would even have been surprising if AZ had done so. It was thus envisaged that, if necessary, the patent attorneys could request clarifications from AZ. The applicants add that the fact that AZ provided a copy of the Luxembourg list to each of its patent attorneys and gave them the date of March 1988 contradicts the proposition that it sought to disguise the interpretation of Regulation No 1768/92 on which its applications were based, since it was clear from the Luxembourg list that it was not the date of technical authorisation. Since there is nothing abnormal in AZ's attitude of providing information only if requested, it cannot constitute clear and convincing evidence of an attempt to deceive or mislead.

421 The applicants further claim that AZ discussed the meaning of 'first authorisation' with several patent attorneys following the filing of the applications. It is clear from the evidence submitted to the Commission during the administrative procedure that the head of the patent department and Mr H., also of AZ's patent department,

explained to the patent attorneys in most of the relevant countries AZ's interpretation of the SPC Regulation. Although the Commission does not accept that evidence, it has adduced no evidence of the extent to which the patent attorneys were aware of the basis of AZ's applications.

— The representations before the Luxembourg patent office (June 1993)

422 The applicants submit that the Commission is wrong to claim, in recitals 682 to 686 of the contested decision, first, that AZ failed to make the Luxembourg patent attorney or the Luxembourg patent office aware of the French technical marketing authorisation date and, second, that AZ did not explain, in its letter of 11 June 1993, the basis of its interpretation to the French patent attorney, so that the latter believed he was sending the publication of the technical authorisation in Luxembourg.

423 They explain that the French patent attorney was instructed to make SPC applications in France and in Luxembourg. He appointed his own patent attorney in Luxembourg, as sub-agent, to make the SPC applications for Astra in Luxembourg. Astra therefore had no direct dealing either with the Luxembourg patent attorney or with the Luxembourg patent office.

424 By letter of 10 June 1993, the French patent attorney asked AZ, for amongst other things, the marketing authorisations in Luxembourg. It is clear from that letter that the date of 15 April 1987, corresponding to the French technical marketing

authorisation, was known to that patent attorney. By letter of 11 June 1993, AZ sent the technical marketing authorisations for omeprazole and omeprazole sodium in Luxembourg. [*confidential*] Consequently, since the French patent attorneys were aware of the French and Luxembourg technical authorisation dates, it is incorrect to assert that AZ had given them the impression that the March 1988 date was the date of publication of the technical authorisation and not the date of publication of the price for marketing authorisation. [*confidential*] In the applicants' view, the patent attorneys concerned ought to have been aware that the publication in the Luxembourg list did not amount to publication of the technical authorisation.

[*confidential*] In the applicants' submission, since the French patent attorney was instructing the Luxembourg agent directly and was aware of the date of the French technical authorisation, it was his responsibility to pass on that information to the Luxembourg agent if he considered that it was important. There is nothing that would give grounds for assuming that AZ gave any instructions to the French patent attorneys not to pass on that information to the Luxembourg sub-agent.

426 The applicants further submit that the Commission has not adduced any proper evidence in support of its claim that it can be inferred from the reference to the national official journal in the letter of 17 June 1993 that the French patent attorney had understood that the date shown was the technical authorisation date. They add that AZ had been unaware of that letter and that it cannot be held responsible for the mistaken view held by the French patent attorney, since AZ had expressly stated that it referred to the publication in the Luxembourg list.

427 Similarly the applicants dispute that the letter sent by the French patent attorney to AZ on 17 June 1993, to which the Commission refers in recital 205 of the contested decision, shows that the French agent believed that the Luxembourg list was the publication of the technical authorisation and that he assumed that AZ intended to use

the same theory for all its products. Although that correspondence refers to the 'dates of publication in *Spécialités pharamceutiques* of the authorisations', the use of the term 'authorisations' is due to its use in Regulation No 1768/92, which itself contains an ambiguity in that regard, since 'authorisation' could refer to either technical authorisation or marketing authorisation. The applicants add that it is clear from the witness statement of the Luxembourg patent attorney that he had not been misled and that he did not regard the French patent attorney as having been either.

428 The applicants also maintain that the fact that the Luxembourg patent attorney received the letter dated 17 June 1993 only after he had filed the SPC application is irrelevant, since he put no date in his initial SPC application and only completed the date of the Luxembourg marketing authorisation, namely 21 March, later by hand.

— The representations before the Belgian patent office (September to November 1993)

429 The applicants state that, in response to the Belgian patent office's request for particulars of the exact date of authorisation in Luxembourg, AZ gave the Belgian patent attorney instructions to [*confidential*].

430 On 10 September 1993, at Astra's request, Astra's Belgian marketing company provided the Belgian patent attorneys with the documents which the latter had requested. On 29 September 1993, the Belgian patent attorneys stated that, in their opinion,

the date of the Luxembourg marketing authorisation was the date appearing on the authorisation signed under Directive 65/65, as amended, and that, unless instructed to the contrary, it would indicate the date of 16 November 1987 as grant date of the marketing authorisation in Luxembourg. On 30 September 1993, the Belgian patent attorneys sent the Belgian patent office the Luxembourg technical authorisation documents signed on 16 November 1987, and informed Astra, on 4 October 1993, that the SPC application had been amended to refer to 16 November 1987 as the date of the Luxembourg marketing authorisation.

431 On 16 November 1993, the Belgian patent office granted the Belgian SPC. The applicants claim that AZ's patent department had not realised that the SPC was based on a wrong date, and did not realise this until 1996, when that SPC was re-examined as a result of the German litigation. In May 1998, AZ filed a request with the Belgian patent office to amend the duration of its SPC and to calculate it from 21 March 1988 to reflect its interpretation of Regulation No 1768/92, which was based on its 'effective marketing theory'. A Belgian court set aside that SPC on 25 September 2002.

432 The applicants dispute the Commission's conclusion that AZ, first, misled the Belgian patent office by indicating the Luxembourg technical authorisation date and, second, did not explain its 'effective marketing theory' to its Belgian patent attorney. They observe that the Commission did not take account of the fact that AZ had sought to ensure that its application reflected its approach based on the effective marketing authorisation date, namely 21 March 1988. They recall, in that regard, that it was at the initiative of the patent attorney that the Luxembourg technical authorisation date was used. Nor did the Commission take into consideration the fact that AZ applied, in May 1998, to amend the Belgian SPC to reflect correctly its approach based on the effective marketing authorisation date of 21 March 1988, making it clear that this was its own interpretation of Regulation No 1768/92. The applicants refer in that

regard to the witness statements of Mr P. and Mr M. AZ also drew the attention of the authorities in question to all the relevant dates. The applicants deny that AZ was compelled to disclose its theory as a result of the *Ratiopharm* case in Germany and the omeprazole sodium application in Belgium and contend that there is no evidence in that respect.

433 They claim that AZ sent the letter before the substance patent had expired and, therefore, never sought to benefit from the extra seven months of protection. If AZ had intended to mislead the patent office in order to obtain seven extra months of protection by filing an incorrect technical authorisation date, it would never have made an application to amend its SPC to reflect the effective marketing date.

— The representations before the Netherlands patent office (November and December 1993)

434 The applicants state that, on 26 November 1993, AZ's Dutch patent attorney sent AZ two identical letters reporting on the examination reports on the SPC applications for omeprazole capsules and omeprazole sodium which had raised an objection to the imprecision of the date of first authorisation. By two identical letters, AZ indicated [*confidential*]. In the applicants' opinion, the date of 16 November 1987 was the date of first marketing authorisation of omeprazole sodium in the Community. However, that date was wrong in relation to the capsules and its citation was therefore the result of an oversight.

435 AZ's patent attorney stated in a letter to the Dutch patent office that the Luxembourg list was the only official publication in Luxembourg, a statement which was in accordance with the belief of Astra's Luxembourg marketing company. The patent office issued an SPC referring to the date of 16 November 1987, the period of which was from 3 April 1999, the date of expiry of the substance patent, until 16 November 2002, rather than April 2002, the date which would have been fixed if the patent attorney had cited the French technical authorisation date. In May 1998, AZ asked the Dutch patent office to correct the 16 November 1987 date, explaining that all authorisations necessary to enable the product to be placed on the market in the first Member State, namely Luxembourg, were granted for the first time on 21 March 1988.

436 The applicants dispute the Commission's inferences that AZ misled the Dutch patent office by citing the technical authorisation date in Luxembourg and by not explaining its interpretation of Regulation No 1768/92, based on the 'effective marketing theory', to its Dutch patent attorney. They maintain, first, that the Commission should have accepted the evidence demonstrating, in their view, that AZ made an inadvertent error in referring to the date of 16 November 1987. They explain that that error was the result of the fact that the two letters in question had been written at the same time and using the same form, and that it was unlikely that AZ took a conscious decision to send instructions to refer to the date of 16 November 1987 for omeprazole, since such instructions were inconsistent with the instructions given for any other countries.

437 Further, the Commission once again ignored the fact that, in May 1998, AZ had submitted to the Dutch patent office a request seeking to have that date corrected and had drawn the authorities' attention to all of the relevant dates. Moreover, AZ submitted that request before the substance patent had expired, which shows that it did not intend to benefit from the extra seven months of protection. The applicants further submit that there is no documentary evidence which allows the Commission to claim

that AZ did not explain its 'effective marketing theory' to the Dutch patent attorney. They refer, in this regard, to the witness statement of AZ's Dutch patent attorneys.

438 In reply to the Commission's argument that the fax of 16 December 1993, to which reference is made in paragraph 9 of the witness statement of the Dutch patent attorney, seeks to convey to the attorney the impression that the publication in the Luxembourg list refers to the technical authorisation, the applicants contend that the fax refers to that list as the notice publishing the grant of the 'marketing authorisation'.

439 The applicants further dispute the Commission's allegation that there is no evidence to support the claim of the head of the patent department, made in paragraph 54 of his witness statement, that AZ had been 'told by its Dutch [patent attorneys] there was nothing it could do', and refer to the handwritten record of a meeting held in London on 11 December 1996, which appears at pages 4489 to 4491 of the Commission's case-file and at paragraph 6.154 of the reply to the statement of objections.

440 As regards the fax of 11 October 1996, from the head of the patent department to the head of the Dutch marketing company, referred to by the Commission, the applicants deny that that document demonstrates that the head of the patent department was aware that the wrong Luxembourg technical authorisation date had been used rather than the French technical authorisation date or the Luxembourg effective marketing date. That fax merely shows that the head of the patent department was aware of the fact that the 'effective marketing theory' might not be accepted by the courts and the patent offices, which, should the case arise, would cause AZ to lose six months of protection by the SPCs.

— Representations before the United Kingdom patent office (January to June 1994)

441 The applicants recall, first, that in December 1993 AZ asked two law firms to advise on Luxembourg national law and Community law.

442 They then state that, in response to the application filed in June 1993, the United Kingdom patent office asked AZ, on 7 September 1993, for the precise date of the first marketing authorisation. By letter of 7 January 1994, Astra's United Kingdom patent attorney informed the United Kingdom patent office that the date of first authorisation in the Community was the date on the Luxembourg list, that is 21 March 1988. By letter of 18 January 1994, the United Kingdom patent office replied that the correct date for the Luxembourg authorisation was 16 November 1987.

443 On 16 June 1994, AZ filed the opinions of the two law firms consulted on Luxembourg national law and Community law with the United Kingdom patent office. AZ also collated information and collected all of the possible relevant dates from the marketing companies in each Member State in order to support its arguments as to effective marketing authorisation. Accordingly, by memorandum of 14 February 1994, the patent department asked Hässle to inform it [*confidential*].

444 In connection with the inquiries addressed to the marketing companies, coordinated by Hässle, Mr S., of Astra Luxembourg, informed Hässle, by fax of 3 March 1994, that the date of signature of the authorisation issued under Directive No 65/65 was 16 November 1987 and that the price agreement corresponded to the letter from the Ministry of 17 December 1987. He also described the publication in the Luxembourg list of March 1988 as publication in 'the *Mémorial*' (*Official Journal of the Grand Duchy*

of Luxembourg), and stated that the first sales had taken place on 11 March 1988. Prompted by the responses forwarded by Hässle to the patent department, indicating inter alia that March 1988 was the date of publication of the authorisation, the patent department asked Hässle to check the dates for the different countries and products. By fax of 8 April 1994, Hässle corrected the date of official publication of the price by putting 21 March 1988 and changed the date of the letter concerning marketing authorisation from 16 November 1987 to the incorrect date of 5 October 1987.

445 In response to a further request for clarification of the relevant dates from Hässle to Mr S., the latter re-sent his fax of 3 March 1994. On 30 May 1994, Hässle again asked Mr S. to confirm that the date of official publication of the price was 21 March 1988. By fax of 8 June 1994, Mr S. replied that the price agreement had been given on 17 December 1987 but that it had not been published, and that official publication of the authorisation in the *Mémorial* had taken place in March 1988.

446 On 16 June 1994, AZ's United Kingdom patent attorney lodged a new submission with the United Kingdom patent office, including a table showing the different steps in the authorisation procedure for omeprazole in different countries and setting out the principal dates connected with those authorisation processes. In the table, 15 April 1987 was listed as the technical authorisation date for France and 21 March 1988 as the official listing and official price publication date for Luxembourg. In that submission, it was stated that, in practice, it was not possible in Luxembourg to market a medicinal product until it appeared in the list of drugs that have received marketing authorisation, published by the Ministry of Health. However, the patent office did not accept AZ's submission and considered that the correct date was that of the authorisation granted in France, namely 15 April 1987.

447 In addition, the applicants refer to paragraphs 8 to 11 of the witness statement of Mr W., external patent attorney to Astra during the material period. They note that AZ expressly pointed out to the United Kingdom patent office its interpretation of Regulation No 1768/92 and why it was proposing the date of 21 March 1988. Moreover, AZ had no difficulty in conveying 15 April 1987 as the date of the French technical authorisation to the United Kingdom patent office and to its patent attorneys. They submit that, in the light of AZ's conduct in relation to the United Kingdom patent office, it is not credible that AZ sought to mislead the authorities in its applications in other countries, and in particular the Benelux countries.

448 The applicants dispute the Commission's inference that it was clear from the request of 14 February 1994 that AZ did not know whether Losec had been sold in Luxembourg before the conclusion of the price negotiations. They maintain that that request concerned all Member States, and not only Luxembourg, and point out that AZ had been informed that, in Luxembourg, price negotiations had to be completed and officially published before a product could be marketed, as is apparent from the memorandum sent by Hässle to the patent department on 30 March 1993.

449 As regards the Commission's submission that the fax of 3 March 1994 shows that AZ knew that the first sales in Luxembourg were on 11 March 1988 and not on 21 March 1988, the applicants state, first, that the fax of 3 March 1994 referred to sales in the sense of the 'official launch' of the product and did not concern sales as a practical matter. They state in that regard that the SPC application noted that doctors and pharmacies did not prescribe or dispense until they had received the list of authorised products. Secondly, they maintain that AZ had real doubts over the accuracy of the information provided by Mr S. in his fax of 3 March 1994. They observe in particular that the fax contained inaccuracies inasmuch as (i) the registration of 16 November 1987 concerned clinical trials only and not marketing authorisation, and (ii) the publication of March 1988 was the publication in the *Mémorial* of the authorisation

granted under Directive 65/65, which was in fact published on 4 December 1987. Further, the applicants reiterate that AZ was informed that price negotiations had to be completed and officially published before a product could be marketed, as is clear from the memorandum sent by Hässle to the patent department on 30 March 1993. Thus, the fact that, according to Mr S., the 'official launch' of the product had been on 11 March does not mean that it was possible to make sales in practice.

450 That is why AZ preferred to rely upon the information it had received previously and which was confirmed by the Luxembourg list, to the effect that 21 March 1988 was the relevant date. The applicants refer, in this regard, to Ms J.'s witness statement. The applicants add that the Commission cannot maintain that the information contained in Mr S.'s fax was the only information AZ possessed, having regard to the context in which that document was provided and to the fact that AZ had the Luxembourg list. Accordingly, there is no proper basis for the Commission to maintain that AZ's reliance on the 21 March 1988 date was in bad faith.

451 The applicants deny that AZ actively encouraged the impression that the Luxembourg list was the publication of the technical authorisation. They maintain that the fax of 16 December 1993 to the Dutch patent attorney, to which the Commission refers, does not contain any such encouragement and in any event was never seen by Mr S.

452 The applicants maintain that, in any event, the fact that AZ gave the date of 21 March and not that of 11 March, which would have been correct according to its interpretation, cannot be a basis for an allegation of fraud, because that fraud had no effect on the United Kingdom patent office which rejected AZ's entire theory.

— The withdrawal of the SPC application in Denmark (November 1994)

453 The applicants submit, first of all, that withdrawal of an SPC application cannot constitute an abuse of a dominant position. Nor, they add, can it be an abuse to act tactically or to exhibit a lack of transparency. Moreover, the notes record that AZ intended to defend its interpretation of Regulation No 1768/92 in Germany. At worst, this was 'forum shopping' on the part of AZ. In the applicants' view, the mere fact that AZ used the March 1988 date in its application in Denmark cannot constitute an abuse, since this was a legitimate application of an interpretation of Regulation No 1768/92. In that regard, the fact that AZ failed to disclose the basis of its legal interpretation of that regulation cannot, in the applicants' view, amount to an abuse.

454 They further point out that, in recital 719 of the contested decision, the Commission accepted that the reason for the withdrawal was, at least in part, that an incorrect patent number had been used, which represented a fundamental flaw in the application. In that regard, reference is made to the witness statements of the Danish patent attorney and a Danish lawyer. Thus, the allegations in relation to the withdrawal of the SPC application in Denmark could not demonstrate an abuse of a dominant position, even if they were proven.

455 As regards the Commission's allegation that AZ withdrew its application in order not to have to explain its basis, the applicants maintain that the minutes of the meeting of 15 November 1994, which are relied on by the Commission in this respect, actually demonstrate that AZ had decided to argue its case in Germany and not in Denmark, and not that it did not want to explain its case. Similarly, the applicants deny that AZ withdrew its application in Denmark so as to prevent unwanted disclosure between patent offices. In their submission, although those minutes show that the United Kingdom patent office contacted the Danish patent office, they do not

indicate that the withdrawal was motivated by a desire to prevent any other contact between patent offices.

— AZ's representations in the second round of SPC applications

456 The applicants dispute the considerations set out by the Commission in recital 721 of the contested decision to the effect that AZ received information showing that Losec was sold before 21 March 1988 and that the price decision was never published. They maintain that, at most, AZ received information, from a source that had supplied other information which had proved to be inaccurate, that suggested that the 'official launch' had been on 11 March 1988. That information was contradicted by earlier information from a source regarded as more reliable, which indicated that the launch date of the product was 21 March 1988 and that the price decision had to be published in Luxembourg for effective marketing of the product to be able to take place.

— Applications in the EEA countries

457 With regard to the considerations set out by the Commission in recital 722 of the contested decision, the applicants submit that the omission of the effective marketing authorisation date in Sweden arose from an oversight in circumstances where the significance of that date was not obvious. Whilst AZ was aware of the authorisation granted by the Swedish authorities with respect to Losec, AZ did not appreciate at the time the significance of that date in the context of its SPC applications. The

applicants state that Regulation No 1768/92 was applied to EFTA countries by Decision No 7/94, which entered into force on 1 July 1994, but that that decision was never implemented in Sweden, which had its own national regime of SPC protection. In their view, while the fact that Sweden never joined the EEA SPC regime does not mean that the Swedish effective marketing date was not relevant, it is understandable that the significance of the Swedish date of effective marketing authorisation was overlooked by AZ.

458 The applicants dispute the Commission's contention that, in the letter of 21 December 1994 to the Swedish patent office, the head of the patent department stated that SPCs for the Union countries had to be based on a Union foundation and SPCs for the EFTA countries on an EEA foundation. On the contrary, it is clear from that correspondence that the head of the patent department was suggesting that the Union authorisation date alone was applicable. The applicants further maintain that there is no evidence that the head of the patent department tried to cover up his position, since, on the contrary, the evidence available to the Commission suggests that the head of the patent department was expressing his view in an open manner. They also observe that the letter of 3 March 1995 from the Swedish patent office to the head of the patent department did not clearly mention that it was the Swedish marketing authorisation date that was relevant, since it stated that it was the date of first marketing authorisation in the EEA 'after the entry into force of the EEA Agreement'. In the absence of implementation of the EEA SPC regime in Sweden, there was thus legitimate doubt as to whether the EEA Agreement governed this point. The applicants add that the memorandum of 26 September 1994 says nothing about whether the correct date was that of authorisation in Sweden or that of authorisation in the Union.

459 The applicants explain that AZ and its patent attorneys for Austria, Finland and Norway met in Vienna (Austria) on 6 December 1994 and discussed AZ's interpretation of Regulation No 1768/92. The patent attorneys subsequently made SPC applications stating that 21 March 1988 was the date of first authorisation in the Community. Consequently, AZ did not attempt to conceal its 'effective marketing theory' from its patent attorneys, which also demonstrates that it did not act differently towards its patent attorneys in France or the Benelux. Furthermore, none of the patent attorneys who were at that meeting raised the question of whether the Swedish date of authorisation of 5 February 1988 should be used.

— Representations before the Irish patent office (October 1995)

460 The applicants state that AZ maintained before the Irish patent office that 21 March 1988 was the correct authorisation date, but also submitted to the Irish patent office the first technical authorisation date in France of 15 April 1987. They dispute the considerations set out by the Commission in recital 725 of the contested decision and again observe that AZ had no difficulty in submitting the date of the first technical authorisation in the Community, of 15 April 1987, which demonstrates that it had not sought to mislead the patent offices of the Benelux countries.

— Representations before the patent offices in the Benelux countries and Finland (May 1998)

461 The applicants equally dispute the Commission's allegation in recital 726 of the contested decision that AZ had in its possession information which unequivocally indicated that effective marketing in Luxembourg had taken place before 21 March 1988, and reiterate that AZ had only inconsistent and inconclusive information.

462 As regards the document dated 23 February 1998, on which the Commission relies, which gives the launch date for omeprazole capsules as 1 February 1988, the applicants state that that document is a list taken from an internal database based on market information. They explain that launch dates for the product were given to AZ's regulatory affairs department in advance by the local marketing companies, which gave only the projected month of launch for the product. The regulatory affairs department was in the habit of supplementing that information by mentioning the first or last day of the month concerned, without checking whether the launch of the product had actually taken place on the dates announced. That document accordingly does not make it possible to prove the actual launch date for the product in Luxembourg and other countries. Moreover, the date of 1 February 1988 mentioned in that document does not correspond either to the date of 11 March 1988, on which the Commission submits that AZ ought to have relied, or to the date of 8 February 1988 proposed in the German proceedings. The applicants maintain that AZ was obliged to present a date to patent offices and that, in the light of the varying information received from various sources available to it, it decided to retain the original date of 21 March 1988, without intending to mislead anyone.

463 The applicants submit that the discredit which the Commission casts on Ms J.'s witness statement is unjustified and maintain that, having regard to the context which surrounded the sending of the Luxembourg list by Astra Belgium, it could be reasonably inferred from this that that list represented the effective marketing authorisation.

— Representations during the court proceedings in Germany

464 The applicants dispute, for the reasons set out above in paragraph 462, the considerations contained in recital 728 of the contested decision and maintain that, even if AZ was mistaken in using 21 March 1988 as the relevant date as regards the first authorisation to place the product on the market, there is no evidence that AZ knew that that date was incorrect. As regards the internal document dated 19 August 1996, which is relied on by the Commission and which cites 1 February 1988 as the effective launch date for the product, the applicants submit that it does not constitute independent evidence, since it was produced by a patent attorney who was not directly involved in the litigation and the annexed schedule of dates does not indicate from where the date of 1 February 1988 is derived. Next, as regards the document dated 9 September 1996, which states '1988-02-01/1988-03-11', the applicants submit that it is not unequivocal evidence demonstrating the existence of a certain prior date of launch for the product, but, on the contrary, denotes considerable uncertainty as to the date of that launch. They also refer to Ms J.'s witness statement.

465 With regard to the Commission's considerations set out in recitals 730 and 731 of the contested decision, the applicants maintain that German counsel conceded that the 8 February 1988 date was correct, based upon the letter sent by AZ to the Luxembourg

authorities on 8 December 1988, by which it submitted to them its price proposal and announced its intention to apply that price as of 8 February 1988. Accordingly, German counsel accepted the correctness of the date of 8 February 1988 on the basis of his acceptance of a particular interpretation of Regulation No 1768/92 to the effect that the relevant date was that of approval of the price by the authorities, enabling AZ to sell the product lawfully at a known and approved price. That interpretation of Regulation No 1768/92 did not accept the relevance of the date of publication of the price of the product, informing the buyers (doctors and pharmacists) of that price. German counsel thus did not accept that 8 February 1988 was the date on which sales had actually taken place. If AZ's interpretation had been applied, the date of 21 March 1988 appeared to be correct. The applicants therefore submit that the Commission erred in considering, in recital 735 of the contested decision, that there had been an admission in the German legal proceedings that sales had taken place before 21 March 1988. The applicants dispute that the distinction between 'selling lawfully' and 'effective marketing' is irrelevant, since it reflects the commercial reality on the basis of which AZ adopted its interpretation of Regulation No 1768/92.

466 They add that the documents on which the Commission relies are inconsistent, since they refer to the dates of 1 February 1988, 8 February 1988 and 11 March 1988. Accordingly, even if AZ had taken that information into account, it would still have been left in a position of uncertainty as to the correct date of effective marketing authorisation. In the applicants' submission, although the documents cited by the Commission indicate, at most, that there was uncertainty as to whether 21 March 1988 was the correct date, they do not show that that date was wrong or what the correct date was. That evidence does not, therefore, demonstrate that AZ had an intention to mislead the public authorities.

— Representations during the court proceedings in Norway

467 As regards recital 733 of the contested decision, in which the Commission cites evidence adduced by the Luxembourg authorities, intended to demonstrate that the Luxembourg list was an 'unofficial document' listing the authorised products, regardless of whether they had obtained price approval, the applicants state, firstly, that no official document had been published at that time. Secondly, the Luxembourg list was published on behalf of a company which represented around half of Luxembourg's pharmacists and pharmaceutical wholesalers. In addition, the Luxembourg list was designed to inform pharmacists on the products authorised and available on the market, and was published by the Luxembourg pharmacy and medicines department. Accordingly, notwithstanding the unofficial nature of the Luxembourg list, AZ acted reasonably in relying on it.

468 The applicants further claim that AZ admitted, in the proceedings on the reference for a preliminary ruling before the Court of Justice, that it did not have the complete list or the part of it showing the price of Losec. This demonstrates that there was no intention to mislead the District Court of Oslo (Norway).

469 In reply to the Commission's allegations that AZ had carried out research indicating that the product had been marketed before 21 March 1988, the applicants maintain that the results of that research were confused and contradictory and did not demonstrate that the Luxembourg list was irrelevant or that that date was inaccurate or inappropriate as the effective marketing date.

— Representations during the court proceedings in Finland

470 The applicants dispute recital 735 of the contested decision and submit that the documents on which the Commission relies do not demonstrate that sales took place before 21 March 1988. They assert that AZ made no such admission in the German proceedings. It is merely a forensic opinion based upon an interpretation of Regulation No 1768/92 and on the fact of price approval, and not on any evidence of actual sales in Luxembourg. Moreover, AZ admitted before the Helsinki District Court (Finland) that it had tried to obtain a full copy of the list and to ascertain the publication's official status in Luxembourg. It also recognised that the situation in Luxembourg was unclear. That evidence therefore discloses no intention on the part of AZ to mislead the Helsinki District Court. In addition, the applicants again contest that the research conducted by AZ demonstrated that it was not the fact that Losec could not be marketed in Luxembourg before 21 March 1988.

— Existence of a strategy designed to mislead AZ's patent attorneys, the national patent offices and the national courts

471 The applicants dispute the Commission's statement in recital 665 of the contested decision that the then head of AZ's patent department admitted, on 21 October 1999, that he had devised a strategy designed deliberately to mislead AZ's patent attorneys, the national patent offices and the national courts. Referring to a fax sent by the head of the patent department to the chief executive officer of AZ, the applicants maintain that it contains no admission of a malevolent strategy. That fax refers only to AZ

having adopted an interpretation of Regulation No 1768/92 in relation to which there were uncertainties, and to the desirability of having the case referred to the Court of Justice so that a definitive answer could be given to the question of how Regulation No 1768/92 is to be interpreted.

472 The applicants also complain that the Commission did not give the author of the fax in question the opportunity to comment on the inferences which are drawn from that message. They also refer to the witness statements of the head of the patent department and of Mr L. and Mr W.

(b) Arguments of the Commission

473 The Commission contests the merits of the arguments put forward in the second plea.

(c) Findings of the Court

The burden of proof

474 The Court notes, as a preliminary point, that the burden of proof of the existence of the circumstances that constitute an infringement of Article 82 EC is borne by the Commission (*Microsoft* v *Commission*, paragraph 32 above, paragraph 688). It is therefore incumbent on the Commission to adduce evidence capable of demonstrating the existence of the circumstances constituting an infringement.

475 In this respect, any doubt of the Court must benefit the undertaking to which the decision finding an infringement was addressed. The Court cannot therefore conclude that the Commission has established the infringement at issue to the requisite legal standard if it still entertains any doubts on that point, in particular in proceedings for annulment of a decision imposing a fine.

476 In the latter situation, it is necessary to take account of the principle of the presumption of innocence resulting in particular from Article 6(2) of the European Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950, which is one of the fundamental rights which, according to the case-law of the Court of Justice, reaffirmed in Article 6(2) EU, are general principles of Community law. Given the nature of the infringements in question and the nature and degree of gravity of the ensuing penalties, the principle of the presumption of innocence applies in particular to the procedures relating to infringements of the competition rules applicable to undertakings that may result in the imposition of fines or periodic penalty payments (see, by analogy, judgment of 12 September 2007

in Case T-36/05 *Coats Holdings and Coats* v *Commission*, not published in the ECR, paragraphs 68 to 70 and the case-law cited).

477 Thus, the Commission must show precise and consistent evidence in order to establish the existence of the infringement. However, it is not necessary for the Commission to adduce such evidence in relation to every aspect of the infringement. It is sufficient if the body of evidence relied on by the institution, viewed as a whole, and whose various elements are able to reinforce each other, meets that requirement (see, to that effect and by analogy, Joined Cases T-67/00, T-68/00, T-71/00 and T-78/00 *JFE Engineering and Others* v *Commission* [2004] ECR II-2501, paragraphs 179, 180 to 275, and Joined Cases T-44/02 OP, T-54/02 OP, T-56/02 OP, T-60/02 OP and T-61/02 OP *Dresdner Bank and Others* v *Commission* [2006] ECR II-3567, paragraphs 62 and 63 and the case-law cited).

The first stage of the abuse of a dominant position

478 As a preliminary point, it should be recalled that, although the Commission noted the single and continuous nature of the first abuse of a dominant position, it distinguished, as is stated in paragraphs 306 and 307 above, two stages in that abuse. The first stage identified by the Commission concerns AZ's misleading representations when sending instructions, on 7 June 1993, to the patent attorneys through whom the SPC applications were filed in seven Member States, amongst them Germany, Belgium, Denmark, the Netherlands and the United Kingdom (see recital 628 of the contested decision). The second stage identified by the Commission consists (i) of misleading representations made in 1993 and in 1994 before patent offices, in reply to their questions on the SPC applications filed by AZ, (ii) of misleading representations made in December 1994 during the second round of SPC applications in three EEA Member States, namely Austria, Finland and Norway, and (iii) misleading representations made subsequently before other patent offices, and before national courts, in

the context of proceedings brought by competing generic manufacturers with a view to invalidating the SPCs in those States (see recital 629 of the contested decision).

479 As regards the first stage of the abuse, the Court would recall the factual circumstances surrounding the first stage of the behaviour that the Commission classified as abusive, as they emerge both from the contested decision and the documents produced before the Court. It is common ground, in the present case, that, in a memorandum of 16 March 1993, the patent department stated that the first 'market registration' in the Community for omeprazole had been issued in France in April 1987. The patent department therefore stated that it did not consider that it was possible to obtain an SPC in Germany and Denmark, as the first market registration was before 1988. The same difficulty was identified in relation to omeprazole sodium and felodipine (see recitals 634 and 635 of the contested decision).

480 It should be noted, in this respect, that, under the transitional rule contained in the second subparagraph of Article 19(1) of Regulation No 1768/92 (see paragraph 299 above), in Germany and Denmark, products eligible to receive a SPC were those whose first authorisation to be placed on the market in the Community had been obtained after 1 January 1988.

481 As of mid-March 1993, AZ's patent department collected information, via Hässle, from the local marketing companies. That collection of information focused solely on products which presented problems as regards the issue date of the first technical authorisation, namely omeprazole, omeprazole sodium and felodipine, as that date was prior to 1 January 1988. On 22 March 1993, the Belgian marketing company

sent Hässle a copy of the technical marketing authorisation for omeprazole in Luxembourg of 16 November 1987, and a copy of the decision approving the price of omeprazole in that country, of 17 December 1987 (see recitals 170, 636 and 637 of the contested decision).

482 In a memorandum by the patent department of 29 March 1993, the first market registration in the Community was identified as being that which had been issued in France in April 1987. However, the patent department stated in that memorandum that, for the purposes of the SPC applications in Germany and Denmark, it would claim before the patent offices that the first marketing authorisation in the Community had not taken place before 1 January 1988 (see recital 638 of the contested decision).

483 In a memorandum sent to the patent department on 30 March 1993, Hässle communicated the information received regarding the dates relating to the authorisations for omeprazole in France and Luxembourg and felodipine in Denmark. As regards omeprazole in Luxembourg, that memorandum confirmed the information received on 22 March 1993 from the Belgian marketing company, namely that the Luxembourg technical marketing authorisation was issued on 16 November 1987 and that the decision approving the price of that product was taken on 17 December 1987, but stated that the date of publication of the price was not yet known. That memorandum also confirmed that the marketing authorisation for omeprazole in France took place in April 1987, and added that the price negotiations were completed in spring 1989 and that the price was published in the *Journal officiel de la République française* on 22 November 1989 — although that memorandum refers to the date of '22.11.1988', the Court considers that the Commission was correct to find, in recital 171 of the contested decision, that that reference was the result of a clerical error and that the author of the memorandum intended to refer to the date of 22 November 1989. As regards felodipine in Denmark, Hässle stated that the marketing authorisation was issued on 29 December 1987, that that authorisation was published on

21 January 1988 and that the price was published on 29 February 1988 in the *Specialitetstaksten* (price list of proprietary medicinal products).

484 In that memorandum, Hässle stated that, in France, Luxembourg and Denmark, prices had to be set and published before a product could be marketed. Hässle thus considered that 'that date [was] decisive'. It stated that it was trying to obtain the same information concerning the other countries, in order to determine the date using the same criteria in the different countries (see recitals 639 to 641 of the contested decision).

485 On 5 April 1993, the Belgian marketing company sent Hässle the cover page and page 246 of the Luxembourg list, and referred to a copy of an official document of March 1998 (which should read 'March 1988') listing the authorised products in the Grand Duchy of Luxembourg. That document was forwarded to the patent department by memorandum of 7 April 1993 (see recitals 172, 173 and 658 of the contested decision).

486 As the Commission observed in recital 173 of the contested decision, the cover page of the Luxembourg list is entitled 'Ministère de la Santé — 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'). At the bottom of the cover page the following items are mentioned: 'éditeur: CEFIP sàrl Luxembourg — Tout droit réservé — Modification au 24.2 comprise — Mars 1988' ('editor: CEFIP sàrl Luxembourg — All rights reserved — Modification to 24.2 included — March 1988'). A list of names of 23 pharmaceutical products in alphabetical order starting with the letters 'lo', then the letters 'lu', and including inter alia two references to Losec, in respect of omeprazole capsules and the injectable preparation of omeprazole (omeprazole sodium), appears on page 246 of that document. No prices appear alongside the products mentioned. The following date appears in the top left hand corner of page 246: '21/03/88'.

It appears that that page comes from a document listing medicinal products approved for sale over several hundred pages.

487 The Commission also stated that AZ had admitted before the Norwegian courts in May 1999 that it did not possess the complete list, or a part of it comprising the price for Losec, despite the efforts made to procure that document (recitals 241 and 661 of the contested decision). Similarly, it observed that, before the Finnish courts, AZ admitted on 30 June 1999 that the situation in Luxembourg 'was unclear' (recitals 245 and 661 of the contested decision). The Commission also considered that AZ's internal documents confirmed that AZ did not know whether Losec might have been marketed before March 1988. The Commission referred, in this respect, to an internal memorandum of 14 February 1994 (recitals 210, 211 and 661 of the contested decision) and to a document from in-house lawyers (recital 230 and footnote 302 and recital 661 of the contested decision).

488 The Commission observed that the date of the alleged effective marketing, namely the date of publication of the price of the product, was not used in all the SPC applications. In fact, that date was used only for omeprazole and omeprazole sodium. As regards felodipine, the date of the first publication of the technical marketing authorisation was used, namely in Denmark on 21 January 1988. For five other products, AZ used the technical marketing authorisation dates, which are all subsequent to 1 January 1988 (see recitals 643 to 645 of the contested decision).

489 As regards the SPC applications for omeprazole, the Commission considered that the misleading representations stemmed from Hässle's decision of 6 May 1993, which was taken in the form of three handwritten annotations in Swedish on the patent department's memorandum of 29 March 1993 (recital 648 of the contested decision). Those handwritten annotations stated that, as regards Luxembourg, the date of March 1988 was to be communicated to the patent offices as the first authorisation

in the Community and that, as regards France, the date of 22 November 1989 was to be provided.

490 That decision of 6 May 1993 was implemented in the instructions of 7 June 1993, which were transmitted to the patent attorneys for the omeprazole SPC applications. The Commission's view that those final instructions were misleading is based on the fact that, without notifying the patent attorneys and national patent offices, AZ gave, in relation to France and Luxembourg, dates which did not correspond to the issue of the technical marketing authorisation, but to what AZ calls the 'effective marketing authorisation', that is to say the alleged date of publication of the price of the medicinal product (recital 651 of the contested decision).

491 The replacement of the issue dates of the technical marketing authorisations in France and Luxembourg by those corresponding to the publications of the price of the medicine in those countries was, in the Commission's view, liable to mislead the patent offices for three reasons. First, the dates given on the application form in relation to seven other countries concerned the issue of the technical marketing authorisation, so that it could be presumed that the dates given for France and Luxembourg also corresponded to the technical marketing authorisations. Second, the numbers corresponding to the French and Luxembourg technical marketing authorisations were retained. Consequently, those numbers appeared alongside the dates of the 'effective marketing authorisations', thus suggesting that those dates corresponded to the technical authorisations. The numbers of the technical authorisations were moreover given for seven other countries. Third, for the purposes of meeting the requirements of Article 8(1)(c) of Regulation No 1768/92, AZ referred to Luxembourg legislation which did not relate to the date of March 1988, but to the technical marketing authorisation, which cites that legislation (see recitals 653 to 655 of the contested decision). Furthermore, for the purposes of producing the copy of the publication of the authorisation in the national official journal required by Article 8(1)(c) of Regulation

No 1768/92, AZ communicated the cover page and page 246 of the Luxembourg list (see recital 656 of the contested decision).

492 It follows from the foregoing that nothing in the manner in which the information in the instructions of 7 June 1993 was presented was of such a nature as to suggest that the dates given in respect of France and Luxembourg did not relate to the technical marketing authorisations. In this respect, even assuming that it were possible to put forward alternative interpretations of the concept of 'authorisation to place the product on the market' in Regulation No 1768/92, it is common ground that both the patent offices and the patent attorneys construed that concept as referring to the 'technical' authorisation. The memorandum of 16 March 1993 indeed clearly suggests that that was also AZ's understanding of that concept, since it initially took the view that the acquisition of SPCs in Germany and Denmark was impossible (see paragraph 479 above).

493 The Court therefore finds that, in view of the context in which those representations to the patent attorneys and patent offices were made, AZ could not reasonably be unaware that, in the absence of an express disclosure of the interpretation that it intended to adopt of Regulation No 1768/92 which underlay the choice of the dates provided in relation to France and Luxembourg, the patent offices would be prompted to construe those representations as indicating that the first technical marketing authorisation in the Community had been issued in Luxembourg in 'March 1988'. Thus, there was no need for the Commission to demonstrate AZ's bad faith or positively fraudulent intent on its part, it being sufficient to note that such conduct, characterised by a manifest lack of transparency, is contrary to the special responsibility of an undertaking in a dominant position not to impair by its conduct genuine undistorted competition in the common market (see, to that effect, *Nederlandsche Banden-Industrie-Michelin* v *Commission,* paragraph 30 above, paragraph 57).

494 Accordingly, the dispute between the parties on the issue whether the misleading nature of the SPC applications stemmed from AZ's bad faith is irrelevant. In any event, the applicants' multiple arguments based on the alleged absence of bad faith on the part of AZ, as regards both the interpretation that it chose to adopt of Regulation No 1768/92 and the manner in which the SPC applications were presented, or the significance that it attached to the Luxembourg list, cannot constitute objective justification for the absence of proactive disclosure of the nature of the dates mentioned in relation to the Luxembourg and French marketing authorisations, on the one hand, and of the interpretation of Regulation No 1768/92 which led to the choice of those dates, on the other.

495 Thus, as regards, first of all, the claim that AZ intended to discuss with the patent offices the dates provided and that AZ expected the patent offices to put questions to it in this respect, the Court finds that those considerations are in any event irrelevant, in view of the highly misleading nature of the representations made to the patent offices for the purposes of the SPC applications. The view cannot be taken that the SPC applications were presented in such a way as to invite the patent offices to put questions regarding the date given in relation to the French authorisation (22 November 1989). Only the imprecise nature of the date mentioned regarding the marketing authorisation granted in Luxembourg (March 1988) might have prompted requests for clarifications in this respect. As the Commission observes, the fact remains that in reply to the requests for clarifications of the patent offices in relation to the authorisation date in Luxembourg, and apart from in its exchanges with the United Kingdom and Irish patent offices, AZ refrained from disclosing with the requisite transparency, first, all the relevant dates for the purposes of the issue of the SPCs, and in particular the date of authorisation issued in France on 15 April 1987, which constituted the first technical marketing authorisation issued in the Community, and, second, the interpretation of Regulation No 1768/92 that underlay the dates given for France and Luxembourg. The applicants' claim that AZ intended to discuss with the patent offices the relevant date for the purposes of Regulation No 1768/92 is not therefore supported by the facts. AZ's conduct over the long term suggests on the contrary

rather that it was motivated by the intention of misleading the patent offices, as is apparent from the second stage of this abuse.

496 Next, AZ's purported good faith in its interpretation of Regulation No 1768/92 and the reasonableness of that interpretation are irrelevant. As the Commission rightly observes in recital 666 of the contested decision, the merits of the interpretation of the regulatory framework are not at all an issue in the first abuse. The fact, put forward by the applicants, that an alternative interpretation of Regulation No 1768/92 could be adopted is not necessarily liable to affect the objectively misleading nature of AZ's SPC applications, since AZ specifically refrained from disclosing that interpretation to the patent offices, as well as the date of 15 April 1987 relating to the technical marketing authorisation issued in France, which was the first technical marketing authorisation issued in the Community. Consequently, it is also irrelevant that, subsequent to the instructions sent to the patent attorneys for the purposes of filing the initial SPC applications with the national patent offices, law firms drafted notes supporting AZ's interpretation of Regulation No 1768/92.

497 As regards, lastly, AZ's purported good faith in the significance that it attached to the Luxembourg list, it is sufficient, here again, to note that that cannot remedy the absence of disclosure to the patent offices of its 'effective marketing theory' and of the date of issue in France of the technical marketing authorisation of 15 April 1987. Moreover, as the Commission found in recital 663 of the contested decision, the Luxembourg list is a document which does not lend itself, by its appearance, to being regarded as the publication of the price of omeprazole in Luxembourg. The Court would point out, in this respect, that no prices appear alongside the products mentioned in the list (see paragraph 486 above). Moreover, in view of the fact that page 246 of that list sets out in alphabetical order the products whose names begin with the

letters 'lo', then the letters 'lu', it is not credible that those products would have been authorised for marketing on the same day, namely on 21 March 1988.

498 For the sake of completeness, the Court would point out, as the examination of the second stage of the abusive behaviour suggests, that the fact that AZ continued to assert the relevance of the Luxembourg list and of the date of 21 March 1988 even though it was in possession of information indicating that Losec had been marketed before that date and that its price had never officially been published (see inter alia recital 700 of the contested decision) tends to discredit the applicants' claims regarding AZ's good faith.

499 As regards the inconsistencies concerning the use by AZ of different types of dates, namely the alleged date of publication of the price of the product for omeprazole and omeprazole sodium, the date of the first publication of the technical marketing authorisation for felodipine and the technical marketing authorisation dates for five other products, it must be observed that those inconsistencies are not directly relevant as regards the first abuse, which concerns only the misleading representations to obtain SPCs for omeprazole. The Commission made mention of those inconsistencies (recitals 643 to 646 of the contested decision) in order to demonstrate that there was an overall strategy for the SPC applications which was designed to conceal knowingly from the patent offices the dates prior to 1 January 1988.

500 Although those findings may have the merit of establishing the context in which AZ's conduct took place, the Court would however point out that they are not strictly necessary for the purposes of demonstrating the first abuse, which consists, during the first stage identified by the Commission, in AZ's notification to the patent offices of the alleged dates of publication of the price of omeprazole in France and Luxembourg without informing them of its interpretation of Regulation No 1768/92 and of its 'effective marketing theory' underlying the choice of the dates provided. Consequently,

all the applicants' arguments seeking to explain those inconsistencies and to dispute that they stem from AZ's bad faith are irrelevant, since they can have no bearing on the abusive nature of the lack of transparency which AZ displayed when filing the SPC applications.

The second stage of the abuse of a dominant position

501 The Commission also identified a series of representations that it also considered to be misleading and that it grouped together in a second stage of the abuse as a direct extension of the conduct identified in the first stage of the abuse. That second stage consists of misleading representations made in 1993 and in 1994 before patent offices, in reply to their questions on the SPC applications filed by AZ, of misleading representations made in December 1994 during the second round of SPC applications in three EEA countries, namely Austria, Finland and Norway, and of misleading representations made subsequently before other patent offices, as well as before national courts, in the context of proceedings brought by competing generic manufacturers with a view to invalidating the SPCs in those countries (see recital 629 of the contested decision).

502 Since the applicants contest each of the Commission's findings, it is necessary to review the findings of facts and the Commission's subsequent assessment of those facts in respect of each of the representations made by AZ at issue in this second stage.

— The representations before the Luxembourg patent office (June 1993)

503 The SPC application for omeprazole was transmitted to the Luxembourg patent office via the French patent attorney, who himself used a Luxembourg patent attorney (recital 202 of the contested decision). By letter of 11 June 1993, AZ transmitted to the French patent attorney the technical marketing authorisation in Luxembourg, stating however that it considered that the date of publication in the Luxembourg list, namely 21 March 1988, was the relevant date for the purposes of Article 3(d) of Regulation No 1768/92. AZ thus gave the instruction to refer to that latter date as the date of first authorisation in the Community. It added that 'no further argumentation is required at this stage' (recitals 203 and 684 of the contested decision).

504 By letter of 17 June 1993, the French patent attorney instructed the Luxembourg patent attorney not to indicate, in the SPC applications, the date on the Luxembourg marketing authorisation 'but the date of publication in the [Luxembourg] official journal *Spécialités Pharmaceutiques* …, that is to say 21 March 1988'. The French patent attorney added that: 'although this position is debatable we ask you to comply with these instructions' (recital 204 of the contested decision). By letter of the same day, the French patent attorney asked AZ whether it wanted the SPC applications for other products also to state 'dates of publication in *Spécialités Pharmaceutiques* of the Authorizations'. In its letter of reply of 21 June 1993, AZ advised the French patent attorney that its instructions of 7 June 1993 applied only to omeprazole and omeprazole sodium (recitals 205 and 206 of the contested decision).

505 Already on 16 June 1993, the Luxembourg patent attorney sent the patent office an incomplete SPC application. He sent the patent office the technical marketing authorisation number in Luxembourg, as requested by AZ, but refrained from

communicating the date of 'March 1988' and the Luxembourg list. In this respect, the attorney stated that a 'copy of the Luxembourg authorisation' would be communicated later. Subsequently, a handwritten annotation stating '16 November 1987' was inserted on the application form, apparently by the Luxembourg patent office itself. An SPC was therefore issued in Luxembourg, which was to expire on 16 November 2002 (recitals 207 and 682 of the contested decision).

506 The Commission found that neither the Luxembourg patent attorney nor the Luxembourg patent office had been made aware of the technical marketing authorisation issued at an earlier stage, on 15 April 1987, in France (recital 682 of the contested decision). Furthermore, it was clear, in the Commission's view, that the French patent attorney had understood AZ's instructions as a request to communicate the date of publication of the technical marketing authorisation and that AZ had refrained from explaining to him the real nature of the date of 21 March 1988 (recital 686 of the contested decision).

507 It must be stated that the misleading nature of the SPC application in Luxembourg lies above all in the lack of transparency regarding the existence of the marketing authorisation granted in France on 15 April 1987, which constituted the first authorisation granted in the Community and which had therefore to be taken into account for the purposes of the duration of validity of the SPC.

508 The applicants attempt to place the responsibility for this onto the French patent attorney, who was aware of the date of the authorisation granted both in France and in Luxembourg. The Court would point out in this respect that AZ's internal documents do not support the proposition that AZ was unaware of the failure to communicate the date of 15 April 1987 relating to the issue of the marketing authorisation in France. It is apparent from the fax of 11 October 1996 (see paragraph 530 below) that

AZ was aware of the erroneous nature of the date of the first marketing authorisation in the Community and that it had assessed the risk associated with not communicating the date of 15 April 1987, being of the opinion that, in the worst-case scenario, it would consist in the loss of six months' SPC protection. That view is backed up by the minutes of the Copenhagen (Denmark) meeting of 15 November 1994 (see paragraph 552 below), in which it is stated that AZ was 'convinced' that, in the countries in respect of which the transitional rules of Regulation No 1768/92 did not pose a problem, but in respect of which use had been made of the Luxembourg authorisation 'for the sake of consistency', it would be possible, in the event of disputes relating to the SPCs, to revert to the French authorisation date, in view of the uncertain state of the interpretation of the regulatory provisions in question at the time of the filing of the SPC applications.

509 Lastly, the instructions that AZ sent to its French patent attorney, who was then required to forward them to the Luxembourg patent attorney, were perfectly clear. An explicit request was made to communicate to the Luxembourg patent office the date of 21 March 1988, and no mention of the date of 15 April 1987 was made. However, as is apparent from the memorandum of 16 March 1993, referred to in paragraph 479 above, even before it had adopted its alternative interpretation of the concept of marketing authorisation, AZ knew that the date of 15 April 1987 was relevant as date of the first marketing authorisation in the Community.

510 If the failure to communicate the date of 15 April 1987 was indeed the result of an inadvertent error, it was in any event incumbent on AZ to request the rectification of the Luxembourg SPC subsequent to its grant, in view of the special responsibility of an undertaking in a dominant position.

511 For the sake of completeness, the Court would note that the fact, alleged by the applicants, that the French patent attorney knew the dates of both the French marketing authorisation and the Luxembourg marketing authorisation does not permit the inference that he knew that the publication in the Luxembourg list (*Spécialités pharmaceutiques*) corresponded to the alleged publication of the price of the product. As the Commission found in recital 686 of the contested decision, AZ did not explain to the French patent attorney the alleged purpose of the publication in the Luxembourg list, or, therefore, the nature of the date of 21 March 1988, even though it was quite clear from the letter of 17 June 1993 to AZ that that patent attorney thought that that date related to the publication of the marketing authorisation itself. Furthermore, as the Commission argues, it is also apparent from the letter of the French patent attorney of 2 August 1996 that he still thought, on that date, that the Luxembourg list and the date of 21 March 1988 corresponded to the publication of the Luxembourg marketing authorisation.

512 In this respect, the Court rejects the applicants' argument that, in its letter of 17 June 1993 to AZ, the French patent attorney understood the word 'authorisation' as meaning effective marketing authorisation. It is clear that that letter was not referring to the concept of authorisation as interpreted by AZ, namely its 'effective marketing theory'. The relevant passage of that letter reads as follows:

'We acknowledge receipt of your instructions to refer on the request forms to the dates of publication in "Spécialité Pharmaceutique" of the Authorizations and not to refer to the date which is mentioned on the Authorizations by themselves.'

513 In addition, it is not at all apparent from the statement of the Luxembourg patent attorney that he and the French patent attorney were not misled.

— The representations before the Belgian patent office (September to November 1993)

514 It is apparent from the contested decision that the Belgian patent attorney notified to the Belgian patent office the date of March 1988 and the Luxembourg technical marketing authorisation number, in accordance with AZ's instructions of 7 June 1993. By letter of 20 July 1993, the Belgian patent attorney requested AZ to provide him with the exact date of the Luxembourg technical marketing authorisation. By letter of 26 August 1993, the Belgian patent attorney repeated that request (see recital 186 of the contested decision).

515 By letter of 10 September 1993, AZ informed its Belgian patent attorney that it considered that the date to use was that of publication in the Luxembourg list, namely 21 March 1988. On the same day, AZ's Belgian marketing company sent the Belgian patent attorney, at his request, a copy of the Luxembourg marketing authorisation. By letter of 29 September 1993, the Belgian patent attorney advised AZ that he considered that the date which should be notified to the patent office was that on the technical marketing authorisation, namely 16 November 1987, and that, unless instructed to the contrary, he would communicate that date. On 30 September 1993, the Belgian patent attorney notified that date to the Belgian patent office and informed AZ thereof by letter of 4 October 1993 (see recitals 187 and 188 of the contested decision).

516 On the basis of that information, the Belgian patent office granted an SPC expiring on 16 November 2002, of which AZ was informed on 25 November 1993. That SPC was set aside by a Belgian court on 25 September 2002 (see recitals 189 and 190 of the contested decision).

517 The Commission observed that AZ had never informed the Belgian patent attorney of the existence of the French technical marketing authorisation of 15 April 1987. It also disputed that the Belgian patent attorney had acted on his own motion, given the similar instructions that AZ had sent to the Dutch and Belgian patent attorneys. The Commission also considered that AZ had not explained its 'effective marketing theory' to the Belgian patent attorney (see recitals 688 and 689 of the contested decision).

518 The applicants' arguments cannot cast doubt on those considerations. As regards, first of all, the fact that AZ gave the instruction to base the SPC application on the effective marketing authorisation date, that is 21 March 1988, the Commission was right to find, in recital 689 of the contested decision, that AZ's letter of 10 September 1993 did not contain any explanation regarding the 'effective marketing theory', AZ having merely indicated in that letter that it considered that the date of publication in the Luxembourg list should be used for the purposes of the SPC applications.

519 As regards, next, the argument that the Belgian patent attorney acted on his own motion and that AZ did not realise, until 1996, that the Belgian SPC was based on the date of 16 November 1987, the Court would point out, as the Commission observes, that in his letter to the Belgian patent office on 8 May 1998 the head of the patent department stated that Hässle had agreed to the Belgian patent attorney's indicating the date of 16 November 1987 and had not sought to get the duration of the SPC to start running from 21 March 1988. It follows from this that AZ's silence following the letter from the Belgian patent attorney of 29 September 1993 stemmed from a deliberate intention to leave that attorney to notify to the Belgian patent office the date of 16 November 1987 as date of first authorisation in the Community. That is confirmed by the observations lodged by AZ on 4 April 1997 in the court proceedings before the Bundespatentgericht (Federal Patent Court, Germany), according to

which [*confidential*], and by its observations before the Bundesgerichtshof, in which it claimed [*confidential*].

520 As regards, lastly, AZ's letter to the Belgian patent office on 8 May 1998, the purpose of that letter was not at all to disclose to it the existence of a technical marketing authorisation in the Community prior to 16 November 1987. The apparent aim of that letter was merely to inform the Belgian patent office of the existence of litigation in Germany in relation to the interpretation of Regulation No 1768/92 and of the 'effective marketing theory' which justified, in AZ's view, the date of 21 March 1988 being used for the purposes of the issue of the SPC in Belgium. There is nothing in that letter therefore to permit the inference that AZ wished to rectify the basis on which the SPC in Belgium had been issued, by advising of the existence of the technical marketing authorisation granted in France on 15 April 1987. The applicants' assertion that AZ drew the authorities' attention to all the relevant dates is not therefore correct.

521 In addition, it is not at all apparent from Mr P.'s statement that he had been informed of the existence of the date of the technical marketing authorisation in France.

— The representations before the Dutch patent office (November and December 1993)

522 In the Netherlands, AZ applied for SPCs in respect of omeprazole and omeprazole sodium, citing the date of 'March 1988' for those two products.

523 By two identical letters of 26 November 1993 concerning omeprazole and omeprazole sodium, the Dutch patent attorney advised AZ that the Dutch patent office had doubts whether the Luxembourg list constituted the publication of the marketing authorisation in the *Mémorial*, the *Official Journal of the Grand Duchy of Luxembourg*, as required by Article 8(1)(a)(iv) of Regulation No 1768/92. The patent attorney also notified AZ that the patent office had raised objections concerning the imprecision of the date relating to the Luxembourg marketing authorisation (March 1988). According to the patent attorney, '[i]t seem[ed] that this date pertain[ed] to the month in which the [Luxembourg list] [had been] published, rather than the actual date of the grant of the marketing authorization'. By two identical letters of 16 December 1993 concerning omeprazole and omeprazole sodium, AZ stated that the date of 21 March 1988 appeared on the Luxembourg list, which constituted the publication of the marketing authorisation for the purposes of Article 8(1)(a)(iv) of Regulation No 1768/92. It stated that the marketing authorisation had been issued on 16 November 1987 and that it considered that the date of 21 March 1988 was the relevant date for the purposes of Article 8(1)(a)(iv) of Regulation No 1768/92. AZ stated however that both those dates could be notified to the examiner (see recitals 191 to 193 of the contested decision).

524 The patent office applied the date of 16 November 1987 and issued an SPC for omeprazole which was valid until 15 November 2002.

525 At a meeting in London on 11 December 1996, the Dutch patent attorney informed the head of the patent department that there was no legal possibility of making corrections at the patent office. At that meeting, AZ decided not to take action vis-à-vis that patent office (see recital 197 of the contested decision).

526 However, by letter of 29 January 1997, the Dutch patent attorney informed AZ that he had contacted an official at the Dutch patent office regarding the possibility of making

a correction to the SPC which had been issued. The Dutch attorney reported that that official had expressed the view that, although there was no formal provision to that effect, it ought to be possible to make such a correction. That attorney therefore suggested making a formal request to the patent office for a 'certificate of correction'.

527 In its letter of reply on 10 February 1997, AZ wrote that it was 'startled' to learn that the Dutch patent attorney had contacted the patent office on this point, in view of what had been agreed at the London meeting. AZ stated that it did not agree with the proposal to make a formal request for a correction of the SPC, since such action could lead to unpredictable and undesirable results. It was stated that the head of the patent department also considered that no action should be taken vis-à-vis the Dutch patent office (see recitals 198 and 199 of the contested decision).

528 The Commission also took the view that it emerged from a fax of 11 October 1996 from the head of the patent department to the Dutch marketing company that AZ was aware, as far back as 1993, of the fact that it would have lost six months of SPC protection if the patent attorney had been instructed to communicate the date of the technical marketing authorisation in France of 15 April 1987 (recital 200 of the contested decision).

529 Further to applications filed by competitors of AZ, the Dutch patent office found, on 29 October 2002, that the correct expiry date of the SPC was 15 April 2002 (see recital 201 of the contested decision).

530 The fax of 11 October 1996 submitted by the Commission casts doubt on the applicants' claim that the notification of the date of 16 November 1987 in respect of the SPC application for omeprazole was the result of an oversight. It is apparent from that fax, from the head of the patent department to the head of AZ's Dutch marketing company, in reply to the latter's fax of 10 October 1996, that AZ was perfectly aware of the erroneous nature of the date of the first marketing authorisation in the Community notified to the Dutch patent office. In his letter of 10 October 1996, the head of the Dutch subsidiary stated that the notification of the incorrect date could either give rise to a rectification of the SPC so that its expiry date would be brought forward by six months, or to annulment of the SPC by way of punishment. In response, the head of the patent department stated that he was 'convinced that the only risk we stand in Holland is that we might lose six months of SPC term'. The head of the patent department added that 'this possibility was evaluated as far back as 1993'.

531 The applicants cannot claim, in this respect, that that letter related to acceptance by the patent office of the 'effective marketing theory', since on any view the patent office had not adopted the proposed date of 21 March 1988, which appeared on the Luxembourg list.

532 In addition, the Court would point out that even assuming, as the applicants claim, that AZ became aware only in 1996 of the alleged error consisting in notification of the date of 16 November 1987 — on which the letters examined above cast doubt — it was in any event incumbent on it, as an undertaking in a dominant position when it made the mistake, to take the action necessary to prevent the anticompetitive consequences to which that error was to give rise. It is common ground that, in its letter of 10 February 1997, AZ rejected the Dutch patent attorney's proposal to rectify the SPC, even though that option appeared possible.

533 Even taken in isolation, outside its context, AZ's refusal to rectify the SPC granting it a period of protection longer than that to which it knew it was entitled amounts to unacceptable behaviour by an undertaking in a dominant position. That reason alone is sufficient in itself to reject as irrelevant the argument that the Dutch patent attorney had stated at the London meeting of 11 December 1996 that nothing could be done, given his subsequent proposal which was rejected by AZ.

534 Furthermore, the Court would point out that, assessed in its context and in particular in the light of the fax from the head of the patent department of 11 October 1996 — which makes the suggestion of an oversight scarcely credible any longer — AZ's reaction to the proposal of the Dutch patent attorney is a continuation of its concealment from the patent office of the existence of the marketing authorisation granted in France on 15 April 1987.

535 As regards the letter of 8 May 1998 to the Dutch patent office, it is identical on all points to that sent on the same day to the Belgian patent office (see paragraph 520 above). That letter was in no way intended to inform the Dutch authority of the existence of the marketing authorisation in France of 15 April 1987.

536 Lastly, the applicants are not justified in claiming that it is for the Commission to adduce evidence that AZ did not explain its 'effective marketing theory' to the Dutch patent attorney. In the light of all the evidence showing that the Dutch patent attorney had not been informed of that theory or of the existence of the technical marketing authorisation in France, the onus is clearly on the applicants to adduce evidence for what they claim. The Court would point out, moreover, that the Dutch patent attorney's statement submitted by the applicants suggests that when it was drawn up

he still thought that the Luxembourg list constituted the publication of the technical marketing authorisation.

537 Moreover, it is apparent from AZ's letter of 16 December 1993 that AZ indicated to the Dutch patent attorney that the Luxembourg list constituted the publication of the marketing authorisation. In view of that context, it is clear that AZ knew that the patent agent would understand that letter as indicating that that publication related to the technical authorisation.

— The representations before the United Kingdom patent office (January to June 1994)

538 The Commission observed that, after the patent attorney notified the date of 'March 1988' to the United Kingdom patent office, that office requested a precise date by letter of 7 September 1993. In a letter in reply of 7 January 1994, the United Kingdom patent attorney stated that the technical marketing authorisation was dated 16 November 1987 and that the date of 21 March 1988 could be used instead of that of 'March 1988'. By letter of 18 January 1994, the United Kingdom patent office stated that the date of 16 November 1987 was the correct date (see recitals 209 and 697 of the contested decision).

539 By internal memorandum of 14 February 1994 to Hässle, the head of the patent department stated that, in order to ensure that the SPCs for Losec lasted as long as possible in the different European countries, its services were arguing that the definition of marketing authorisation was not clear. [*confidential*] The head of the patent department added that its services were trying to get that later date accepted as the relevant one, since it ensured the longest SPC term and the possibility of maintaining

the SPC in Germany and of receiving an SPC in Denmark. The head of the patent department requested information on the date on which Losec was marketed for the first time in each of the Member States and went on to state (see recitals 210 and 211 of the contested decision):

'Specifically inform me if we sold Losec in any EU state prior to having the price negotiations concluded in that country.'

540 By memorandum of 3 March 1994, the Luxembourg marketing company notified Hässle inter alia that the first sale of Losec in Luxembourg had taken place on 11 March 1988 and that the price agreement, concluded on 17 December 1987, had not been published. AZ's subsidiary in Luxembourg also stated that the marketing authorisation for Losec had been published in the *Mémorial* in March 1988. That last item of information was however incorrect, since the publication in the *Mémorial* had been on 4 December 1987. Following a request for confirmation from Hässle on 17 May 1994, Astra Luxembourg resent, on 18 May 1994, its fax of 3 March 1994. On 30 May 1994, Hässle again sought confirmation of that information from Astra Luxembourg and, by fax of 8 June 1994, the latter repeated its message of 3 March 1994, and thus stated that the date of the price agreement, which had not been published, was 17 December 1987, and that the authorisation was officially published in the *Mémorial* in March 1988 (see recitals 211 and 212 of the contested decision).

541 By letter of 16 June 1994, the United Kingdom patent attorney submitted to the United Kingdom patent office a request to secure acceptance that the concept of marketing authorisation should be extended to mean the effective marketing of the product, that is when all the steps in the administrative procedure necessary in order that a product may, in practice, be marketed have been completed. That letter contained in annex a table setting out the various steps in the authorisation procedure for omeprazole in

various countries. That table mentioned the date of 15 April 1987 as date of the marketing authorisation in France and the date of 21 March 1988 as date of the official listing and of the official price publication in Luxembourg. The legal opinions of two law firms, of 8 March and 8 June 1994, supporting AZ's interpretation of Regulation No 1768/92 were also annexed to that letter. The United Kingdom patent attorney maintained that, in Luxembourg, it was in practice not possible to market a product until it appeared in the list of the Luxembourg Ministry of Health, the '*Spécialités pharmaceutiques*' (the Luxembourg list), which had been published on 21 March 1988. It was claimed that the first sales in Luxembourg had taken place at the end of March 1988 (see recitals 213 and 214 of the contested decision).

542 However, the patent office rejected AZ's arguments and found that the first marketing authorisation in the Community had been on 15 April 1987. On 30 September 1994, it issued an SPC with an expiry date of 14 April 2002 (see recitals 215 and 216 of the contested decision).

543 The Court notes that AZ's behaviour before the United Kingdom patent office was more transparent than its behaviour before the Luxembourg, Belgian and Dutch authorities. Instead of merely accepting the decision of the United Kingdom authority to adopt the date of 16 November 1987 as date of first marketing authorisation in the Community, AZ sought to explain why it proposed adoption of the date of 21 March 1988 and to set out its interpretation of the concept of marketing authorisation.

544 In the contested decision, the Commission emphasises that AZ ignored the information provided by AZ's subsidiary in Luxembourg, which tended to negate the significance that AZ sought to attach to the Luxembourg list and the date of 21 March 1988. The Commission noted that Astra Luxembourg indicated on three occasions that the

price approved on 17 December 1987 had not been published and that the first sales of Losec had taken place on 11 March 1988, that is before 21 March 1988.

545 In this respect, it is true that AZ was in possession of information which did not support the role that it wished to attribute to the Luxembourg list. As already observed in paragraph 497 above, that document could hardly be viewed as an official publication of the price of Losec, since no prices appeared alongside the products mentioned. The fact that Astra Luxembourg stated that no publication of the price had taken place further discredited the proposition that that document constituted the publication of the price of Losec.

546 Similarly, the information that the first sales of Losec took place as early as 11 March 1988 also contributed to negating the relevance that AZ sought to attach to the Luxembourg list. In this respect, the discussion concerning whether the 'official launch' of the product, to which AZ's subsidiary in Luxembourg referred and gave that date, may be understood as meaning the first actual sales is not capable of affecting the argument that it was actually possible to market Losec independently of the publication of the Luxembourg list.

547 In any event, the Court considers that AZ's representations to the United Kingdom patent office for the purposes of securing acceptance, in the context of its 'effective marketing theory', of the date of 21 March 1988 ceased to be misleading as of the letter of 16 June 1994, in which AZ openly referred to the existence of the first French marketing authorisation of 15 April 1987 and of the interpretation of Regulation No 1768/92 that it was seeking to defend. That is also reflected in recital 774 of the contested decision, in which the Commission found that the first abuse ended on 16 June 1994 in the United Kingdom.

548 None the less, it is absolutely clear from all the documentary evidence submitted for the Court's attention, and in particular from the fax of 11 October 1996 examined in paragraph 530 above, and from the minutes of the Copenhagen meeting of 15 November 1994, examined in paragraphs 551 and 552 below, that the initial SPC application filed with the United Kingdom patent office was part of an overall strategy on SPC applications, designed to base those applications on the date of 21 March 1988 instead of on the date of 15 April 1987, which corresponded to the first marketing authorisation granted in the Community.

549 Consequently, in the light of that context, the sudden change in attitude displayed by AZ vis-à-vis the United Kingdom authorities in its letter of 16 June 1994 does not affect the misleading nature of the representations initially made to those authorities in the SPC application, or the abusive nature of its behaviour before the other national patent offices, to which AZ did not disclose the relevant information, so that they were misled regarding the duration of the SPCs to which AZ was entitled.

— The withdrawal of the SPC application in Denmark (November 1994)

550 On 30 September 1994, AZ withdrew its SPC application filed at the Danish patent office. That application was based on the Luxembourg date of March 1988.

551 The minutes of a meeting of 15 November 1994 in Copenhagen between the head of the patent department, a Danish lawyer and the Danish patent attorney summarises AZ's strategy on SPC applications up to that point in time and makes clear the reasons

for the withdrawal of that application. That document states that AZ decided to claim that the date of first marketing authorisation corresponded to the time that the price was also approved, which led to the Luxembourg date of March 1988 being used, thus making it possible to file an SPC application in Germany and Denmark. It is stated in those minutes that the filing of those applications would not have been possible if the French marketing authorisation of 15 April 1987 had been used. That document mentions that AZ decided not to continue to argue its case before the United Kingdom patent office and decided to accept an SPC based on the date of the French authorisation, without prejudice to the interpretation of Regulation No 1768/92 that it was seeking to defend in Germany.

552 Furthermore, those minutes state that AZ was 'convinced' that in the countries in which the transitional rules of Regulation No 1768/92 did not pose a problem, but in which use had been made of the Luxembourg authorisation 'for the sake of consistency', it would be possible, in the event of disputes relating to the SPCs, to revert to the French authorisation date, in view of the uncertain state of the interpretation of the regulatory provisions in question at the time of the filing of the SPC applications. That document states that the Danish patent office had indicated informally that it did not regard the Luxembourg date as the 'first authorisation' date. The Danish patent office intended to adopt the same position as the United Kingdom patent office, with which it had close contacts in relation to SPC matters. However, the Danish authority had a different formal ground for rejecting the SPC application, thereby avoiding a dispute as to what the first authorisation was. The minutes of that meeting state that, finally, on reflection, AZ had decided not to argue its case in Denmark and to retain the argument based on the 'effective marketing theory' for the SPC application in Germany, and, after discussion with its Danish representatives, to withdraw the SPC application in Denmark to make it look as if it was due to a mistake in citing the patent number (see recitals 219 and 220 of the contested decision).

553 The Court considers that, assessed in the light of the fax of 11 October 1996 from the head of the patent department to the head of AZ's Dutch marketing company (see paragraph 530 above), the minutes of the Copenhagen meeting of 15 November 1994 are an important item of evidence regarding the deliberate nature of the failure to indicate the date of 15 April 1987 relating to the marketing authorisation in France to the Belgian, Luxembourg and Dutch patent offices. It is quite clear that where the patent offices refused to take into consideration the date of 21 March 1988 AZ refrained from disclosing to them the date of 15 April 1987 and allowed them to base the SPCs on the date of 16 November 1987 relating to the issue of the Luxembourg technical authorisation, which those offices believed to be the date of the first authorisation in the Community. In the event that the date of 15 April 1987 came to light, AZ intended to rely on the alleged uncertain interpretation of the regulatory framework in order to explain the notification of the incorrect date. Furthermore, in the administrative procedure before the Commission and in the proceedings before this Court, the applicants plead an inadvertent error in order to explain the notification of the incorrect date (see paragraphs 435 and 530 above).

554 Those minutes also suggest that AZ withdrew its SPC application in Denmark in order to avoid a rejection decision, which would create a precedent which might prejudice its chances of obtaining an SPC in Germany, a country which, like Denmark, did not grant SPCs in respect of products which had obtained a first technical marketing authorisation prior to 1 January 1988.

555 In the light of that evidence, the Court considers that the Commission is justified in finding that, in the absence of contact between the United Kingdom and Danish patent offices, it is probable that AZ's strategy would have made it possible to obtain an SPC in Denmark (recital 719 of the contested decision).

— Applications in the EEA countries (December 1994)

556 In the contested decision the Commission observed that, in December 1994, AZ's patent attorneys had initiated a second round of SPC applications in Austria, Finland and Norway, on the basis of AZ's instructions of 18 November 1994. Those instructions contained only the date and number of the first authorisation in the EEA and did not list the dates and numbers of the marketing authorisations in 10 Member States. In its instructions, AZ also supplied the date of 21 March 1988 as date of the first marketing authorisation in the Community and the Luxembourg technical marketing authorisation number of 16 November 1987. It attached the Luxembourg list to those instructions as relevant publication of that authorisation and a copy of the Luxembourg law relating to technical marketing authorisation (see recitals 183, 184 and 232 of the contested decision).

557 The Commission noted that the Swedish authorities had authorised the marketing of Losec on 5 February 1988. That product was actually launched on 28 February 1988 (recital 232 of the contested decision).

558 In Austria, the patent attorney requested additional information in order to be able to explain to the patent office why the date on the marketing authorisation (21 March 1988) was not the relevant date of the first authorisation in the Community. However, the Austrian patent attorney notified the date of 21 March 1988 to the patent office, and that office therefore issued an SPC on the basis of that date and expiring on 24 August 2005 (see recital 233 of the contested decision).

559 In Norway, AZ's patent attorney filed the SPC application on 21 December 1994, in line with AZ's instructions. On 14 April 1997, the Norwegian patent office issued an SPC for omeprazole on the basis of the date of 21 March 1988, which was to expire on 21 March 2003. That SPC was challenged by competitors before the District Court of Oslo, and the case was then brought before the appeals court. The SPC was eventually revoked on 29 June 1999 (recitals 234 and 242 of the contested decision).

560 In Finland, the SPC application was filed by the Finnish patent attorney on 30 December 1994. The Finnish patent office issued an SPC on the basis of the date of 21 March 1988. That decision was challenged on 21 December 1998 by a competitor before the Helsinki District Court. The proceedings before that court were still pending at the time of adoption of the contested decision (recitals 243 and 244 of the contested decision).

561 According to the Commission, despite the fact that AZ received the authorisation to market Losec in Sweden on 5 February 1988, AZ preferred to communicate the date of 21 March 1988, which was however no longer the first date of effective marketing of Losec (recital 722 of the contested decision).

562 The applicants and the Commission disagree as to whether AZ knowingly refrained from communicating the date of 5 February 1988, a question which was relevant in the light of AZ's interpretation of the concept of 'authorisation' as date of the first effective marketing authorisation in the EEA. The Commission relies on various letters — the relevance and probative value of which the applicants dispute — for the purposes of demonstrating that AZ knew that the first authorisation in the EEA was the relevant date.

563 There is no need for the Court to make any findings on those points, it being sufficient to note that, as was the case in other countries, AZ notified to the patent offices the date of 21 March 1988 instead of the relevant date of 15 April 1987 relating to the marketing authorisation in France, which was the first marketing authorisation in the Community and, accordingly, in the EEA.

564 It must therefore be stated that the Commission was entitled to consider that AZ had misled the national authorities by refraining from providing the relevant patent offices with all the relevant information enabling them to grant the SPCs in full knowledge of the facts.

565 The Court would also point out that, in the reply, the applicants state that the head of the patent department considered that the Union authorisation date alone was applicable. The onus was therefore on AZ to provide also the date of 15 April 1987 to the patent office, since that was the date relating to the first authorisation in the Community according to the most widely shared interpretation of Regulation No 1768/92. It is worth reiterating, in this respect, that given that AZ was seeking to defend a particular interpretation of Regulation No 1768/92 the onus was on it to communicate the various relevant items of information in a transparent manner, in order to enable the public authority to adopt the appropriate decision and not to be misled as a result of an undisclosed ambiguity.

— The representations before the Irish patent office (October 1995)

566 The Commission observed that, in reply to a question from the Irish patent office in 1995, relating to the indication 'March 1988', AZ had submitted the date of the first marketing authorisation in the Community, namely the authorisation issued in France on 15 April 1987, whilst claiming that the date to take into consideration was 21 March 1988. According to the Commission, in view of the information which AZ had, it could not claim however that the effective marketing of Losec had not been possible before 21 March 1988 (recital 725 of the contested decision).

567 As was observed in relation to the SPC application in the United Kingdom, AZ displayed, at that stage, the requisite transparency by communicating the date of 15 April 1987. The fact that AZ held information which caused its statements to lose a large part of their credibility does not influence that finding.

568 However, as the Court found in paragraph 549 above, the transparency displayed by AZ vis-à-vis the Irish patent office does not cause the representations before the other national patent offices, and in particular those of the Benelux countries, to lose their misleading nature.

— Representations before the patent offices in the Benelux countries and Finland (May 1998)

569 The Commission observed that, when, by letters of 8 May 1998, the head of the patent department informed the Belgian, Finnish, Luxembourg and Dutch patent offices that AZ was appealing in Germany against the decision of the Bundespatentgericht before the Bundesgerichtshof, he claimed that the first authorisation to place the product on the market in the Community within the meaning of Regulation No 1768/92 had taken place on 21 March 1988, since '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'.

570 The Commission recalled that, at the time that that statement was made, AZ was in possession of unequivocal information from which it was clear that Losec had already been marketed before that date. It also observed that, in its submissions before the Bundespatentgericht, AZ had acknowledged, as early as 4 April 1997, that the date on which the price was fixed, 8 February 1988, was the relevant date of effective marketing. In addition, the Commission observed that AZ had a fourth internal document of 23 February 1998, from which it was apparent that omeprazole capsules 20 mg had been marketed on 1 February 1988 (recitals 726 and 730 of the contested decision).

571 The applicants dispute that the document of 23 February 1998 is a reliable source of information as to the exact launch date of Losec. It is apparent from this, however, that they do not dispute that the launch of Losec in Luxembourg took place, at the very least, in the course of February 1988, and therefore before 21 March 1988.

572 Moreover, as the Commission observed in recital 224 of the contested decision, it is apparent from an AZ internal document of 9 September 1996 that AZ knew that Losec had been marketed before 21 March 1988, although the exact launch date of the product was not clearly determined at that stage, given that both 1 February 1988 and 11 March 1988 were mentioned in this respect. Similarly, an internal document of 19 August 1996 mentions 1 February 1988 as the launch date of Losec in Luxembourg.

573 In view of that documentary evidence, in addition to all the other evidence relating to the SPC applications in the various countries mentioned above, the Court considers that the Commission was right to find that AZ was not acting in good faith when it represented to the patent offices of the Benelux countries and Finland that it was not possible, in practice, to market Losec before 21 March 1988.

— Representations during the court proceedings in Germany

574 It is apparent from the contested decision that the German patent attorney filed an SPC application with the German patent office in accordance with AZ's instructions of 7 June 1993. The application form showed that '21' was added by hand to the typewritten date 'März 1988'. On 10 November 1993, the German patent office issued an SPC on the basis of that date with an expiry date of 21 March 2003 (recital 221 of the contested decision).

575 On 18 June 1996, a generic manufacturer, Ratiopharm, brought proceedings against AZ before the Bundespatentgericht, claiming that the SPC issued to AZ should be invalidated on the grounds that the first technical marketing authorisation in the Community had been granted on 15 April 1987 in France (see recital 222 of the contested decision).

576 The Commission takes the view that AZ made misleading representations during the court proceedings in Germany. On 9 October 1996, AZ claimed that, back in June 1993 when it filed its SPC applications, it 'did not know otherwise' than that, since it corresponded to the date of publication of the authorisation and included the fixing of the price, the date of 21 March 1988 was the decisive date for the first marketing authorisation, and it was from that date only that it had been possible to market the product as a reimbursable product at fixed price (recitals 223 and 728 of the contested decision).

577 The Commission observed, moreover, that when that representation was made AZ had additional information in its possession according to which the decision of 17 December 1987, relating to the fixing of the price, had not been published and omeprazole capsules had been launched before 21 March 1988, namely on 11 March 1988 according to the reply of the Belgian marketing company in 1994, or on 1 February or 11 March 1988 according to AZ's internal notes of 19 August 1996 and 9 September 1996. In this respect, the Commission observed that the internal note of 9 September 1996 stated that the marketing authorisation and its publication, as well as the letter advising of the fixing of the price, had been awaited before the launch of the product. That note stated however that the publication of the 'list' by the Health Ministry had 'seemingly' not been awaited. That note identified three 'problems', namely that, first, the authorisation and publication of the authorisation had taken place on 1 January 1988, second, the date of 16 November 1987 had been adopted as the basis for the SPC, despite the efforts to have the date of 21 March 1988 accepted, and, third, the product had been launched prior to the publication of the Luxembourg list (see recitals 224 and 729 of the contested decision).

578 The Commission also observed that, in its later submissions to the Bundespatentgericht, on 4 April 1997, AZ had repeated that it had assumed that the product could be marketed legally only as of the publication of the fixing of the price, on 21 March 1988, and that the reasons which led it to take the view that the date of 21 March 1988 was the relevant date were entirely understandable 'even though, in the final analysis, 8 February 1988 [was] the date which [was] decisive for the fixing of the price'. The Commission stated, in this respect, that, although AZ had implicitly admitted, at that stage, that the publication of the Luxembourg list was not a *sine qua non* for marketing the product, it had refrained from mentioning that information in its letters of 8 May 1998 to the patent offices of the Benelux countries and of Finland (recitals 225 and 730 of the contested decision).

579 The applicants dispute that AZ intended to mislead the German judicial authorities and that it knew that the date of 21 March 1988 was not the correct date of the first marketing authorisation. In this respect, as regards, first of all, the applicants' arguments that (i) the date of 1 February 1988 indicated on the internal note of 19 August 1996 comes from information submitted by a patent attorney and is of indeterminate origin and (ii) the document of 9 September 1996 reveals uncertainty about the launch date of Losec, the Court observes that the applicants do not substantiate their arguments by producing the document of the patent attorney which is alleged to have referred to that date. Furthermore, the applicants do not put forward any evidence permitting the finding that the information relating to the date of 1 February 1988, which was allegedly communicated by the patent attorney, is of no value or is less credible than the date of 21 March 1988.

580 The Court notes, again, that all the information available to AZ, although uncertain about the exact launch date of the product, was consistent in showing that the effective marketing of Losec had taken place prior to the date stated on the Luxembourg list, namely 21 March 1988. Furthermore, as was already observed (see paragraphs 497 and 545 above), the Luxembourg list could not reasonably be interpreted as constituting the publication of the price of Losec, in the light of the way in

which it was presented and of the fact that AZ's Luxembourg marketing company had stated, back in March 1994, that the Luxembourg decision fixing the price had not been published.

581 As regards, next, the position adopted by AZ's representatives during the proceedings before the Bundespatentgericht, the applicants maintain that the admission of the correctness of the date of 8 February 1988, as relevant date to be taken into account, was based on a particular interpretation of Regulation No 1768/92 to the effect that the relevant date was that of approval of the price by the authorities. The applicants thus dispute that AZ considered in reality that the Luxembourg list was irrelevant. In this respect, and regardless of the accuracy of the applicants' claim, it is again sufficient to note that, as early as March 1994, AZ possessed information showing that the Luxembourg decision fixing the price had not been published. In addition, the Luxembourg list, on which the date of 21 March 1988 appeared, contained no information about the price of Losec. The applicants cannot therefore, in any event, claim that AZ could seriously hold the view that 21 March 1988 constituted the date of publication of the price, which amounted to a regulatory condition for marketing the product.

582 It follows from the foregoing that the Commission was right to find that, during the proceedings before the German courts, AZ had made incorrect representations, even though it possessed consistent information showing that the Luxembourg list and the date of 21 March 1988 were not relevant as regards the date to be taken into account upon its own interpretation of Regulation No 1768/92 and according to its 'effective marketing theory'. It is thus apparent that AZ was merely attempting to defend the validity of the SPC granted to it in Germany on the basis of its misleading representations, which had indicated 21 March 1988 as the date of the first marketing authorisation in the Community.

— Representations during the court proceedings in Norway and Finland

583 As regards the proceedings before the District Court of Oslo, the Commission observed that, in its submissions of 12 February and 20 May 1999, AZ defended the relevance of the date of 21 March 1988 and the Luxembourg list, despite the information in its possession showing that Losec had been launched before that date. The Commission also found that AZ had made no mention of the date of 8 February 1988, which it had put forward before the Bundespatentgericht, and that it had claimed that the publication of the Luxembourg list, which allegedly contained the authorised products whose prices had been approved, was a necessary condition in order that Losec could be marketed in Luxembourg (recitals 235, 236 and 733 of the contested decision).

584 Furthermore, the Commission found that, during those proceedings, AZ had admitted that it did not possess all of the Luxembourg list or any other part thereof comprising the price of Losec. In this respect, the Commission noted that AZ had however defended the relevance of that list before the patent attorneys, the patent offices and the courts. The Commission observed that the proceedings in Norway had disclosed the existence of another Luxembourg publication, the '*liste luxembourgeoise des prix pharmaceutiques*' (the Luxembourg list of pharmaceutical prices), of which AZ had submitted a page containing a reference to Losec, in respect of which the date of 16 January 1988 was stated. The results of the enquiries made by the complainants with the Luxembourg authorities, which were submitted to the Norwegian courts, also showed that the Luxembourg list was not, at the material time (March 1988), an official publication, since its purpose was solely to inform doctors, pharmacists and pharmaceutical undertakings of products authorised for sale, irrespective of whether they had received price approval (see recitals 239, 240 and 734 of the contested decision).

585 As regards the proceedings before the Helsinki District Court, the Commission observed that AZ had made, on 25 February 1999, submissions identical to those lodged before the District Court of Oslo on 12 February 1999. It then noted that on 30 June 1999 AZ had reiterated that it had not been possible to market Losec in Luxembourg before 21 March 1988 and that it had not been marketed in an EEA country. AZ had also stated that both the plaintiff in those proceedings, Merck Generics Oy, and itself had tried to ascertain the publication's legal status in Luxembourg and to find a full version of the Luxembourg list, and that the 'situation in Luxembourg was quite unclear'. The Commission stated once again that AZ had made those representations despite the information in its possession, from which it was unequivocally clear that the first sales of Losec had taken place before 21 March 1988 (recitals 244, 245 and 735 of the contested decision).

586 As was already held earlier, the Court rejects the applicants' argument that AZ could reasonably rely on the Luxembourg list for the purposes of claiming that the effective marketing authorisation date was 21 March 1988. AZ's defence before the District Court of Oslo was clearly no longer tenable, in particular after the Luxembourg authorities confirmed that the Luxembourg list did not constitute an official publication. Even after the existence of the 'liste luxembourgeoise des prix pharmaceutiques' had been disclosed and AZ had itself produced a page from that publication, mentioning Losec and the date of 16 January 1988, AZ continued to maintain that no list comprising Losec with an indication of its price had been published before 21 March 1988 and that the Luxembourg list also comprised information about the price of Losec (recital 241 of the contested decision).

587 In the light of all the information in its possession, which — contrary to what the applicants claim — was consistent in showing that Losec had been launched before 21 March 1988, the Court considers that the Commission was right to find, in essence,

that AZ could not reasonably rely on the Luxembourg list (see also, in this respect, recitals 236 and 237, and recitals 733 and 734 of the contested decision).

588 It is therefore necessary to reject the applicants' argument that AZ's admission, in the context of the reference for a preliminary ruling before the Court of Justice, that it did not have the complete Luxembourg list or the part of it showing the price of Losec, demonstrates that there was no intention to mislead the public authorities. Moreover, any claim to the contrary by it before the Court of Justice would have compelled it to produce that entire list or any other relevant part of it, which it was unable to do. It therefore had no option, in any event, but to admit that it did not possess those documents.

589 That assessment applies just as much as regards AZ's representations before the Helsinki District Court. It is clear that AZ adopted the same course of conduct before that court of maintaining that it had not been possible to market Losec before 21 March 1988, even though it possessed consistent information showing that that product had been launched prior to that date and that the Luxembourg list was not relevant to the issue whether that product could be marketed legally.

590 The Court therefore finds that, as was the case before the German courts, AZ merely attempted, before the Norwegian and Finnish courts, to defend the validity of the SPCs granted in those countries on the basis of its misleading representations indicating 21 March 1988 as date of first authorisation in the EEA.

Conclusion on the first abuse of a dominant position

591 It follows from the examination of the two stages of the first abuse that AZ's conduct consisted, first of all, in notifying to the patent offices in Germany, Belgium, Denmark, Ireland, Luxembourg, the Netherlands and the United Kingdom the date of 'March 1988' as date of the first marketing authorisation in the Community, without informing them either of the basis on which that date had allegedly been chosen, namely the alternative interpretation that AZ wished to adopt of the concept of 'authorisation to place the product on the market' used in Regulation No 1768/92, or of the existence of the marketing authorisation issued in France on 15 April 1987. The Commission was right to consider that that first notification to the patent offices was misleading, in view of its overall presentation, which gave the impression that 'March 1988' related to the date of issue of the first technical marketing authorisation in the Community.

592 On the basis of that first communication, and following a clarification regarding the exact date to which 'March 1988' was referring, an SPC was granted in Germany on 10 November 1993, with an expiry date of 21 March 2003.

593 AZ's conduct consisted, next, in failing to disclose the date of 15 April 1987, relating to the French marketing authorisation, following requests for clarifications from the patent offices regarding 'March 1988'. That absence of disclosure prompted the Belgian, Luxemburg and Dutch patent offices to consider that the date of 16 November 1987, corresponding to the issue of the technical marketing authorisation in Luxembourg, had to be taken into account as date of the first marketing authorisation in the Community. They therefore granted SPCs on the basis of that date.

594 It must be observed in this respect that AZ did not subsequently intervene at those patent offices in order to rectify the SPCs, even though (i) AZ's internal documents show that it was aware of their incorrect basis and (ii) the Dutch patent attorney had expressly suggested to it that it might so intervene.

595 The Court would point out, however, that, following the questions put by the United Kingdom and Irish patent offices, AZ disclosed the existence of the French technical marketing authorisation of 15 April 1987. Because of the contact between the Danish patent office and the United Kingdom patent office, AZ found it necessary to withdraw its SPC application in Denmark.

596 AZ none the less continued to make misleading representations for the purposes of obtaining SPCs on the basis of the date of 21 March 1988 before the patent offices of the EEA countries (Austria, Finland and Norway). Those representations prompted those patent offices to issue SPCs on the basis of the date of 21 March 1988.

597 Lastly, AZ's conduct consisted in defending the validity of the SPCs which had been granted on the basis of its misleading representations before the German, Finnish and Norwegian courts.

598 It follows from all the foregoing that AZ adopted a consistent and linear course of conduct, characterised by the communication to the patent offices of misleading representations for the purposes of obtaining the issue of SPCs to which it was not entitled (Germany, Finland, Denmark and Norway), or to which it was entitled for a shorter period (Austria, Belgium, Luxembourg, Ireland and the Netherlands).

599 The numerous items of evidence in the documents before the Court and the extent of the conduct in question, which lasted from June 1993, when the SPC applications were filed before the national patent offices (recital 185 of the contested decision), to June 1999, the time of AZ's defence before the Helsinki District Court of the validity of the SPC granted in Finland, and which was implemented more or less consistently and with varying degrees of success in nine Member States of the Community and of the EEA, permits the conclusion that the Commission was right to find that AZ had deliberately tried to mislead the patent offices.

600 In view of all the documentary evidence on which the Commission relies, the Court finds that those considerations cannot be called in question by the statements submitted by the applicants for the purposes, inter alia, of defending AZ's good faith. Apart from the fact that those statements tend, in certain respects, to corroborate the correctness of the contested decision, they do not make it possible, in any event, to discount the significant quantity of documentary evidence and body of facts found, which, assessed in their entirety, conclusively support the Commission's findings.

601 In the light of the examination of all the factual elements carried out in this plea, a response must be given, to the extent still necessary, to the applicants' arguments put forward in the first plea which seek to dispute the existence of an abuse of a dominant position in Germany, Belgium, Denmark, Norway, the Netherlands and the United Kingdom on the basis that the misleading representations did not produce any effects.

602 As regards, first of all, the degree of success of the anticompetitive practices identified, the Court would point out that the fact that those misleading representations did not enable AZ to obtain SPCs in Denmark or, on the basis of a date which did not correspond to that of the first marketing authorisation granted in the Community, in the United Kingdom, does not mean that its conduct in those countries was not

an abuse, since it has been established that those representations were very likely to result in the issue of SPCs.

603 It follows from the examination of this plea and the documentary evidence submitted by the parties that, although AZ displayed a more transparent attitude before the United Kingdom patent office, to which it openly disclosed its alternative interpretation of the concept of marketing authorisation and the existence of the French technical marketing authorisation of 15 April 1987, the initial SPC application was objectively misleading and was designed to obtain an SPC on the basis of a date which did not correspond to the first marketing authorisation granted in the Community (see paragraphs 548 and 549 above).

604 As regards Denmark, it is also apparent from the documentary evidence submitted to the Court that AZ withdrew its SPC application there in order to avoid a rejection decision by the patent office, which would create a precedent which might prejudice its chances of obtaining an SPC in Germany, a country which, like Denmark, did not grant SPCs in respect of products which had a first technical marketing authorisation prior to 1 January 1988 in the Community (see paragraph 554 above). However, as the Commission observes, the ability of the misleading representation to the Danish patent office to result in the issue of an unlawful SPC is confirmed by the fact that SPCs were issued by the patent offices in Germany, Belgium, Norway and the Netherlands on the basis of the misleading representations that AZ submitted to them.

605 Similarly, the fact that, in Germany, the SPC was revoked in June 1997, prior to the expiry of the basic patent, as a result of a legal action brought by Ratiopharm, a generic manufacturer, does not affect the legal classification of the conduct of AZ, which obtained an SPC in those countries on the basis of its misleading representations. That SPC was destined to continue after the expiry of the basic patent and to extend

the exclusivity conferred by that patent. If no proceedings had been brought by competitors, that SPC would have thus produced significant anticompetitive effects, assuming that the mere existence of an SPC were not already, in itself, able to produce such effects even prior to the expiry of the basic patent.

606 Furthermore, the fact that the additional period of supplementary protection obtained in Belgium and the Netherlands on the basis of the misleading representations extends from April 2002 to September and October 2002 respectively, that is after AZ's dominant position had ceased in those Member States, does not, for the reasons set out in paragraph 379 above, affect the classification of the conduct in question as an abuse of a dominant position.

607 With regard, lastly, to Norway, as was observed in paragraphs 559 and 596 above, it is common ground that AZ was granted an SPC by the Norwegian patent office on 14 April 1997 on the basis of the date of 21 March 1988 (see also recital 234 of the contested decision). That SPC was revoked on 29 June 1999, as a result of a legal action brought by a competitor. Consequently, even assuming that AZ held a formulation patent which still prevented the market entry of generic products on the day that the SPC was revoked, AZ's misleading representations enabled the issue of an SPC to which it was not entitled. Those misleading representations were objectively of such a nature as to restrict competition and constitute, for that reason, an abuse of a dominant position. For the sake of completeness, it is apparent from both recital 16 of the contested decision and the replies of the parties to questions put by the Court that the ability of a formulation patent to confer exclusivity on a product is not equivalent, in any event, to that of a substance patent, since an active substance can be incorporated into different formulations.

608 Lastly, the Court would point out that it follows from the examination of the second plea that the misleading representations made by AZ for the purposes of obtaining SPCs to which it was not entitled, or to which it was entitled for a lesser period, constituted a practice based exclusively on methods falling outside the scope of competition on the merits. Such conduct solely serves to keep manufacturers of generic products, wrongfully, away from the market by means of the acquisition of SPCs in a manner contrary to the regulatory framework establishing SPCs.

609 It follows from all the foregoing that the Commission did not err in concluding that AZ had abused its dominant position within the meaning of Article 82 EC in Germany, Belgium, Denmark, the Netherlands and the United Kingdom and within the meaning of Article 54 of the EEA Agreement in Norway.

610 It is therefore necessary to reject all the second plea relating to the first abuse of a dominant position.

611 However, the contested decision contains an error in so far as, in its recital 774, it was found that, in Germany, Belgium, Denmark, the Netherlands and the United Kingdom, that abuse had commenced on 7 June 1993, when AZ transmitted its instructions to the patent attorneys. As the Court held in paragraphs 370 to 372 above, that abuse started when the SPC applications were transmitted to the national patent offices.

612 Consequently, as found in paragraph 381 above, the Court finds, in the light of recital 185 of the contested decision, that the first abuse of a dominant position started on 30 June 1993 at the latest.

613 On the other hand, the applicants have failed to show that the Commission's other conclusions in recital 774 of the contested decision are vitiated by error inasmuch as they find that the abuse ended in Germany at the end of 1997, in Belgium and the Netherlands at the end of 2000, in Denmark on 30 November 1994 and in the United Kingdom on 16 June 1994. Similarly, the applicants have failed to demonstrate the existence of errors which would vitiate the Commission's view that, in Norway, the abuse occurred between 21 December 1994 and the end of 2000.

D — *The second abuse of a dominant position: selective deregistrations of marketing authorisations for Losec capsules*

1. *Regulatory framework and conduct objected to*

614 In its version in force at the material time, in 1998, Directive 65/65, as amended in particular by Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36), and Council Directive 93/39/EEC of 14 June 1993, also amending Directives 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22), provides, in Article 3, first paragraph, that '[n]o medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State'.

615 The third paragraph of Article 4 of that directive specifies the information and documents that the person responsible for placing the product on the market must submit for the purposes of obtaining a marketing authorisation. Point 8 of the third paragraph of Article 4 of Directive 65/65 is worded as follows:

'8. Results of:

— physico-chemical, biological or microbiological tests,

— pharmacological and toxicological tests;

— clinical trials.

However, and without prejudice to the law relating to the protection of industrial and commercial property:

(a) The applicant shall not be required to provide the results of pharmacological and toxicological tests or the results of clinical trials if he can demonstrate:

...

(ii) or by detailed references to published scientific literature presented in accordance with the second paragraph of Article 1 of Directive 75/318/EEC that the constituent or constituents of the proprietary medicinal product have a well established medicinal use, with recognised efficacy and an acceptable level of safety;

(iii) or that the proprietary medicinal product is essentially similar to a product which has been authorised within the Community, in accordance with Community provisions in force, for not less than six years and is marketed in the Member State for which the application is made; this period shall be extended to 10 years in the case of high-technology medicinal products within the meaning of Part A in the Annex to Directive 87/22/EEC or of a medicinal product within the meaning of Part B in the Annex to that Directive for which the procedure laid down in Article 2 thereof has been followed; furthermore, a Member State may also extend this period to 10 years by a single Decision covering all the products marketed on its territory where it considers this necessary in the interest of public health. Member States are at liberty not to apply the abovementioned six-year period beyond the date of expiry of a patent protecting the original product.

…'

616 Article 10(1) of Directive 65/65 provides inter alia that an authorisation is valid for five years and renewable for five-year periods on application by the holder at least three months before its expiry.

617 In its judgment in Case C-223/01 *AstraZeneca* [2003] ECR I-11809, paragraphs 49 and 58, the Court of Justice held that, in order for an application for marketing authorisation of a generic medicinal product to be dealt with by way of the abridged procedure provided for in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65, it was necessary and sufficient that the marketing authorisation of the reference medicinal product was in force in the Member State concerned on the date that that application was filed.

618 In its version in force at the material time, Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1975 L 147, p. 13), as amended, inter alia, by Directive 93/39, established, in its Chapter Va, a pharmacovigilance system for the purposes of obtaining information about adverse reactions to medicinal products authorised in the Community. Articles 29c and 29d of Directive 75/319 thus imposed on the undertaking responsible for placing the medicinal product on the market pharmacovigilance obligations, consisting in the follow up of adverse reactions produced by a medicinal product and the submission to the competent authorities at regular intervals of records accompanied by scientific evaluations.

619 In the present case, the conduct of AZ objected to by the Commission consists in the submission of requests for deregistration of the marketing authorisations for Losec capsules in Denmark, Norway and Sweden, in combination with the substitution, on the market, of Losec MUPS tablets for Losec capsules, that is to say the launch on the market of Losec MUPS tablets and the withdrawal from the market of Losec capsules (recital 860 of the contested decision).

2. *First plea in law, alleging an error of law*

(a) Arguments of the applicants

Regulatory and factual framework

620 The applicants state that, although the Commission stated in recital 830 of the contested decision that it did not take issue with AZ's interpretation of Community pharmaceutical law, the Commission's interpretation of the regulatory framework, set out in recitals 255 to 264 of the contested decision, is not consistent with that of AZ. The applicants set out, in this respect, the content of the relevant regulatory framework, as it appears from Articles 3 and 4 and Article 10(1) of Directive 65/65, and from Chapter Va of Directive 75/319.

621 The applicants claim that the purpose of the introduction by Directive 87/21 of the abridged procedure referred to in point 8(a)(i) to (iii) of the third paragraph of Article 4 of Directive 65/65 was to create a limited exception to the general principle that the original applicant should be exclusively entitled to the benefit of its own data. That exception was not intended to facilitate the authorisation of generic products, but to protect innovation until a reasonable time had elapsed, during which the company concerned could recoup its investment, after which cross-referral to information already provided would be allowed in order to avoid unnecessary repetition of tests on humans or animals.

622 They submit that, as the Commission acknowledged in recitals 832 and 833 of the contested decision and argued in the proceedings in Case C-94/98 *Rhône-Poulenc Rorer and May & Baker* [1999] ECR I-8789, the holder of a marketing authorisation is entitled to withdraw it as it pleases, or to let it expire, without being obliged to provide a reason in this respect and without concerning itself with the effect of that decision on generic manufacturers or parallel importers.

623 The applicants state that, in Denmark, AZ obtained a marketing authorisation for Losec capsules in 1989, and for Losec MUPS tablets on 22 September 1997. On 23 February 1998, the complainants applied for a marketing authorisation under the abridged procedure for a generic version of Losec capsules. On 6 April 1998, the marketing authorisation for Losec capsules was withdrawn at the request of AZ. On 30 September 1998, the complainants were granted a marketing authorisation for a generic version of Losec capsules. AZ challenged the grant of the marketing authorisation before the Danish courts, on the ground that, at the time of that grant, there was no marketing authorisation in force for the reference product in the Member State concerned. In answer to a question submitted in a reference for a preliminary ruling, the Court of Justice held that the marketing authorisation of the reference medicinal product had to be in force in the Member State concerned at the date of the application (*AstraZeneca*, paragraph 617 above, paragraph 58).

The Commission's legal analysis

624 The applicants submit that in the contested decision there is a lack of legal analysis of the abuse of a dominant position identified. They submit that the Commission's legal

reasoning is to be found solely in recital 820 of that decision, in which it considered that an undertaking in a dominant position which has a specific entitlement, such as a marketing authorisation, has a duty to make reasonable use of it and not to use it with the clear purpose of excluding competitors. However, in the applicants' view, the case-law relied on by the Commission in order to make that argument concerned different situations.

625 As regards, first, *Compagnie maritime belge transports and Others* v *Commission*, paragraph 242 above, the company in a dominant position entered into an agreement that granted it an exclusive right and then took steps to ensure that it enjoyed the exclusivity provided for by that agreement. The circumstances are different in the present case, since AZ did not enter into an agreement in order to obtain exclusivity in the market. AZ was required to obtain a marketing authorisation in order to place Losec capsules on the market, which did not confer any exclusivity on it in the market. The marketing authorisation did not prevent competition from generics or parallel imports, or the placing of rival PPIs on the Danish, Norwegian and Swedish markets. The applicants add that that case did not concern property rights of any kind, and that the finding of abuse of a dominant position did not involve the imposition of positive obligations on the abusers, whereas, in this case, maintaining the marketing authorisations would impose continuing pharmacovigilance obligations.

626 The applicants maintain, next, that the circumstances of the present case are different from those in Case 226/84 *British Leyland* v *Commission* [1986] ECR 3263, in so far as, in the present case, the holder of a marketing authorisation is subject to significant obligations relating to 'updating' and pharmacovigilance while that authorisation remains in force. In addition, AZ did not enjoy an administrative monopoly as a result of obtaining an authorisation for Losec capsules. Moreover, that authorisation was not indispensable for competing products to be able to enter the market and its

withdrawal did not have any automatic effect on existing authorisations for generics and on approvals for parallel imports. The applicants add that another distinguishing feature lies in the fact that, in the present case, AZ did not encourage the development either of trade in generic copies of Losec or of parallel imports, whereas in the proceedings in *British Leyland* v *Commission*, British Leyland had allowed a trade in left-hand-drive Metros to develop. Finally, there were no proprietary rights in commercially confidential information at stake in that case, in contrast to the present case.

627 In *Hilti* v *Commission*, paragraph 242 above, the Court found that Hilti had abused its dominant position because it was not prepared to grant licences of right on a voluntary basis. The abuse of the dominant position also consisted in demanding fees six times higher than the amount ultimately set by the relevant public body, thereby needlessly protracting the proceedings for the grant of licences of right. However, in the applicants' submission, in the present case, the marketing authorisation did not confer on AZ any exclusive right and it was entitled to request the withdrawal of its marketing authorisation at any time. In addition, AZ was subject to a number of significant positive obligations in relation to 'updating' and pharmacovigilance.

628 The applicants further observe that, in proceedings before the Court of Justice relating to the issue of whether or not the holder of a marketing authorisation was entitled to request its withdrawal, the Commission has consistently submitted that the concept of a compulsory licence was unknown in Community pharmaceutical law. The applicants also maintain that the abovementioned judgments, on which the Commission relies, do not deal with the case made by AZ and that the Commission has failed to take account of the case-law concerning 'refusal to supply' and 'essential facilities'. In the applicants' submission, even if the facts as found by the Commission are correct, AZ's conduct cannot constitute an abuse of a dominant position in the light of the case-law on the exercise of intellectual property rights and 'essential facilities'. They

draw attention, in that regard, to the case-law resulting from the judgments in *Magill* and *IMS Health*, paragraph 229 above, Case C-7/97 *Bronner* [1998] ECR I-7791 and Case T-504/93 *Tiercé Ladbroke* v *Commission* [1997] ECR II-923, paragraph 131.

629 The applicants claim that the data packages that AZ submitted in order to obtain marketing authorisations for Losec capsules pursuant to Directive 65/65 contained commercially confidential information which was entitled to legal protection. However, point 8(a)(i) and (iii) of the third paragraph of Article 4 of Directive 65/65 created an exception to the confidentiality of data to which AZ was entitled, in so far as it excused a subsequent applicant from being required to provide its own data package. The applicants observe that it is common ground that AZ was entitled to request the withdrawal of its marketing authorisation for Losec capsules and that the effect of the case-law is that the abridged procedure in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 is inapplicable after withdrawal of the marketing authorisation of the reference medicinal product. After that withdrawal, AZ therefore retained the right to enforce the confidential nature of its data package.

630 In that regard, the applicants dispute the Commission's assertion that, once the period of 6 to 10 years of data exclusivity has expired, a producer of generics does not need to go through the entire marketing authorisation procedure, since the national authority can rely on the data available to it under the original authorisation. That interpretation of Directive 65/65 is irreconcilable with the judgment in *AstraZeneca*, paragraph 617 above (paragraphs 48 and 50), the effect of which is that a national authority may rely on the data from the original application for authorisation only if that authorisation is still in force at the time of the application relating to the generic product. The applicants add that the original applicant has a property right in the data packages submitted to the national authorities, on which point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 constitutes a limited restriction, in that it creates an exception to the original applicant's right to control the use of those rights (Case C-368/96 *Generics (UK) and Others* [1998] ECR I-7967, paragraphs 77 to 87,

and the Opinion of Advocate General Ruiz-Jarabo Colomer in that case, point 68). Apart from that exception, the original applicant retains the right to prohibit the unauthorised use of its confidential information by a national authority or a third party.

631 In the applicants' submission, those considerations undermine the Commission's argument that the case-law on 'essential facilities' is inapplicable in this case as a result of the fact that AZ's property rights have expired, so that it no longer enjoys property rights. In reply to the Commission's argument based on Case T-65/98 *Van den Bergh Foods* v *Commission* [2003] ECR II-4653, the applicants maintain that, in the present case, there is a de facto transfer of assets, in the sense that generic manufacturers could benefit from the confidential information without AZ's consent, since the latter would not even be able to require payment for use of that information. In their view, the fact that, in recital 820 of the contested decision, the Commission fails to recognise the property right enjoyed by AZ warrants the annulment of the contested decision in that respect.

632 In the alternative, the applicants claim that access to AZ's data package was not indispensable for the access of other products to the market. In that regard, they note that a number of competing PPIs entered the market during the relevant period. Moreover, the withdrawal of the marketing authorisation obtained by AZ did not prevent the emergence of a new product for which there was consumer demand. By definition, the abridged procedure under point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 is available only to products that are essentially similar to AZ's Losec capsules. The applicants point out that the withdrawal of the marketing authorisation was justified in the light of the fact that AZ was subject to ongoing 'updating' and pharmacovigilance obligations in respect of an authorisation for which it had no

further commercial use. In any event, the withdrawal of the marketing authorisation for Losec capsules did not exclude all competition on the relevant market, given that AZ faced competition from generics, parallel imports and rival PPIs.

633 The applicants also dispute the relevance of the fact that AZ asked for the withdrawal of its authorisations rather than waiting for them to expire. The practical effect of withdrawal of an authorisation is the same as that of its expiry, in that the authorisation holder regains control of its confidential data package. They therefore reject the Commission's contention that the *Magill* case-law, paragraph 229 above, is inapplicable to the present case because what is involved here is not a refusal to assist competitors, but active behaviour on the part of AZ to prevent competitors from entering the market.

No abuse of a dominant position in any event

634 The applicants deny having conceded that requesting withdrawal of the marketing authorisations for Losec capsules was part of a strategy in which a key goal was to prevent, or at least delay, the entry of generic omeprazole capsules onto the markets concerned and to prevent parallel imports of Losec capsules into those markets.

635 They submit that even a company in a dominant position should not be required to maintain its marketing authorisations in force so that it is easier for generics and parallel imports to come onto the market and compete with it. That is particularly the case where the company no longer has a commercial interest in selling the product to which the marketing authorisation relates and, therefore, has no further interest in maintaining that authorisation in force in a situation where such maintenance would impose upon it continuing 'updating' and pharmacovigilance obligations.

636 In that regard, the applicants dispute the Commission's assertion that compliance with pharmacovigilance obligations in one Member State can be transposed to another Member State; that is because of the nature of the obligations imposed and because of the diversity of views of the national authorities as regards the implementation of those obligations.

637 Furthermore, during the administrative procedure, AZ submitted to the Commission reports produced by a law firm and by Professor S., which demonstrate that the published literature exemption would have been available to potential competitors of AZ by early 1998. In that regard, the applicants dispute the Commission's arguments set out in recitals 851 and 852 of the contested decision. They state that, contrary to what the Commission claims, it is not true that the published literature exemption is seldom applied. Moreover, that circumstance, just as the fact that the Commission was not aware of any such applications having been made in relation to omeprazole, is in any event irrelevant, since AZ has demonstrated that that exemption was available in relation to Losec and the Commission has not produced any evidence to the contrary. For that same reason, the Commission cannot assert that a generic application in respect of omeprazole during the first part of 1998 would have constituted 'very much a borderline case'. Nor, in the applicants' view, does the Commission's assertion that

the published literature exemption involves complex assessment rebut the evidence produced by AZ.

638 The applicants add that the requirement, for the purpose of applying the published literature exemption, of at least a decade of use was only introduced by 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 1999 L 243, p. 9). In any event, by 1998 omeprazole had been in use for more than a decade.

639 The applicants also argue that the Commission's assertion in recital 853 of the contested decision that AZ's internal documents made no reference to the availability of the published literature exemption is irrelevant, since they have in any event demonstrated that fact. As regards the assertion set out in recital 854 of the contested decision, the applicants observe that the Commission does not give any indication as to the length of the delays suffered by generic manufacturers as a result of the withdrawal of the marketing authorisations. The Commission's admission of its ignorance as to the length of that delay thus renders its argument hypothetical. The applicants also add that any delay arising from the assessment of an application for marketing authorisation cannot be open-ended, since the applicable legislation requires assessment under point 8(a) of the third paragraph of Article 4 of Directive 65/65 to be completed within 120 days or, in exceptional cases, within 210 days (Article 7 of that directive). Since the assessment of the delay suffered in relation to making an application under the published literature exemption would have to take account of those time-limits, the maximum hypothetical delay could only be a few months at the most, which cannot justify the finding of an abuse lasting several years.

640 Finally, the applicants submit that it follows from the judgment in *ITT Promedia* v *Commission*, paragraph 311 above (paragraph 56), that AZ's challenging of the right of its competitors to benefit from the abridged procedure under Directive 65/65 in order to protect itself from parallel imports and generics is not conduct that can be characterised as abusive. They state that, in recital 502 of the statement of objections, the Commission accepted that AZ's conduct to protect its marketing authorisations was not objectionable.

(b) Arguments of the Commission

Regulatory and factual framework

641 As a preliminary point, the Commission states that recital 830 of the contested decision does not mean that it agrees with AZ's presentation and interpretation of Directive 65/65. That recital simply stands for the proposition that AZ's interpretation of Community pharmaceutical law is not part of the second abuse of a dominant position and that the second abuse does not depend on the correct interpretation of the regulatory framework.

642 The Commission argues that point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 strikes a balance between the interests of innovative firms and those of producers of generics by introducing an abridged authorisation procedure for medicinal products that are essentially similar to a product already authorised, while allowing for a period of 6 or 10 years of data exclusivity, which starts to run from the grant of the first marketing authorisation in the Community, during which the

abridged procedure is not available to generic products, thereby allowing the original applicant to benefit from the results of the pharmacological and toxicological tests and clinical trials placed in the file concerning the product. The Commission refers, in that regard, to the *AstraZeneca* judgment, paragraph 617 above (paragraphs 42 to 44 and 52).

643 The Commission states that the legislature was aware of the danger that the period of data exclusivity could result in an artificial prolongation of the effects of a patent, and point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 sought to address this concern by preserving the liberty of Member States 'not to apply the … six-year period beyond the date of expiry of [the] patent'. The Commission disputes that the legislature envisaged that provision as an exception to, or encroachment on, property rights in commercially confidential information, as claimed by the applicants. The applicants' approach would lead to the conclusion that the data contained in the file on the original medicinal product could never be relied on by the pharmaceutical authorities either before or after the 6- or 10-year period. Moreover, the use by a pharmaceutical authority of the pharmacological, toxicological or clinical references in the file on an original medicinal product is not such as to interfere with the confidentiality of certain commercial information, since the latter is never made public or disclosed to the second applicant.

644 The Commission rejects the applicants' argument that generic competition is somehow 'parasitic'. In its view, the rewards for innovation are primarily ensured by the systems of patents and SPCs, which confer on the producer of an original product a temporary monopoly in the commercial exploitation of its invention. The threat of the entry of generic products forces companies to innovate so as to be rewarded in the form of patents, SPCs and data exclusivity.

645 AZ's second abuse of a dominant position undermined that system. AZ withdrew the marketing authorisation for Losec capsules so that, despite the expiry of the 6- or 10-year period of data exclusivity and the impending expiry of the patent relating to omeprazole, the abridged registration route would not be available to producers of generic omeprazole. In so doing, AZ sought to maintain artificially its market exclusivity by seeking to nullify the right not to provide data contained in the files of initial applications which the regulatory framework confers on the second and subsequent applicants when the period of data exclusivity ends.

646 The Commission makes clear that, in the contested decision, it does not state that the introduction of a new product formulation (tablets) and the decision to stop marketing Losec capsules in Denmark, Norway and Sweden, were abusive in themselves, considered singly or in combination. The introduction of Losec tablets and the withdrawal of capsules are necessary but not sufficient conditions for the abuse of a dominant position to be established. The abuse became apparent when that switch operation was combined with the requests for deregistration. The Commission therefore stresses that, as is apparent from Article 1(2) of the contested decision, the abuse consists of three elements, namely the requests for deregistration in Denmark, Norway and Sweden, combined with the launch of Losec MUPS tablets and the withdrawal of Losec capsules in those three countries. In the light of that analysis, the Commission challenges what it considers to be an attempt on the part of the applicants to dissociate the elements of the abuse of a dominant position, and in particular the requests for deregistration of the marketing authorisations. Moreover, in the contested decision, the Commission does not call in question AZ's interpretation of Directive 65/65 or to its having brought actions for the protection of its patents or its marketing authorisations.

The Commission's legal analysis

647 The Commission disputes, first, that the legal reasoning in the contested decision is limited to recital 820. It refers, in that regard, to recitals 325 to 328, 817 and 818, and 788 to 847 of the contested decision.

648 Secondly, the Commission recalls that the case-law has found it abusive for a dominant company to procure advantages on the market through the exploitation of government procedures or regulation. It contends that the case in *British Leyland* v *Commission*, paragraph 626 above, presents significant similarities to the second abuse of a dominant position found in the contested decision. The applicants cannot maintain that the approach adopted in that judgment is not applicable in the present case on the ground that the validity of the marketing authorisation for Losec capsules was not indispensable for competing products to be able to enter the market. The judgment in *British Leyland* v *Commission*, paragraph 626 above, does not lay down any conditions in that regard. That judgment does not suggest that the product in question did not face any competition or was in a market of its own. On the contrary, whether with or without parallel imports, the company concerned faced competition from dozens of other car manufacturers. The Commission also observes that that judgment concerned conduct which goes beyond that at issue in the present case, in that it relates to British Leyland's inaction upon the expiry of a national type approval certificate, whereas the present case concerns positive steps to procure deregistration.

649 In reply to the applicants' observations relating to the fact that, in contrast to AZ, British Leyland allowed parallel trade to develop, the Commission adds that an abuse of a dominant position resulting in eviction of competitors from the market is no less an abuse than an abuse preventing competitors from entering the market. It disputes, in any case, that parallel trade in Losec in the three countries concerned did not develop

before deregistration was requested (tables 25, 28 and 29 in the Annex to the contested decision). Moreover, regarding the applicants' argument that the British Leyland case did not involve any intellectual property rights in commercially confidential information, the Commission points out that obtaining type approval for a vehicle under Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers (OJ, English Special Edition 1970 (I), p. 96) also requires the provision of expensive and technically complex information through a time-consuming procedure. Parallel importers could nevertheless be exempted from that requirement, inasmuch as the authorities already had a technical file the contents of which they were careful not to disclose. The confidentiality rights which AZ has are therefore not different in any respect from those of British Leyland.

650 As regards the judgment in *Hilti* v *Commission*, paragraph 242 above, the Commission contends that it also concerns the instrumentalisation of a regulatory scheme by a dominant company in order to gain an advantage on the market, since that company exploited the procedural arrangements for the granting of licences in the exercise of its right to negotiate fees. Moreover, the case which gave rise to the judgments of the Court of Justice and the Court of First Instance in *Compagnie maritime belge transports and Others* v *Commission*, paragraphs 329 and 242 above, is also relevant, in that it concerns a dominant company which relied on a legal entitlement derived from a contract in order to exclude competitors.

651 As regards the case-law on 'essential facilities', the Commission submits that it is not applicable in this case. The judgments in *Magill* and *IMS Health*, paragraph 229 above, and *Tiercé Ladbroke* v *Commission and Bronner*, paragraph 628 above, deal with the refusal by a dominant company to deal with other companies and to allow them, through contractual means, to utilise an asset in respect of which the legal system in principle gives an exclusive right. As the applicants themselves agree, the marketing authorisation did not confer on AZ any exclusive right apart from the 6- to 10-year exclusivity period for the data and information submitted to the authorities. However, that period had expired in this case. The Commission contends that, once the

period of exclusivity has expired, the second applicant is entitled not to provide data which are known to the authorities since they are in the file of the initial application. However, AZ sought to nullify that right.

652 The Commission observes, furthermore, that the case-law on 'essential facilities' is not relevant to situations which do not involve any question for the dominant company of transferring an asset or concluding contracts with persons which it has not selected (order in Case C-552/03 P *Unilever Bestfoods* v *Commission* [2006] ECR I-9091, and judgment in *Van den Bergh Foods* v *Commission*, paragraph 631 above, paragraph 161). The Commission disputes that allowing the pharmaceutical authorities to refer to the information available in the original file, but without disclosing it to competitors and third parties, can be considered to entail a transfer of an asset. In its view, the present case does not involve any intellectual property rights and does not concern a passive refusal to assist competitors by dealing with them, but active behaviour designed to prevent competitors from entering the market. In this case, the dominant company actively sought to exclude its competitors from the market at a point in time when its proprietary rights and exclusive rights had expired, using the regulatory framework in such a way as to impede the system provided for in it, which allows the entry of generics when the exclusivity period for information filed with the medical authorities has expired.

653 With regard to the applicants' position that the distinction between positively deregistering marketing authorisations and allowing those authorisations to expire is irrelevant for the purposes of Article 82 EC, the Commission points out, first, that, in the contested decision, it does not address a hypothetical situation in which AZ would have let the marketing authorisations expire, since it only found an abuse of a dominant position in the factual circumstances of the present case. It nevertheless

adds that, in any event, the judgment in *British Leyland* v *Commission*, paragraph 626 above, provides support for the argument that allowing the authorisation to expire as part of an exclusionary strategy displaying the characteristics found in this case could constitute an abuse of a dominant position. That being the case, such an exclusionary strategy displaying all the characteristics found in this case apart from the active requests for deregistration is unlikely, given that an essential element of an exclusionary strategy, which must ensure the synchronisation of a number of factors, is the timing of termination of the authorisations, since the desired objective is to exclude generics and parallel trade. In that regard, the Commission observes that, in contrast to the request for deregistration, the expiry of an authorisation as a result of its non-renewal is a foreseeable event.

654 In addition, the Commission submits that the request for deregistration of the product in Denmark, Norway and Sweden with the aim of excluding competition was not an action within the scope of the substance of AZ's marketing authorisation, but quite the opposite, an attempt to maintain the exclusion of competitors when the company no longer enjoyed exclusive rights capable of excluding them. It refers, on this point, to recital 843 of the contested decision.

655 The Commission submits, in addition, that, although analogies may be drawn with the cases involving refusals to give access to assets covered by property rights, it is noteworthy that AZ's strategy consisted in preventing the introduction of a product which it no longer offered, despite the existence of a demand for that product; that constitutes a case of abuse of a dominant position identified in *Volvo*, paragraph 229 above, and in Case 53/87 *CIRCA and Maxicar* [1988] ECR 6039. In that regard, the Commission disputes that generic producers or parallel importers intended to duplicate the product already offered by AZ.

656 The Commission also rejects the applicants' argument relating to the lawfulness of the request for deregistration in pharmaceutical law. It points out in that regard that the illegality of abusive conduct under Article 82 EC is unrelated to its compliance or non-compliance with other legal regimes and that, in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law. Thus, in the contested decision, the Commission does not call into question the applicants' interpretation of pharmaceutical law. It finds only that it is contrary to Article 82 EC for a dominant company to request early deregistration of marketing authorisations for Losec capsules in the context of a general plan intended and likely to prevent the market entry of generics and parallel imports (recitals 817 to 820 of the contested decision).

The alleged absence of abuse of a dominant position in any event

657 The Commission denies, first, that the contested decision imposes a positive obligation on AZ to request the renewal of the marketing authorisation. The abuse consisted in requesting early deregistration of the marketing authorisation for omeprazole capsules in Sweden, Denmark and Norway, which must be distinguished from allowing the authorisation to lapse without requesting its renewal. It makes clear that the contested decision does not contain any finding to the effect that it would have been abusive for AZ not to request renewal of the marketing authorisation.

658 The Commission rejects the justification put forward by the applicants for requesting early deregistration of the marketing authorisations in the three countries concerned, namely the significant obligations incumbent on the holder of a marketing authorisation under the pharmacovigilance system. The Commission points out that AZ was

in any case required to comply with pharmacovigilance obligations as holder of the marketing authorisation for Losec capsules in Spain, Italy, Austria, France, Germany and the Netherlands and that it was therefore obliged to compile and transmit the same information to the authorities in the various Member States. The additional cost or bureaucratic burden which would have been faced by AZ if it had not made the requests for early deregistration would therefore have been negligible.

659 Moreover, pharmacovigilance satisfying the requirements of Directive 75/319 can ordinarily be guaranteed through cooperation with the national authorities of the other Member States by means of access to the documents and data produced by the manufacturer in respect of the old version of the product in the Member States in which that version is still marketed on the basis of a marketing authorisation still in force (Case C-172/00 *Ferring* [2002] ECR I-6891, paragraphs 36 and 38). The Commission observes, in addition, that AZ did not request deregistration of the marketing authorisations in Germany and the Netherlands, despite the capsules having been withdrawn from those markets. Furthermore, none of AZ's strategy documents mentioned the alleged burden of maintaining the marketing authorisations as a consideration to be taken into account in deciding on their deregistration.

660 Secondly, the Commission rejects the applicants' argument that AZ's competitors could have relied on the published literature in order to obtain a marketing authorisation, in accordance with the procedure referred to in point 8(a)(ii) of the third paragraph of Article 4 of Directive 65/65. The Commission submits that the applicants' analysis relies erroneously on the assumption, derived from the 'essential facilities' theory, that requests for deregistration cannot be abusive unless the abridged procedure was indispensable for generic products and parallel imports to enter the market. In its view, the fact that the regulations make available an alternative route to obtain registration does not legalise behaviour seeking to prevent competitors from using the abridged procedure intended by the legislature to facilitate access of

generics to the market. Moreover, the theoretical availability of an alternative route cannot be dissociated from the degree of uncertainty as to success and from the cost and time involved in attempting to obtain authorisation by such a route. As was set out in recitals 851 and 852 of the contested decision, that route has rarely been used in general and has never been used in connection with omeprazole. The prospects of success of that option were uncertain since the circumstances of this case constituted a 'borderline case' and would at any rate have entailed a time-consuming process. The Commission adds that the applicants do not dispute its findings set out in recitals 852 to 854 of the contested decision. It maintains that the considerable difficulties involved in that route are a relevant factor which must be taken into account, since they determine how exclusionary AZ's behaviour was likely to be in practice.

661 The Commission submits, in that regard, that the second abuse of a dominant position is a textbook example of behaviour raising competitors' costs. From that perspective, the fact that competitors were also able to follow the full marketing authorisation procedure does not take away the abusive character of the behaviour.

662 As regards the applicants' argument alleging that the Commission did not give any indication of the length of the delay in the market entry suffered by competing products as a result of using the published literature procedure, the Commission states that it is impossible to estimate it on account of the hypothetical nature of that alternative route. In any event, the delay caused to competitors using that possibility would have been considerable, amounting to several months, and not limited to the period of 210 days applicable at the material time (and not 120 days, as the applicants assert), since generic producers were informed about deregistration only after the event and only then had to start the process of researching, acquiring and compiling the data. Any delay caused to competitors represented further, very large sales revenue, given the volume of Losec sales which were involved. The Commission points out, in addition,

that the delay was relevant, since it served to extract higher reimbursement prices in the negotiations concerning esomeprazole, the following generation of PPIs that AZ intended to launch on the market.

663 The Commission observes that AZ itself considered that the use of the published literature procedure in respect of omeprazole was a negligible risk since it did not devote the slightest attention to it in its strategic analysis of how best to prevent entry of generics on the market (recital 853 of the contested decision).

664 In addition, the Commission challenges the relevance of Mr S.'s witness statement. It points out that there is no evidence that Mr S. made a detailed review of all the available literature and observes that he does not contest that filing an application based on 'well-established medicinal use' would take time. The Commission also refers to the Danish Agency's defence before the Danish courts, which argues that, in the procedure referred to in point 8(a)(ii) of the third paragraph of Article 4 of Directive 65/65, the applicant is required to establish the harmlessness and efficacy of the medicinal product by submitting bibliographical documentation based on an extensive and costly study, which cannot always necessarily be carried out.

665 The Commission argues, finally, that the second abuse of a dominant position does not relate to litigation in which AZ may have been involved to protect its marketing authorisations, but to the requests for deregistration of the marketing authorisations for Losec capsules filed in order to prevent or delay the market entry of generic omeprazole and parallel imports.

(c) Findings of the Court

Regulatory context

666 As a preliminary point, the Court observes that point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 established an abridged procedure aimed at enabling the manufacturers of medicinal products which are essentially similar to already authorised medicinal products to save the time and expense needed to gather data relating to the results of pharmacological and toxicological tests and of clinical trials and to avoid the repetition of tests on humans or animals where not absolutely necessary. However, in laying down the conditions which must be met in order to have recourse to that abridged procedure, the legislature also took account of the interests of innovating firms, in particular by making that procedure subject to the condition that the reference medicinal product has been authorised within the Community for 6 or 10 years (*Generics (UK) and Others*, paragraph 630 above, paragraphs 4, 72 and 73, and *AstraZeneca*, paragraph 617 above, paragraphs 42 and 43).

667 That provision therefore confers on the owner of an original proprietary medicinal product the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials placed in the file on that product for a period of 6 or 10 years from the grant of the first marketing authorisation in the Community. That period of exclusivity is the result of a balancing by the legislature of the interests of innovative firms, on the one hand, and those of manufacturers of essentially similar products, and of the interest in avoiding repetition of tests on humans or animals unless necessary, on the other (see, to that effect, *Generics (UK) and Others*, paragraph 630 above, paragraphs 81 and 83).

668 Consequently, after the expiry of a period of 6 or 10 years which starts to run from the grant of the first marketing authorisation, Directive 65/65 no longer confers on the owner of an original proprietary medicinal product the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials placed in the file. On the contrary, it allows that information to be taken into account by the national authorities for the purposes of granting marketing authorisations for essentially similar products under the abridged procedure provided for in point 8(a)(iii) of the third paragraph of Article 4 thereof.

669 However, the Court of Justice has held that the interest of safeguarding public health, which constitutes a primary purpose of Directive 65/65, required, in order for an application for marketing authorisation of a generic medicinal product to be dealt with by way of the abridged procedure provided for in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65, that the marketing authorisation of the reference medicinal product still be in force in the Member State concerned on the date that that application is lodged, and therefore precluded the continued availability of the abridged procedure after withdrawal of the marketing authorisation of the reference medicinal product (*AstraZeneca*, paragraph 617 above, paragraphs 49 to 54).

670 It follows from this that, for reasons relating to the safeguarding of public health, the deregistration of the marketing authorisation of the original proprietary medicinal product has the effect of preventing the applicant for a marketing authorisation in respect of an essentially similar medicinal product from being exempted, pursuant to point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65, from having to carry out pharmacological and toxicological tests and clinical trials for the purposes of demonstrating the harmlessness and efficacy of that product. Thus, in the present case, although the legislation no longer conferred on AZ the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials placed in the file, the strict public health protection requirements which have informed the Court of Justice's interpretation of Directive 65/65 enabled it to prevent or make more difficult, by the deregistration of its marketing authorisations, the acquisition, by way of the abridged procedure under point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65, of marketing authorisations for essentially

similar medicinal products, to which the manufacturers of generic products were none the less entitled.

The legal approach adopted by the Commission

671 Article 82 EC imposes on an undertaking in a dominant position, irrespective of the reasons for which it has such a dominant position, the special responsibility not to impair, by using methods other than those which come within the scope of competition on the merits, genuine undistorted competition in the common market (see, to that effect, *Nederlandsche Banden-Industrie-Michelin* v *Commission*, paragraph 30 above, paragraph 57; Case T-83/91 *Tetra Pak* v *Commission* [1994] ECR II-755, paragraph 114, and *Compagnie maritime belge transports and Others* v *Commission*, paragraph 242 above, paragraph 106, read in conjunction with *AKZO* v *Commission*, paragraph 243 above, paragraph 70).

672 Thus, whilst the fact that an undertaking is in a dominant position cannot deprive it of its entitlement to protect its own commercial interests when they are attacked (Case T-65/89 *BPB Industries and British Gypsum* v *Commission* [1993] ECR II-389, paragraph 69), it cannot use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of grounds relating to the defence of the legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.

673 The applicants' arguments (i) seeking to distinguish the present case from *Compagnie maritime belge transports and Others* v *Commission*, paragraph 242 above, *British Leyland* v *Commission*, paragraph 626 above, and *Hilti* v *Commission*, paragraph 242 above, and (ii) disputing the relevance of the Commission's reference to those judgments in recital 820 of the contested decision, are not capable of affecting that consideration.

674 In the present case, the Court observes, as the applicants claim, that the data relating to the results of the pharmacological and toxicological tests and of the clinical trials which AZ carried out for the purposes of obtaining an original marketing authorisation are the fruit of an investment that it had to make for the purposes of being able to market Losec capsules. Such an investment is characteristic of practices which come within the scope of competition on the merits and which are liable to benefit consumers. As was noted in paragraphs 666 to 668 above, Directive 65/65 has recognised the interest in protecting such investment by providing for a period of exclusivity during which only the owner of those data could use them. However, after the expiry of that period of exclusivity, point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 no longer confers on the owner of an original proprietary medicinal product the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials placed in the file and enables manufacturers of essentially similar medicinal products to benefit from the existence of those data in order to be granted a marketing authorisation under an abridged procedure.

675 In those circumstances, it must be stated that, after the expiry of the period of exclusivity referred to above, the conduct designed to prevent manufacturers of generic products from making use of their right to benefit from the results of the pharmacological and toxicological tests and clinical trials produced for the purposes of marketing the original product was not based in any way on the legitimate protection of an investment which came within the scope of competition on the merits, precisely

because, under Directive 65/65, AZ no longer had the exclusive right to make use of the results of those pharmacological and toxicological tests and clinical trials.

676 It appears, however, as will be examined in more detail in the second plea, that AZ's deregistration of the marketing authorisations was only such as to prevent applicants for marketing authorisations in respect of essentially similar medicinal products from being able to make use of the abridged procedure provided for in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 and, therefore, to obstruct or delay the market entry of generic products. Similarly, depending on the attitude adopted by the national authorities towards deregistration of the marketing authorisation for a product for reasons unrelated to public health, such deregistration may be such as to prevent parallel imports. The examination of the question whether, in view of the relevant factual and legal context in the present case, the Commission has demonstrated to the requisite legal standard that the deregistration of the marketing authorisations for Losec capsules was such as to exclude parallel imports of that product will be carried out in the examination of the second plea.

677 Furthermore, the fact, relied on by the applicants, that AZ was entitled to request the withdrawal of its marketing authorisations for Losec capsules in no way causes that conduct to escape the prohibition laid down in Article 82 EC. As the Commission observes, the illegality of abusive conduct under Article 82 EC is unrelated to its compliance or non-compliance with other legal rules. It must be observed, in this respect, that, in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law.

678 The applicants further claim that the compatibility with Article 82 EC of the conduct objected to must be assessed according to the criteria set out in the case-law on 'essential facilities'.

679 On that point, the Court notes, as a preliminary point, that the case-law on 'essential facilities' relates, in essence, to circumstances in which a refusal to supply by an undertaking in a dominant position, by virtue, in particular, of the exercise of a property right, may constitute an abuse of a dominant position. That case-law therefore relates in particular to situations in which the free exercise of an exclusive right, being a right which rewards investment or innovation, may be limited in the interest of undistorted competition on the common market (see, to that effect, Opinion of Advocate General Jacobs in *Bronner*, paragraph 628 above, paragraphs 57 to 65, and the judgment in *Microsoft* v *Commission*, paragraph 32 above, paragraphs 331 to 333).

680 In this respect, it should be observed, for the reasons set out in paragraph 668 above, that Directive 65/65 no longer conferred on AZ the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials placed in the file, but, on the contrary, allowed that information to be taken into account by the national authorities for the purpose of granting marketing authorisations for essentially similar products under the abridged procedure provided for in point 8(a)(iii) of the third paragraph of Article 4. As was noted in paragraph 667 above, the period of 6 or 10 years during which the owner of an original medicinal product has the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials contained in the file is the result of a balancing by the legislature of the interests of innovative firms, on the one hand, and those of manufacturers of essentially similar products, and of the interest in avoiding unnecessary repetition of tests on humans or animals, on the other.

681 Inasmuch as, as the applicants claim, that information were to be considered to be the property of the undertaking which produced it, given that, as the Commission observes, it is in any event never made public or disclosed to applicants for marketing authorisation in respect of essentially similar products, the fact remains that Directive 65/65 in any event restricted any such property right by establishing, in point 8(a)(iii) of the third paragraph of Article 4 thereof, an abridged procedure which

enables national authorities to rely on the data produced in the original application for marketing authorisation.

682 Thus, the conduct at issue is not a refusal to give access to the results of the pharmacological and toxicological tests and clinical trials contained in the file, since AZ cannot, in any event, use its alleged property right to prevent the national authorities from relying on the data in question in the abridged procedure. Instead, the conduct at issue relates to the steps by which the marketing authorisations were deregistered so as to render inapplicable the abridged procedure provided for in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 and, consequently, the restriction which that provision effected with regard to the exclusive use of the information derived from the pharmacological and toxicological tests and clinical trials.

683 As is apparent from *AstraZeneca*, paragraph 617 above (paragraphs 49 to 54), the reason for the fact that the abridged procedure referred to in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 is no longer available after withdrawal of the marketing authorisation of the reference medicinal product is not the concern to ensure that the manufacturer of the reference medicinal product has exclusivity with regard to the data that he has supplied, but the concern to ensure that public health is safeguarded, which constitutes a primary purpose of Directive 65/65.

684 In those circumstances, the case-law on 'essential facilities' to which the applicants refer cannot be applied to the facts at issue in the present case.

The alleged absence of abuse of a dominant position in any event

685 The applicants plead that AZ no longer had a commercial interest in selling Losec capsules and, therefore, in maintaining the marketing authorisation in a situation where such maintenance imposed upon it continuing 'updating' and pharmacovigilance obligations.

686 In this respect, it should be observed at the outset that that plea of objective justification is being raised for the first time at the stage of the proceedings before the Court. The Court would point out that, although the Commission is required to take into account a possible objective justification for conduct which may constitute an abuse of a dominant position, it is still necessary for the undertaking concerned to raise that objective ground of justification during the administrative procedure and put forward arguments and evidence in support thereof (see, to that effect, Case C-95/04 P *British Airways* v *Commission* [2007] ECR I-2331, paragraph 69, and *Microsoft* v *Commission*, paragraph 32 above, paragraph 1144). That is more specifically the case where the undertaking concerned is alone aware of that objective justification or is naturally better placed than the Commission to disclose its existence and demonstrate its relevance.

687 According to settled case-law, the lawfulness of a Community act is to be assessed in the light of the information available to the Commission when it was adopted. In proceedings before the Community judicature, no one, therefore, can rely on matters of fact which were not put forward in the course of the administrative procedure (see, to that effect, Joined Cases 15/76 and 16/76 *France* v *Commission* [1979] ECR 321, paragraph 7; Case T-58/05 *Centeno Mediavilla and Others* v *Commission* [2007] ECR II-2523, paragraph 151; and Case T-268/06 *Olympiaki Aeroporia Ypiresies* v *Commission* [2008] ECR II-1091, paragraph 55).

688 In this respect, as the Commission maintains, the burden arising from the pharmacovigilance obligations was never mentioned in AZ's internal documents relating to its commercial strategy. That absence of any mention in those documents of that objective ground of justification meant that the Commission was unable to take cognisance of it and in any event makes it scarcely credible that the deregistration of the marketing authorisations was due to that ground.

689 Moreover, it is common ground that AZ had not requested the deregistration of its marketing authorisations in Germany, Austria, Spain, France, Italy and the Netherlands. The Court finds that the applicants have failed to demonstrate before it that the additional burden on AZ, if it had not deregistered its marketing authorisations in Denmark, Norway and Sweden, would have been so significant that it would have constituted an objective ground of justification.

690 As the Commission pointed out at the hearing, Article 29d of Directive 75/319 requires the undertaking responsible for placing the medicinal product on the market (i) to report to the competent authority, immediately or within 15 days at the latest, all suspected serious adverse reactions which are brought to its attention by a health care professional and (ii) to submit to the competent authority detailed records of all other suspected adverse reactions and to accompany them with a scientific evaluation. Reports on other suspected adverse reactions must be submitted immediately upon request, or, where the marketing authorisation was granted more than five years previously, at five-yearly intervals together with the application for renewal of the authorisation.

691 It is common ground that, when its requests for deregistration of the marketing authorisations for Losec capsules were made in Denmark, Norway and Sweden, on 19 March, 12 October and 20 August 1998 respectively, AZ had had those authorisations for well over five years. Accordingly, it can be reasonably assumed that there was a low probability that serious adverse reactions — of which there had been none until then — might appear in connection with Losec capsules.

692 Furthermore, the obligation to submit, at five-yearly intervals, reports on other suspected adverse reactions does not constitute such a significant pharmacovigilance burden that it could constitute a serious objective ground of justification. Whilst it is true that Article 29d of Directive 75/319 does not prevent Member States from laying down additional requirements when granting marketing authorisations, the applicants have failed to show, in their replies to the Court's questions, that the Danish, Norwegian and Swedish authorities laid down such significant additional obligations. Quite to the contrary, as the Commission observed at the hearing, it is apparent from the actual replies of the applicants to the Court's questions that, in Germany, a country in which AZ had never ceased to market Losec capsules, the public authorities laid down stricter pharmacovigilance obligations than in Denmark, Norway or Sweden.

693 Similarly, the applicants have not shown that the Danish, Norwegian and Swedish authorities applied the pharmacovigilance obligations set out in Chapter Va of Directive 75/319 so differently from the other countries in which Losec capsules were still marketed that significant additional pharmacovigilance burdens would have resulted from this for AZ.

694 For all those reasons, it is therefore necessary to reject the applicants' argument, put forward for the first time at the stage of the proceedings before the Court, that, in the present case, the pharmacovigilance obligations to which AZ was subject in Denmark, Norway and Sweden constitute an objective ground of justification for the requests for deregistration of the marketing authorisations for Losec capsules in those countries.

695 The applicants also maintain that the behaviour objected to cannot be classified as an abuse of a dominant position, since, in any event, potential competitors could have followed the procedure provided for in point 8(a)(ii) of the third paragraph of Article 4 of Directive 65/65, which enables the applicant to demonstrate, merely by detailed references to published scientific literature, that the proprietary medicinal product for which a marketing authorisation has been applied has recognised efficacy and an acceptable level of safety. They also complain that the Commission did not assess the delay suffered by competing undertakings manufacturing generic products. The merits of those arguments, which are reiterated in the second plea, will be examined in paragraphs 829 to 835 below, when that plea is examined.

696 Without prejudice to the examination of the merits of that last set of arguments, it must be held, for all the foregoing reasons, that none of the applicants' arguments reveal an error of law by the Commission in classifying the second course of conduct objected to as an abuse of a dominant position. It is therefore necessary to reject the first plea, but without prejudice to the merits of the arguments cited in the previous paragraph which will be examined later.

3. *Second plea in law, alleging errors of fact*

(a) Arguments of the applicants

697 The applicants claim that it is normal for the owner of an expiring patent to seek to profit from sales of the product and to maintain its market share. It will thus seek, in various ways, to prevent or reduce the sales of generic producers and parallel importers as far as possible, this being part of routine competition in pharmaceutical product markets in the Union. From that point of view, there is nothing unusual about the documents referred to by the Commission, since they merely evidence the ordinary aims and concerns of any pharmaceutical company that has lost, or is about to lose, an important patent. The applicants therefore dispute that the fact, found in recitals 798 and 799 of the contested decision, that AZ had the stated aim of preventing or delaying generic market entry and parallel trade is a matter of complaint. To consider that AZ could not legitimately pursue such an aim is tantamount to prohibiting that company from competing with its competitors. In that regard, they dispute that withdrawing a marketing authorisation for a product that has itself been taken off the market is an act which does not come within the scope of competition on the merits, and refer to recital 842 of the contested decision, in which the Commission accepted that it was not the purpose of marketing authorisations to facilitate entry to the market of generic products.

698 The applicants maintain, secondly, that deregistering a marketing authorisation is not unlawful. They deny that that deregistration was carried out with the sole or principal intention of preventing the authorisation of generics and parallel imports. Losec tablets were introduced in the countries in question because they were a better quality

product and because the local marketing companies considered that it was preferable to have just one product on the market. Given that AZ was replacing one product with another, it was natural for it to deregister the marketing authorisation for the product that it was no longer producing.

699 The applicants submit that the Commission does not adduce sufficient evidence for a finding of infringement of Article 82 EC and observe that the Commission itself has admitted that it had little hard evidence (transcript of the oral procedure on 16 and 17 February 2004, p. 162). The contested decision is based solely on inferences drawn unfairly and erroneously from documents provided by AZ. The Commission had no interviews with the authors of the documents upon which it relies and conducted no independent inquiries with regard to generics, parallel imports, medical product agencies or consumers.

Reasons for the development and marketing of Losec MUPS

700 The applicants maintain that Losec MUPS was developed because it was a better product. They explain that the active ingredient in Losec, omeprazole, degrades rapidly and loses its efficacy if it is exposed to the acid conditions of the stomach. Consequently, Losec capsules, launched in 1988, comprise enteric-coated beads in a gelatine-based capsule, which do not release the active substance in the stomach and allow its absorption in the small intestine. However, those Losec capsules had certain shortcomings [*confidential*].

701 In 1991, Astra undertook a feasibility study into developing a new dispersible Losec tablet containing several hundred enteric-coated beads of omeprazole, known as the 'Multiple Units Pellets System' (MUPS) and, in 1994, after several years of further research, decided to launch its development. Patent protection for the new manufacturing process was applied for under the reference WO 96/1623, whose 'priority date' was 8 January 1994. The applicants explain that AZ still encountered a number of difficulties in developing a satisfactory tablet formulation, and Losec MUPS was eventually ready for launch in 1998. They maintain that the decision not to launch Losec MUPS earlier was driven by the time taken to develop MUPS and prepare the comprehensive data file for the local regulatory authorities.

702 The applicants submit that, although the decision to develop Losec MUPS was taken by Astra centrally on account of the fact that it involved the mobilisation of considerable research and development resources, it was for the local marketing companies to decide on the timing and method of launch of the product in the light of local circumstances. AZ's central marketing team encouraged local companies to launch Losec MUPS because of the advantages which that product offered, and supervised the timetable for the launch of Losec MUPS and, where relevant, for the withdrawal of Losec capsules in order to ensure the orderly and timely supply of both products to the markets.

703 Losec MUPS was launched in different national markets on different dates because of the different conditions which prevailed in those markets and the variable lengths of time taken to deal with applications for marketing authorisations. The decision not to launch that product in Spain, Italy, Greece, Austria, Portugal and France is justified by commercial reasons. The applicants maintain that the local marketing companies did not decide on their strategies by reference to the effects of their decisions on parallel trade or generic entry and did not expect to prevent generic entry. They do not deny, however, that AZ's central marketing team envisaged that withdrawing Losec capsules entailed the risk of enabling generic capsules to gain ground at the expense of the MUPS product if the latter did not meet with success. Moreover, AZ's central

team also looked at the implications of the decisions adopted by the local marketing companies for generic entrants and parallel importers. That being so, the Commission itself acknowledged that the legal challenges brought against the marketing of generics and against parallel imports, following the local marketing companies' decisions to withdraw the marketing authorisations, did not constitute an abuse.

704 In the United Kingdom, [*confidential*].

705 Following that meeting, AZ's central coordinating team examined the implications of the withdrawal of the Losec capsule marketing authorisations for generic manufacturers and parallel traders. The applicants maintain, however, that it was for the local marketing companies, not Astra's central coordinating team, to decide whether Losec MUPS should be placed on the market, whether Losec capsules should be withdrawn from the market and, if so, whether the related Losec capsule marketing authorisation should be withdrawn.

706 As regards Sweden, the applicants explain that, in June 1995, Astra circulated a memorandum, known as 'Minisignal', to the marketing companies worldwide, informing them of the development of Losec MUPS and adding a questionnaire regarding the respective marketing companies' plans as to the new product. In February 1996, the Swedish marketing company answered the Minisignal, stating that Losec capsules and Losec MUPS would both be available in Sweden, but that Losec capsules would be withdrawn over time depending on consumer acceptance of the new formulation.

707 In January 1997, the marketing companies were informed by fax that the Losec MUPS dossier was available for them to use for making applications for marketing authorisations and would be distributed to them upon request. It was therefore up to the local marketing companies to request the file and, consequently, to decide whether and when to apply for a marketing authorisation and whether and when to launch the product.

708 A marketing authorisation was sought in Sweden by Astra Sweden for Losec MUPS on 2 May 1997 and was granted on 19 December 1997. The applicants maintain that that marketing company decided to withdraw Losec capsules over time following four market research studies (including a study conducted in spring 1998) and a patient preference test. As Astra Sweden stated in answer to the Minisignal, it was clear from those studies that Losec capsules should be completely replaced by Losec MUPS. There was thus no reason to keep that product on the market.

709 As regards the marketing companies established in Norway and Denmark, they also determined for themselves the launch strategy for Losec MUPS in their national markets. The applicants point out that there is no discussion in the files of those marketing companies as to whether the Losec capsule authorisations should be withdrawn or allowed to lapse. They submit that this reflects the fact that there was no need to maintain an authorisation for a product which had been withdrawn from the market and that there was no reason to take account of any other considerations in that regard.

710 The applicants point out that Astra's central marketing team [*confidential*]. On the other hand, Astra's central coordinating team was responsible for evaluating the legal implications [*confidential*].

711 The applicants explain that Astra's central coordinating team decided not to market Losec MUPS in Spain and Italy. [*confidential*].

[*confidential*]

[*confidential*]

[*confidential*]

Challenging of evidence

715 The applicants challenge the evidence on the basis of which the Commission justified its conclusion that the introduction of Losec MUPS and the withdrawal of the Losec capsule marketing authorisations was in the nature of a general strategy designed to prevent the entry of generics and parallel imports into the market. With regard to the minutes of an internal meeting of the Marketing Advisory Council (MAC) that took place on 9 August 1996, referring to work being done on the Losec Post-Patent Strategy ('the LPP Strategy') (see recital 266 of the contested decision), the applicants claim that that term must be understood as meaning that Astra proposed to plan how certain matters should be dealt with, but that there is no basis for presuming that any bad faith was involved. They claim that the fact that AZ was looking at the competitive threat and ways of 'countering' it is part of the everyday commercial life of a company. In their submission, in so far as that document discussed 'legal ways

… to disturb/delay generic approval/introduction', it does not reveal any concern unconnected with competition on the merits. They further add that none of the documentary evidence relied on by the Commission shows that AZ operated a malevolent strategy to withdraw the marketing authorisations in Denmark, Norway and Sweden in order to delay market entry by generics and prevent parallel trade.

716 The applicants reiterate that Astra coordinated centrally the legal actions brought against generic competitors, recommended the launch of the Losec tablets and provided support to national marketing companies in obtaining marketing authorisations and in producing and supplying Losec. However, the local marketing companies produced their marketing plans individually. The applicants refer to Chapter 7 of AZ's reply, and in particular paragraphs 7.108 to 7.155, and to the witness statements of Dr N., Executive Vice President of AstraZeneca plc and President and Chief Executive Officer of AstraZeneca AB (pages 104 to 119 of the transcript of the oral procedure of 16 and 17 February 2005).

717 As regards the questionnaire sent out to the local marketing companies in 1996, cited in recital 267 of the contested decision, by which Astra asked that the legal ways of disturbing or delaying generic approval or introduction be identified for it, the applicants submit that those are legitimate questions for the central marketing team to put. They stress that it was a question of lawful legal means and that the Commission has not shown that Astra intended to resort to unlawful means. In addition, the Commission did not raise any objection to the court proceedings brought by Astra in order to establish the extent to which applications for marketing authorisations for generic products or applications for parallel import licences would be affected by the withdrawal of the marketing authorisation on which they depended (paragraph 502 of the statement of objections).

718 The applicants maintain that the Astra central marketing team and the Astra central coordinating team did not coordinate an exclusionary strategy for Denmark, Sweden and Norway and stress the decentralised nature of AZ's organisation. They refer, in that regard, to the witness statement of Dr N., a member of the board of AZ at the material time, from which it is apparent that external consultants had described Astra's organisation as 'strangely decentralised'. They submit that the Commission cannot disregard that witness statement without demonstrating that it is not trustworthy.

719 They dispute that the mere fact that the companies established in Denmark, Norway and Sweden were wholly owned by AZ is sufficient for the latter to be considered to have exercised a decisive influence over their commercial policy. It should, in their view, be ascertained whether the parent company was in a position to exert a decisive influence and whether it did exert a decisive influence (Case 107/82 *AEG-Telefunken* v *Commission* [1983] ECR 3151, paragraphs 48 to 50). They point out, in that regard, that a subsidiary is not under the decisive influence of its parent where the subsidiary can determine its own market behaviour autonomously (*Europemballage and Continental Can* v *Commission*, paragraph 267 above).

720 As regards the examination of Astra's overall strategy, set out in recitals 268 to 274 of the contested decision, which relies on the LPP Strategy document dated 29 April 1997 and on a speech dated October 1999, the applicants note that the Commission considered that the strategy fell into three phases, namely (i) diversifying the Losec product range, (ii) delaying generic market entry through the use of technical and legal means, and (iii) introducing new improved products with their own patent protection. They maintain that the Commission cannot assert that it is objectionable to take action to protect volumes of sales, since that amounts to asserting that it is objectionable to compete. Astra simply sought to enforce its intellectual property rights, such as its formulation patents, to ensure that the legal rules relating to the grant of marketing authorisations for generic products were observed and to improve its own

ulcer-healing product range by extending that line and by creating a new generation of products. Such behaviour is not abusive.

721 In that regard, the applicants point out that the Commission does not take issue, in recital 830 of the contested decision, with Astra's interpretation of the legal rules on the granting of marketing authorisations. Further, in recitals 502 and 458 respectively of the statement of objections, the Commission accepted that Astra's conduct to protect its marketing authorisations was not objectionable and that Astra's legal actions to protect its intellectual property rights were not abusive. The applicants submit that, by launching Losec MUPS and withdrawing Losec capsules, Astra was seeking to gain a legitimate competitive advantage in the market. In that respect, they observe that, in recital 793 of the contested decision, the Commission itself conceded that that commercial behaviour was not, as such, abusive.

722 With regard to the six elements of the second phase of Astra's strategy, set out in recital 271 of the contested decision, the applicants submit that there is nothing illegitimate in them. As regards, firstly, document protection, this reflects Astra's legitimate interest in protecting the confidential information supplied to national authorities in connection with applications for marketing authorisations. As regards, secondly, upgrading of product quality, that behaviour fell within the scope of competition based on the merits of products. With regard to securing additional offensive and defensive patents, there is nothing objectionable in the filing of such patents. The surveillance programme to keep under review the activities of competitors marketing generics is also a legitimate practice, since the granting of interim relief in infringement proceedings is often dependent on the claimant's acting diligently. With regard to the bringing of legal actions, these are intended to enforce Astra's intellectual property rights and are brought only on the basis of solid legal grounds. Finally, as regards the total

switch from Losec capsules to Losec tablets, this is behaviour consistent with competition on the merits of products.

723 The applicants challenge the Commission's argument that Astra intended to market Losec tablets in markets where its substance patent was about to expire. They claim that it was Astra's intention and in its interests to introduce a tablet formulation of Losec as early as possible because of the disadvantages of Losec capsules, but that it encountered technical difficulties in the course of developing Losec MUPS. The applicants concede that Astra's desire to launch a tablet formulation gained urgency as the expiry dates of the omeprazole substance patent approached. However, that urgency does not mean that the timing of the launch of Losec tablets was designed to coincide with the patent's expiry, or that the purpose of that launch was to prevent the market entry of generics.

724 The applicants deny that the speech given in October 1999 to a meeting of AZ's management, referred to by the Commission in recital 273 of the contested decision, demonstrates that AZ was operating an anticompetitive strategy. That document shows only that AZ operated a strategy of defending its industrial property. They also submit that the 'Losec Post-Patent Strategy' document shows that Astra was engaged in competition based on the merits of products, [*confidential*].

725 The applicants submit that the Commission's claim, in recital 274 of the contested decision, in reference to a set of slides dated May 1997, that Astra was wrong to contemplate how it could prevent parallel trade in Losec from markets in which the patent had expired, is ill-founded. They maintain that those slides do not contribute to proving an abuse of a dominant position since they do not suggest that Astra had any intention of using illegitimate or unlawful means, or that it did so.

726 With regard to recitals 275 to 306 of the contested decision, in which the particular facts relating to the launch of Losec MUPS tablets, the withdrawal from the market of Losec capsules and the withdrawal of the Losec capsule marketing authorisations are examined, the applicants maintain that, since the Commission conceded, in recital 793 of the contested decision, that the launch of Losec MUPS and the withdrawal of Losec capsules did not, as such, constitute an abuse of a dominant position, it was obliged to produce evidence that deregistration in Denmark, Norway and Sweden was intended to exclude generics and parallel imports from the market. However, no such evidence was produced.

727 It is apparent from the 'Losec® MUPS STEPSUM' document, cited by the Commission in recital 276 of the contested decision, and in fact dated January 1997, that the Astra central marketing team had drawn the attention of local marketing companies to the fact that there were commercial risks in withdrawing Losec capsules and that a decision to withdraw the capsules needed to be carefully judged in each market. Consequently, Astra's central marketing team invited each local marketing company to make its own decision on whether and when to withdraw the Losec capsules. That document demonstrates that the decision to withdraw Losec capsules from the market, in Sweden, Denmark and Norway in particular, stemmed from an independent and rational commercial strategy on the part of the local companies, implemented on

the ground that it was the best way to market Losec MUPS, and not from a plan to prevent the market entry of generics or parallel imports.

728 The applicants submit that the Commission's inference, in recital 278 of the contested decision, from the minutes of an internal meeting which took place on 18 September 1997, that Astra's decision to launch MUPS was motivated by a desire to restrict competition, is ill-founded. They accept that Astra's central coordinating team had looked into the national regulatory issues relating to a launch of Losec tablets and a withdrawal of the capsules. However, they point out that those minutes simply stated that a proposal for an MUPS strategy was to be prepared for 3 October 1997. Moreover, the Commission has not demonstrated that the regulatory considerations determined Astra's central strategy or the decisions of the local marketing companies. The applicants add that the author of that document, Dr N., provided oral evidence and a witness statement affirming that there was no strategy on AZ's part.

729 With regard to the fax headed 'MUPS', cited by the Commission in recital 279 of the contested decision, the applicants explain that it contains a report of a meeting held on 24 September 1997 and records a compilation of all the national plans to convert sales of Losec capsules to sales of Losec MUPS. They claim that AZ explained, in its written reply (reply, chapter 7, section V, paragraphs 7.143 to 7.147), that those decisions were taken for legitimate commercial reasons and that they contain no suggestion that the launch of Losec tablets and the withdrawal of Losec capsules were decided on by the local marketing companies, for other reasons.

730 With regard to the draft document dated 3 October 1997 called 'Losec MUPS Strategy', cited in recital 280 of the contested decision, the applicants submit that it simply shows that Astra intended to introduce a better-quality product into the market, which is entirely in keeping with competition on the merits. Moreover, as the covering memorandum to the document indicates, the document was intended to introduce the discussion and contained no agreed plan.

731 It follows from the foregoing that the Commission is wrong to maintain, in recital 281 of the contested decision, that Astra had a central plan to restrict competition by taking advantage of the legal implications of a withdrawal of capsule authorisations and that it directed the local marketing companies accordingly. Moreover, the passages of documents cited in that recital show that Astra did not intend to act in disregard of competition law and that it took legal advice from national experts.

732 With regard to recital 282 of the contested decision, the applicants submit that there is nothing illegitimate in the fact that Astra's priority was to launch MUPS in markets in relation to which expiry of the substance patents was imminent, since the intention of that decision was to compete positively by launching the Losec MUPS tablets, and not to compete negatively by deregistering the capsules. Moreover, Astra's decision to avoid launching Losec MUPS first in a low-priced market is justified by the concern to ensure that the pricing of that product by the national authorities of other countries was not influenced downwards. The geographic selectivity which characterised the Losec MUPS marketing strategy was thus governed by financial and commercial and not by regulatory considerations or by the desire to impede parallel trade or market entry by generics.

733 As regards recitals 283 to 285 of the contested decision, in which the Commission cites an in-house counsel's advice as to the likely effects of withdrawal of the capsule authorisations, the applicants submit that this advice does not show that the decision on marketing Losec MUPS and withdrawing the capsules from the market was taken by reference to the likely effects of withdrawal of a marketing authorisation, or that the decisions in respect of Denmark, Sweden and Norway were taken centrally. It shows only that Astra's central coordinating team looked into the legal issues raised by the withdrawal of the capsule marketing authorisations. Similarly, the passage cited in recital 285 of the contested decision shows at the very most that Astra was aware of the competition rules at the time of the launch of Losec tablets and the withdrawal of Losec capsules.

734 The applicants state that, in recitals 286 to 295 of the contested decision, the Commission quoted passages from three documents, namely, that dated 29 April 1998 headed 'Losec/H 199 Scenario', a memorandum of 30 November 1998 headed 'Draft Paper for GITA [gastrointestinal therapeutic area] Team Meeting 4 December 1998' ('the GITA team') and a document dated 12 May 1999 headed 'The Gastrointestinal Franchise Plan, Horizon 1-3, 1999-2007 (and beyond)'. On the basis of those documents, the Commission endeavoured to show that Astra, firstly, had launched Losec MUPS with the intention of delaying or disrupting generic market entry and parallel trade, secondly, had launched line extensions in order to maintain its leading market position until it was ready to launch an entirely new esomeprazole product (Nexium) and thirdly, had intended to draw attention to any deficiencies in the quality of generic products on the market.

735 The applicants do not dispute the Commission's allegations on those matters, but stress that Astra used only legitimate means to exclude and damage its competitors. In their submission, it is clear from the 'Losec/H 199 Scenario' document that Astra was engaging only in competition on the merits. Losec MUPS was a superior product

compared with Losec capsules, a fact which had the effect of dampening demand for the latter, whether they were generics or parallel imports. Moreover, the applicants point out that AZ explained, at paragraphs 70 to 74 of the reply to the letter of facts, that the Commission had erred in citing that document in order to show an admission on the part of Astra that deregistration of marketing authorisations was unprecedented and exclusionary. Reference is also made, in that regard, to the witness statement of Mr R., concerning the representations made by him in the legal proceedings in Denmark.

736 As regards the internal draft GITA team meeting document, the applicants submit that that document shows Astra's desire to compete on the merits, by legitimate means. They further maintain that a close analysis of the document headed 'The Gastrointestinal Franchise Plan, Horizon 1-3, 1999-2007 (and beyond)' does not reveal any malevolent intent on the part of Astra to exclude illegally competition from generics and parallel imports in Denmark, Norway and Sweden. They then give a detailed account of the content of that document before concluding that it shows only that Astra centralised the information concerning intellectual property and regulatory issues and disseminated it to the local marketing companies.

737 The applicants also maintain that the fact that Astra regarded Losec MUPS as an intermediate product between Losec capsules and Nexium is irrelevant, since there was no reason to prevent the launch of Losec MUPS merely because Nexium was in prospect. In addition, the competitive nature of the market did not allow Astra to delay marketing Losec MUPS for any significant length of time. Moreover, in 1997 and 1998, Astra did not know whether Nexium would secure marketing authorisations and had therefore not yet decided to launch it.

738 The applicants repeat that the reason for the marketing companies' decision to withdraw the marketing authorisations for Losec capsules is connected with the fact that the authorisations were no longer needed. There is no obligation on AZ to protect the interests of companies marketing generics or of parallel importers wishing to take advantage of the data filed in support of applications for marketing authorisations. There was therefore no intention on the part of AZ to withdraw the marketing authorisations in order to prevent competition from generics. Astra's central team even envisaged that one of the risks of withdrawing Losec capsules was that generic capsules would gain ground at the expense of the MUPS product if the latter was not a success.

739 With regard to the findings made by the Commission in recitals 296 to 303 of the contested decision, the applicants do not deny that Astra intended, by launching line extensions such as Losec MUPS, to delay generic market entry and parallel trade in order to maintain its leading market position until it was ready to market Nexium. Nor do they deny that Astra intended to launch Losec MUPS before generic omeprazole products entered the market in large volumes and drove prices down to lower levels. They submit, however, that those objectives did not constitute an abuse of a dominant position, since no unlawful means were used.

740 The applicants submit that the conclusions which the Commission draws, in recital 296 of the contested decision, from a fax sent by Astra on 29 May 1998, distort the facts. It is apparent from that fax that Astra suggested to the local marketing companies that they draw up individual plans to defend the Losec patent and guard themselves against the launch of generics. That fax thus shows that the decision-making process for the launch of Losec tablets was decentralised, although Astra centrally took responsibility, on the one hand, for coordinating legal actions against generic competitors who had infringed its intellectual property rights and, on the other, for evaluating the legal implications of the withdrawal from the market of Losec capsules and the deregistration of the related authorisations. Moreover, the fact that the

author of that fax complains that Astra's activities were not coordinated corroborates the fact that the decision-making process regarding the launch of Losec MUPS was largely left to the local marketing companies.

741 The applicants state that the author of the fax wanted Astra to take all steps legitimately available to it to prevent generic companies from infringing its rights. In reply to the Commission's arguments, they explain that that fax does not concern the implementation on a country-by-country basis of a plan to withdraw the marketing authorisations, but Astra's activities in defending its Losec patents. They further note that by the date of that fax, namely 29 May 1998, Losec capsules had already been replaced by Losec MUPS tablets and the marketing authorisation had already been withdrawn in Denmark, that Losec MUPS had already been launched in Sweden and that a marketing authorisation for Losec MUPS had been applied for in Norway. For that same reason, the fax of 27 May 1997 and the letter of 22 October 1998, which are cited by the Commission, cannot support its argument that AZ coordinated the withdrawal of the marketing authorisations, since those documents look at coordinating patent activity after 27 May 1998.

742 As regards recitals 304 to 306 of the contested decision, the applicants set out, in a table, all the dates, in 15 countries, relating to the launch of Losec MUPS, the withdrawal from the market of Losec capsules, the applications for withdrawal of capsule marketing authorisations and the actual revocation of those authorisations. They assert that the withdrawal of Astra Denmark's marketing authorisation was not effected until 6 April 1998, not 19 March 1998 which is when the Commission alleges that the second abuse of a dominant position commenced. The dates in question in the various countries show that the local marketing companies acted differently according to

the particular circumstances in the national markets. The applicants observe, in particular, that the dates for the launch of Losec tablets were approximately nine months apart between Sweden and Norway and approximately eight months apart between Denmark and Norway, and that the withdrawals of the marketing authorisations were approximately five months apart between Sweden and Denmark and approximately seven months apart between Denmark and Norway. They also point out that Astra's intention to impede the activities of generic entrants and parallel importers is refuted by the fact that it did not request withdrawal of the Losec capsule authorisations in the Netherlands and in Germany, the latter having been the first country in which generics were introduced.

743 In the applicants' submission, the fact that Astra took a central decision not to market Losec tablets in Greece, Luxembourg, Portugal, Italy and Spain does not support the conclusion that the decisions about the launch of Losec MUPS, the withdrawal from the market of Losec capsules and the withdrawal of the marketing authorisations in Denmark, Norway and Sweden were adopted centrally. No document proves the existence of a central strategy or that, if there was such a strategy, it was operated with the intention of restricting competition. Similarly, the evidence of the existence of abuse of a dominant position on which the Commission seeks to rely does not demonstrate that the subsidiaries in Denmark, Norway and Sweden were more under the influence of AZ than the subsidiaries in Belgium, the Netherlands or the United Kingdom, which did not deregister the marketing authorisations. However, if AZ did in fact exercise a decisive influence over its subsidiaries, it would have been logical for the subsidiaries in Belgium and the Netherlands to withdraw the marketing authorisations, since they were the first to face competition from generics. In addition, the fact that only three of AZ's 33 marketing companies worldwide withdrew the marketing authorisations is not consistent with the allegation that AZ exercised a decisive influence over its subsidiaries.

Effects

744 As regards the effects of Astra's conduct in Denmark, the applicants submit that the Commission did not establish, in recitals 307 to 311 of the contested decision, that market entry of generic products was delayed by the withdrawal of the Losec capsule marketing authorisation, and that the Commission erred in attributing the difficulties encountered by generic entrants to the withdrawal of the authorisation. They argue that generic companies could readily have relied on the published literature exemption under Directive 65/65, as the Commission conceded in recital 830 of the contested decision. AZ adduced evidence in that regard, showing that the competent authorities in the relevant Member States would have granted marketing authorisations on the basis of that exemption to companies applying for them. Reference is made, on this point, to the witness statement given by Professor S. prior to the oral procedure and the submission made by Mr D.-S. at the oral procedure on 16 and 17 February 2004. The applicants dispute, for those reasons, the Commission's assertion that the fact that one generic company has been excluded means that further applications for authorisation of generics could not succeed, that assertion being, furthermore, unsubstantiated.

745 Moreover, since Astra holds a formulation patent until 2007, withdrawal of the Losec capsule authorisation would have had no effect on the degree of generic competition attainable in Denmark. In reply to the Commission's argument that AZ itself considered that those patents would not hold up in Denmark after the substance patent expired in April 1999, the applicants maintain that the question of how third parties perceive the strength of the patent and the effect of the presence of that patent on third parties is alone decisive. They further assert that that patent was sufficiently strong for AZ to obtain injunctions.

746 The applicants admit that four parallel importers who had been selling Losec capsules in Denmark since 1995 left the market when Astra withdrew the Losec capsule marketing authorisation. They submit, however, that the Commission has failed to show the reasons for those departures. Moreover, the contention that maintaining the parallel import licences in Denmark would have resulted in significant sales of Losec capsules is without foundation. AZ explained, in chapter 7, section VII, paragraph 7.241, of its written reply that, because of the success of Losec MUPS, sales of Losec capsules declined substantially between 1998 and 2000 in Sweden, Norway and the Netherlands, whereas in Sweden, parallel importers were permitted to maintain their import licences for capsules even after the withdrawal of the marketing authorisations, and, in the Netherlands, no abuse of a dominant position was identified by the Commission. The applicants dispute that the causal link between the withdrawal of the marketing authorisations and the cessation of parallel trade can be merely presumed. Moreover, the Commission has not shown that, if the authorisation had stayed in place, there would have been an appreciable demand for parallel imports of Losec capsules. The applicants argue, in that regard, that, on the basis of what has happened in other markets, there is very unlikely to be a material demand for parallel imports of Losec capsules.

747 Similarly, the applicants submit that the Commission erred, in recitals 312 and 313 of the contested decision, in attributing the absence, in Sweden, of generic omeprazole capsules to the difficulties faced by generic product companies in obtaining marketing authorisations. Generic product companies were unable to sell generic omeprazole capsules in Sweden because of the SPCs held by Astra until 4 February 2003 in respect of omeprazole sodium and the omeprazole substance. Moreover, the Commission took no account of the fact that generic product companies could have obtained marketing authorisations on the basis of the published literature in respect of omeprazole. The applicants further observe that, in recital 855 of the contested decision, the Commission conceded that the complainant in this case was able to access the market prior to the withdrawal of the marketing authorisation in Sweden. Thus, the withdrawal of the marketing authorisation had no effect on generic entry in Sweden. Similarly, in its pleadings, the Commission admits that it does not know the

extent to which the obtaining of marketing authorisations by other generic producers was obstructed in Sweden as a direct result of the withdrawal of AZ's authorisation.

748 With regard to the effect of the withdrawal of the marketing authorisation on parallel trade, the applicants point out that the Commission itself concedes, in recital 857 of the contested decision, that it is not able to say with any certainty what effect that withdrawal had, since the drop in imports of Losec capsules may be due, inter alia, to the popularity of Losec MUPS tablets. Moreover, in that same recital, the Commission conceded that the parallel trade licences were withdrawn and then reinstated in Sweden.

749 Those observations are also valid with regard to Norway, a country in relation to which the Commission failed to show any more conclusively, in recital 323 of the contested decision, that withdrawal of the marketing authorisation foreclosed market access for generic products. The applicants reiterate, firstly, that generic product companies could have obtained marketing authorisations on the basis of the published literature and, secondly, that the Commission conceded, in recitals 855 and 858 respectively of the contested decision, on the one hand, that the complainant was able to access the market prior to the withdrawal of the marketing authorisation in Norway and that the Commission could not ascertain the extent to which the obtaining of marketing authorisations was obstructed solely as the result of withdrawal of the authorisation, and, on the other, that Astra's strategy was unsuccessful in respect of parallel imports.

750 The applicants add that the Commission's contention that the withdrawal of the marketing authorisations in Denmark, Norway and Sweden had a direct effect on competition in those countries is not consistent with recitals 830 and 842 of the contested decision, in which, respectively, it considered, on the one hand, that generic producers and parallel importers were not dependent on the existence of a marketing authorisation in order to be able to compete with the holder of a former authorisation and supply the same or similar products and, on the other, that it was not the purpose of marketing authorisations to facilitate the market entry of generic products. Moreover, it is essential that the Commission should be able to identify the effects that flowed from the withdrawal of the marketing authorisations. However, it has failed to demonstrate those effects.

(b) Arguments of the Commission

751 The Commission contests the merits of the second plea.

752 More specifically, with regard to the effects of the conduct at issue, the Commission observes that evidence of such effects is not needed to establish an infringement of Article 82 EC where it is demonstrated that the conduct is capable of having them.

753 In this respect, it rejects the applicants' assertion that the causal link between the elimination of parallel trade and the behaviour objected to has not been established. An AZ Denmark board document, mentioned in recital 311 of the contested decision, describes the effects on parallel trade of actions previously implemented as part of the MUPS strategy. Similarly, the Norwegian LPP Strategy document, mentioned in

recital 302 of the contested decision, expected the elimination of parallel trade from 1 February 1999. The applicants themselves, when discussing authorisation based on published literature, accept that AZ's actions delayed generic entry. The Commission adds that, in any event, that causal link can be presumed, given that parallel traders were legally prevented from importing their products.

754 As regards parallel imports in Denmark, and in reply to the applicants' argument that there would not have been an appreciable demand in that country for parallel imported Losec capsules if the authorisation had stayed in place, the Commission refers to recital 298 of the contested decision, in which it is shown that AZ Denmark had considered that it risked losing '75% of our market' if competition from generic products were not counteracted.

755 As regards parallel imports in Sweden, the Commission makes clear that, in recital 857 of the contested decision, it had stated that it could not measure the effect of de-registration. However, it maintains that the revocation of parallel-trade licences must necessarily have caused the decrease in those imports, even though it was not its sole cause. It refers, in that regard, to the Swedish medical products agency's explanation that, without the marketing authorisation for the reference product, there was no longer any 'basis for the parallel-trade licences' (recitals 313 to 315 and 395 to 398 of the contested decision), and to the rapid contraction in sales (recital 316 of the contested decision). In any event, it was not necessary for the Commission to inquire into the actual effects of exclusionary conduct, since there is no doubt that the second abuse in Sweden pursued the objective of restricting competition and was capable of having that effect (see recital 318 of the contested decision).

756 Finally, as regards parallel imports in Norway, the Commission states that the applicants adduce no specific evidence and refers to recitals 852 to 854 of the contested decision. It contends that the failure of the parallel trade strategy is due to the fact that the Norwegian medicines control agency upheld the parallel-trade licences for Losec capsules in a move that the applicant considered illegal (recitals 858 and 321 of the contested decision).

(c) Findings of the Court

757 For the purposes of examining the applicants' complaints, it is appropriate, first of all, to set out the facts surrounding the conduct constituting the second abuse of a dominant position identified by the Commission. Although the Commission's finding of those facts is not, in itself, being challenged by the applicants, they do however call in question the Commission's assessment of them and the conclusions that it drew from them. It is therefore necessary to set out a part of the content of the documents discussed by the parties. Next, the Court will also set out certain facts relating to AZ's implementation of the conduct objected to and its effects.

758 The Court will then examine the Commission's assessment of those facts in the light of the applicants' complaints.

Factual context of the second abuse of a dominant position identified by the Commission

— Minutes of the MAC meeting of 9 August 1996

759 The minutes of an internal meeting of the Marketing Advisory Council (MAC) that took place on 9 August 1996 constitute what the Commission considers to be the first sign of the LPP Strategy. Those minutes state that AZ '[was] working on a full pre- and post- patent strategy for Losec which [would] be ready during September'. That document also mentions a 'possible strategy for MUPS in Europe which has been discussed with Astra Hässle, legal affairs, the patent department and Astra UK' (see recital 266 of the contested decision).

— Memorandum of 20 December 1996 on the LPP Strategy

760 The Commission also noted the existence of a memorandum of 20 December 1996 on the LPP Strategy, which is not in the file of documents before the Court, from the managing director of the Swedish marketing company to the managing directors of the Danish and Norwegian marketing companies, which contains a number of questions relating, inter alia, to the way in which generic products would penetrate the market under a 'do-nothing' scenario. The Commission states that in that document it was asked inter alia what the possible legal ways of disturbing or delaying

the market introduction of generic products were and how much time could thus be bought (see recital 267 of the contested decision).

— LPP Strategy document of 29 April 1997

761 In the contested decision, the Commission then focused its attention on the LPP Strategy document of 29 April 1997. In that document, it is noted that '[t]he main patent in the "omeprazole patent family", the substance patent, will expire in most major markets in the time period 1999 – 2004'. AZ states in that document that '[i]n 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] Europe in particular'. The authors of the document further state that, '[i]n a "do nothing scenario", [they] project sales decay of Losec, following patent expiry, to 20-30% in 2006 of peak sales year 2000' (see recital 268 of the contested decision).

762 In the section of the document dealing with the purpose of the LPP Strategy, it is stated that 'the primary aim of the [LPP 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' (see recital 269 of the contested decision).

763 In the section of the document dealing with the basic principles of the LPP Strategy, three principles are identified. The first principle consists in the diversification of Losec before the patent expires by introducing 'bioequivalent' line extenders offering practical benefit. Those line extenders include Losec MUPS. That diversification of the brand before patent expiry is intended to protect sales in the short- to medium-term after that expiry through customer loyalty/use habits in the absence of similar generic products.

764 The second principle consists in delaying generic introduction through technical and legal barriers. In this respect, the document makes the following recommendations:

'Every day of protected sales of Losec is worthwhile considering the huge sales volume projected at patent expiry. Creating such barriers is a major priority and include[s] a range of actions:

— documentation protection;

— upgrade of product quality (e.g. change of synthesis method, reduction of impurities);

— secure additional offensive/defensive patents around Losec and its presentations (e.g. formulation patents);

— broaden the base of intellectual property rights (e.g. trade names, tablet shapes);

— establish a comprehensive surveillance programme to identify existing and potential suppliers/products/companies etc. of generic omeprazole in future key markets;

— prepare and take firm and immediate legal action (e.g. infringement of formulation patents) against companies introducing generic omeprazole;

— consider total switch of Losec® capsules for tablets (e.g. MUPS) where local substitution rules would make such an action effective … This approach is probably relevant for markets with early patent expiry considering the timing of [esomeprazole] market availability (e.g. … Denmark, Norway, Germany).'

765 The third principle consists in the introduction of patent protected products with clinical benefits and/or significant differential over generic omeprazole. That principle is described in the document as 'the most important and critical part of the strategy and serves the purpose of generating longer term revenue after expiry of the [omeprazole] patent'. The first two principles are described as 'relevant for the short/medium term period after patent expiry' [*confidential*] (see recitals 270 to 273 of the contested decision).

766 In Section 11, headed 'The Astra Hässle Process', it is stated that the LPP Strategy 'at Astra Hässle will be handled through four separate functions, the Losec Board, the Working Party, the Task Force and the [esomeprazole] project'. AZ adds that, '[b]ased

on priorities set by [the Senior Management Team], [the Losec Board] is the decision making body in matters of key strategic and budgetary importance related to Losec' (see recital 812 of the contested decision).

— Speech by the head of the AZ patent department in October 1999 and slides of May 1997

767 The Commission further observed that, at a speech in October 1999, the head of AZ's patent department had confirmed that the aim of the LPP Strategy was to slow down generic market entry 'to give time for … esomeprazole' (see recital 273 of the contested decision).

768 In the contested decision, the Commission also referred to slides, which the applicants submit were dated May 1997, on which it was apparent that AZ intended to delay the market entry of generic products by defending the patents and gain time for esomeprazole. The Commission noted that AZ asked itself the following question: 'How could Astra prevent importation to the EU states of low-priced Danish (or German) omeprazole?'. The Commission also noted that other slides (not submitted before the Court) raised the possibility of filing a 'patent-cloud' of mixtures, uses, formulations, new indications and chemical substances, so as to slow down the market entry of generic products and create uncertainty (see recital 274 of the contested decision).

— 'Losec® MUPS STEPSUM' document submitted by memorandum of 26 February 1997

769 As regards the switch from Losec capsules to tablets, described by the Commission as the 'MUPS strategy' within the LPP Strategy, the Commission noted first of all the existence of a document headed 'Losec® MUPS STEPSUM', submitted by the memorandum of 26 February 1997. [*confidential*] (see recital 276 of the contested decision).

770 In that document, AZ noted that most of the national marketing companies had commented that they intended to withdraw Losec capsules over time, depending on market acceptance of Losec MUPS and the desire to limit patient/prescriber confusion (see recital 277 of the contested decision).

— Minutes of the 'Losec MUPS i Europa — "Brain Storming"' meeting of 18 September 1997

771 The Commission also noted that it emerged from the minutes of a meeting on 18 September 1997, the object of which was 'Losec MUPS i Europa — "Brain storming"', that AZ's senior management in Sweden, including its Chief Executive Officer, had requested a draft pan-European MUPS Strategy to be delivered by 3 October 1997. Those minutes refer to the evaluation of the consequences of a total switch to Losec MUPS in the light of the respective national regulatory rules and raise the questions of how those national rules could be exploited, whether Losec capsules should be withdrawn or whether they could be maintained on the market. In-house counsel was assigned the task of carrying out that evaluation and a member of AZ's senior

management was assigned the task of preparing country-by-country plans regarding the expiry of the patents (see recital 278 of the contested decision).

— Memorandum of 25 September 1997

772 The Commission furthermore observed that, in a memorandum of 25 September 1997, a member of AZ's staff had stated inter alia that '[t]he plan, at least in Europe (save IT; ES and possibly PT and GR), is to convert all sales from the capsule to MUPS' (see recital 279 of the contested decision).

— MUPS Strategy of 3 October 1997

773 In the document of 3 October 1997 setting out the draft MUPS strategy, AZ stated as follows:

'The Losec line extenders serve the primary purpose of:

— [*confidential*];

— [*confidential*];

— [*confidential*];

— [*confidential*];

— putting more resource and time pressure on companies developing omeprazole … generics;

— [*confidential*].'

774 As regards its marketing strategy, AZ intended to launch Losec MUPS in all European countries, with a few exceptions, and to base that launch on a total switch of the products, at a rate judged to be possible/appropriate in the individual market [*confidential*] (see recital 280 of the contested decision).

775 In that document, AZ stated that '[t]he launch of Losec® MUPS [would] vitalise the Losec® brand and [that] the switch strategy [was] intended to increase the protection of the Losec® brand (vs future generics) and make the brand more competitive'. It went on to state that 'Losec MUPS [was] seen predominantly as a major line extender to protect current business and [that it was] not expected to generate major incremental

sales, beyond that following the continued market penetration of the Losec® brand' (see recital 280 of the contested decision).

776 In the part headed 'Legal and regulatory considerations of a withdrawal and de-registration of Losec® capsules when Losec® MUPS is authorised', AZ states that, when Losec MUPS is launched, it will be possible to withdraw the capsules from the market and therefore surrender their marketing authorisations, except in Sweden. It states that '[t]he consequences of [those actions] from a regulatory and legal viewpoint will be further investigated'. As regards generic products, AZ asks inter alia whether 'generic competitors will be able to obtain authorisations for capsule formulations by reference to Astra's capsule data if Astra's capsule authorisation is no longer in force', [*confidential*]. AZ also mentions the European rules on competition and free movement of goods as aspects which must be taken into consideration (see recital 281 of the contested decision).

777 Under the heading 'Supply strategy', AZ states inter alia that '[m]arkets with early patent expiry or having special strategic needs (e.g. Sweden) should be prioritised regarding delivery of Losec® MUPS'.

778 Lastly, under the heading 'Recommendation', AZ states as follows (see recital 282 of the contested decision):

— '[*confidential*];

— total switch is recommended;

— …

— it is important that the first launch of Losec® MUPS does not occur in a low price market;

— …

— Losec® MUPS not to be launched in Italy/Spain;

— [*confidential*];

— strongest possible legal defense in all markets to defend Astra from generic competition regardless of formulation.'

— Memorandum of 22 October 1997 headed 'Consequences of MUPS strategy — interim report'

779 In the internal memorandum of 22 October 1997, headed 'Consequences of MUPS strategy — interim report', AZ observes, in relation to generic products, that, '[s]ince

the MUPS applications are based on the capsule data, [AZ] will not be able to withdraw the capsule documentation even if the authorisation of the capsules will be surrendered in European countries'. It therefore considers that, when the data exclusivity has expired for the capsules, it will be possible for generic competitors to refer to those data, provided that they can show that their products and the product which is on the market, i.e. MUPS, are essentially similar (see recital 284 of the contested decision).

780 As regards parallel imports, AZ states that, '[i]f [its] [Losec] capsule [marketing] 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[; t]his could follow …, 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[;t]here are indications that several of the Scandinavian authorities generally would take this position'. Referring to scenarios of disputes which could arise between parallel importers and the manufacturer on whether or not the parallel import licence should be upheld, AZ adds 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[; i]t can, for example, be important to show that [authorisations] for the new formulations have been sought in all EU countries or that there are objective reasons for not doing so' (see recitals 283 and 285 of the contested decision).

— 'Losec/H199 scenario' document of 29 April 1998

781 In an internal document of 29 April 1998, headed 'Losec/H199 scenario', AZ noted that 'formulation conversion [was] not precedented' (see recital 286 of the contested decision).

— Draft paper of 30 November 1998 for the GITA team meeting of 4 December 1998

782 As regards, next, the document of 30 November 1998 headed 'Draft paper for GITA team meeting of 4 December 1998', concerning the period 1999-2000, AZ stated therein that '[t]he overall aim with regulatory protection [was] to prevent or delay generic entry' (see recital 287 of the contested decision).

783 In that document, AZ described the actions that it intended to take or had already taken in certain countries (Australia, Denmark, Finland and Norway) with a view to making it less easy to demonstrate the existence of an essential similarity between generic products and the original product. Those actions included the preparation by AZ of technical files regarding the relative quality of certain generic products in relation to Losec and the submission of those files to the national authorities in order to alert them to the bad quality of generic products even before they had been approved, or the improvement of specifications for Losec on national bases, so as to improve the quality of the original product and make it more difficult for generic products to

comply with those specifications. [*confidential*] (see recitals 289 and 290 of the contested decision).

— Document concerning the 'The Gastrointestinal Franchise Plan' of 12 May 1999

784 As regards the document of 12 May 1999, headed 'The Gastrointestinal Franchise Plan, Horizon 1-3, 1999-2007 (and beyond)', the Commission observed that it covered AZ's long-term strategy for the whole gastrointestinal therapeutic area. As regards the period 1999-2002, the only relevant period in this case, and which the document refers to as 'horizon 1', AZ again stated that '[t]he overall aim [was] to prevent or delay generic market entry of generic omeprazole by prolonging the market exclusivity for Losec or by requiring generic companies to include more data/documentation in their applications to get market authorisation'. AZ mentions three principles governing the actions taken for that purpose, the third one being to 'increase technical, biopharmaceutical and quality hurdles for generics' (see recitals 291 to 293 of the contested decision).

785 The Commission also observed that that document listed the 'actions already taken' and those relating to the period '1999 – 2002'. Among those actions, AZ mentions, inter alia, 'submission of technical file in Germany, Denmark, Holland, UK, Belgium and Sweden[;] Losec specifications [were to] be upgraded as a further hurdle against generic omeprazole products'. AZ also refers to '[monitoring of] regulatory impact of the Losec MUPS switch on generic/parallel imports and generic substitution' (see recital 294 of the contested decision).

— National strategy documents

786 The Commission observed that several marketing companies had drafted national strategy documents in line with the general strategy documents emanating from AZ's management. That was the case with the companies established in Finland, Norway (October 1998), the Netherlands (October 1998), Denmark (November 1998) and Sweden (February 1999). The Commission takes the view that it is apparent from a fax of 29 May 1998 from AZ's management, which advocated the adoption of those national strategies in order to 'ensure, as far as possible, that generics do not enter [the market]', that the elaboration of the Danish, Finnish and Norwegian national strategies was centralised by AZ in Sweden (see recital 296 of the contested decision).

787 It is apparent from the description and from the passages cited by the Commission of the documents setting out the LPP Strategy in Denmark, Norway and Sweden, dated 2 November and 23 November 1998 and 26 February 1999 respectively, that AZ was aware of the competitive threat posed by the introduction of generic products, which created the risk, in its view, of its losing the majority of the market, of bringing prices down and of making it very difficult to obtain a price for esomeprazole comparable to that of Losec capsules, in view of the practice of the national authorities, in particular the Norwegian authorities, of setting prices and reimbursement levels by reference to the cheapest comparable products on the market. Those documents underline the importance of marketing esomeprazole before generic omeprazole was introduced on the market (see recitals 298 to 301 of the contested decision).

788 The Commission thus found that the national LPP Strategy documents were essentially directed against the introduction of generic capsules as well as against parallel imports. In this respect, the Commission stated that, in the Norwegian LPP Strategy document, it was envisaged that, following the deregistration of the Losec capsule marketing authorisations on 1 November 1998, conversion 'will mimic the situation

that has already taken place during the MUPS® introduction by Astra Denmark' and that 'parallel trade of Losec® capsules will gradually cease and be virtually non existing from February 1, 1999' (see recital 302 of the contested decision).

— Effective implementation of the LPP Strategy

789 The Commission noted that, in Denmark, where the omeprazole substance patent expired in April 1999, the launch of Losec MUPS had taken place on 9 March, the request for deregistration on 19 March and the deregistration itself on 6 April 1998. In Finland, where the SPC risked being revoked and where the substance patent expired in April 1999, the launch of Losec MUPS took place on 20 May, the request for deregistration on 28 September and the deregistration itself on 1 October 1998. In Norway, where the SPC also risked being revoked and the substance patent expired in April 1999, the launch of Losec MUPS took place on 1 September and 1 November, the request for deregistration on 12 October and the deregistration itself on 1 December 1998. In Sweden, where the SPC was due to expire in February 2002 or in February 2003 (according to the divergent information given in this respect in footnote 398 and in recital 313 of the contested decision), the launch of Losec MUPS took place on 2 February and 1 August, the request for deregistration on 20 August 1998 and the deregistration itself on 1 January 1999 (see recital 304 of the contested decision).

790 In Germany, where AZ risked losing its SPC for omeprazole in April 1999, AZ launched Losec MUPS on 1 December 1998 and withdrew the three capsule formulations from the market in March and October 1999 and in December 2002. In

the Netherlands, AZ launched Losec MUPS in May 1999 and withdrew Losec capsules from the market in December 1999. In the United Kingdom, AZ launched Losec MUPS on 27 September 1999 and initially withdrew Losec capsules from the market in September/October 1999, but reintroduced them in December 1999 because pharmacists were not able to endorse a prescription for tablets when prescriptions were for capsules. In Belgium, AZ introduced Losec MUPS on 1 December 2000 and withdrew Losec capsules in September 2001 and September 2002. In Ireland, AZ introduced Losec MUPS on the market on 1 November 1999 and withdrew capsules from the market on the same date. The Commission states that, as at 13 December 2002, the deregistration of the marketing authorisations had not taken place or had not been requested in any other country apart from the four 'Nordic countries', namely Denmark, Finland, Norway and Sweden (recital 305 of the contested decision).

— Effects of the deregistrations of the marketing authorisations

791 In the contested decision, the Commission observed that, in Denmark, the complainants had filed a marketing authorisation application for a generic version of Losec on 23 February, which the Danish Medicines Agency approved on 30 November 1998. On 27 April 1999, AZ appealed against the decision of the Danish Medicines Agency, arguing that point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 required not only that the reference product be effectively marketed at the point in time when a generic manufacturer files its application for marketing authorisation but also at the point in time when the national authority decides on the application (see recital 307 of the contested decision).

792 In January 2000, AZ succeeded in obtaining an injunction against the marketing of the complainant's product by invoking its formulation patent. AZ also obtained injunctions against two other competitors (GEA/Hexal and Biochemie) in March 2001 and October 2003 respectively (recital 309 of the contested decision).

793 On 30 September 1998, the Danish Medicines Agency rejected an application for marketing authorisation filed under the abridged procedure for generic products, on the grounds that that application had been filed after the marketing authorisations for Losec had been deregistered on 6 April 1998 and that, consequently, it failed to meet the requirements laid down in point (8)(a)(iii) of the third paragraph of Article 4 of Directive 65/65. Subsequently, on 23 May 2001, the Østre Landsret (the Danish regional court) referred to the Court of Justice a question for a preliminary ruling in order to determine the interpretation to be given to Directive 65/65. On 25 May 2001, Ratiopharm received a marketing authorisation for a generic version of the omeprazole capsules, by reference to Losec MUPS. However, Ratiopharm was obliged to provide the results of certain extra tests (recital 310 of the contested decision).

794 As regards parallel imports, the Commission observed, in the contested decision, that, in an internal document, the board of AZ Denmark had noted that the withdrawal of Losec from the market in April 1998 had excluded parallel imports. According to the Commission, the board stated therein that 'Losec [had] reached the best result so far' (recital 311 of the contested decision).

795 In Sweden, one of the complainants obtained a marketing authorisation for its generic omeprazole capsules on 29 December 1998, three days before the deregistration of the Losec capsule marketing authorisations took effect. That generic omeprazole was launched on the market in May 2000.

796 However, at AZ's request, the Stockholm District Court issued an injunction prohibiting the sale of that generic product on 17 November 2000, on the basis of AZ's Swedish SPC for omeprazole sodium, which was valid until 15 November 2002. The Commission observed that the injunction was not based on the Swedish SPC for omeprazole because, following the deregistration of the marketing authorisation for Losec with effect from 1 January 1999, the Swedish patent office had revoked AZ's SPC for omeprazole. However, the patent appeals court upheld AZ's appeal, taking the view that the new marketing authorisation for Losec MUPS was sufficient to keep in force AZ's Swedish SPC for omeprazole, whose expiry date, according to what is stated in recital 313 of the contested decision, was 4 February 2003.

797 In January 2003, two other manufacturers of generic products, Biochemie and Ratiopharm, obtained marketing authorisations and, in February 2003, launched generic versions of omeprazole capsules. AZ brought legal proceedings against those companies for infringement of its formulation patent (recitals 312 and 313 of the contested decision).

798 As regards parallel imports, the Swedish Medical Products Agency revoked the import licences following the deregistration of the marketing authorisations for Losec capsules, which took effect on 1 January 1999. At the request of a parallel importer, the Swedish Agency extended the duration of the validity of the import licence by six months, that is until 30 June 1999 (recitals 314 and 315 of the contested decision).

799 A number of parallel importers brought an action against the Agency's revocation of the Swedish import licences, an action which gave rise to administrative proceedings before the Uppsala County Court, then before the kammarrätt (the Administrative Court of Appeal, Sweden), the latter finding in favour of AZ in a judgment of 26 February 1999. Those proceedings were then continued before the Regeringsrätten (Supreme Administrative Court, Sweden), which referred a question to the Court of Justice for a preliminary ruling (recitals 316 and 317 of the contested decision).

800 As regards Norway, the Commission observed that the complainant had filed an application for marketing authorisation for omeprazole capsules before the effective deregistration of the Losec authorisation and obtained that authorisation on 1 November 1999, which enabled it to launch the product on the market in the same month. However, the marketing of that generic product was prohibited, in May 2000, as a result of the grant of an injunction based on AZ's formulation patent. On 2 July 2001, another generic version of the omeprazole capsules received marketing authorisation (recital 320 of the contested decision).

801 Parallel imports fell sharply from 1998, but did not cease entirely. The Norwegian Medicines Control Agency granted import licences for Losec capsules on the basis of the marketing authorisations for Losec MUPS, as the latter are themselves based on the capsule authorisations (recital 321 of the contested decision).

The abusive nature of AZ's conduct

— The LPP Strategy

802 As regards, first of all, the LPP Strategy, the applicants comment on the factual findings made by the Commission in recitals 266 to 303 of the contested decision and dispute that that strategy developed by AZ is objectionable in the light of Article 82 EC.

803 In this respect, the Court would point out that it is apparent from all the documentation gathered by the Commission that, before the Losec capsule substance patents expired, AZ was aware of the threat which the market entry of generic products posed for sales volumes and price levels of Losec capsules and of the need to react in order to prevent significant deterioration in its competitive position. To that end, AZ developed the LPP Strategy, which is centred around three elements, namely, first, Losec line extenders including Losec MUPS, second, the raising of technical and legal barriers designed to delay the market entry of generic products and, third, the introduction of a new generation product, esomeprazole (or 'Losec H199/18'), which was supposed to distinguish itself from generic omeprazole through its significant clinical benefits (see paragraphs 761 to 765 above). That strategy was essentially aimed at limiting the erosion of Losec sales volumes [*confidential*]. The switch of sales towards Losec MUPS and the raising of technical and legal obstacles were also intended to contain the entry of generic products and parallel imports pending the launch of esomeprazole (see paragraphs 765 and 767 above).

804 It should be observed that the preparation by an undertaking, even in a dominant position, of a strategy whose object it is to minimise erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers.

805 In the contested decision, the Commission does not express a view on the compatibility with Article 82 EC of the series of actions envisaged in the framework of the three principles at the centre of the LPP Strategy. The abuse of a dominant position identified by the Commission consists solely in the deregistration of the Losec capsule marketing authorisations in Denmark, Norway and Sweden, in combination with the conversion of sales of Losec capsules to Losec MUPS, that is to say the launch of Losec MUPS and the withdrawal from the market of Losec capsules (see recital 860 of the contested decision). Thus, the applicants' arguments seeking to defend the conformity with Article 82 EC of the series of actions envisaged overall in the LPP Strategy are irrelevant inasmuch as they do not relate to the conduct objected to.

— The abusive nature of the conduct objected to

806 As regards, next, the abusive nature of the conduct in question, it should be recalled that the conduct classified by the Commission as an abuse of a dominant position consists in the deregistration of the Losec capsule marketing authorisations in Denmark, Norway and Sweden, in combination with the conversion of sales of Losec capsules to Losec MUPS, that is to say the withdrawal from the market of Losec capsules and the introduction on the market of Losec MUPS.

807 As the Commission stated in reply to the Court's questions and at the hearing, although it defined the abuse of a dominant position as the combination of those elements, the central feature of the abuse consists in the deregistration of the Losec capsule marketing authorisations, the conversion of sales of Losec capsules to Losec MUPS being the context in which the deregistrations of the marketing authorisations were carried out.

808 In this respect, the Court observes that the conversion of sales of Losec capsules to Losec MUPS, namely the withdrawal from the market of Losec capsules and the introduction on the market of Losec MUPS, was not capable, in itself, of producing the anticompetitive effects alleged by the Commission in the present case, namely the creation of regulatory obstacles to the market entry of generic omeprazole and to parallel imports of Losec capsules.

809 As regards generic medicinal products, the Court of Justice has held that, for the grant of a marketing authorisation on the basis of the abridged procedure provided for in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65, it is only necessary that all the particulars and documents relating to the reference medicinal product remain available to the competent authority concerned by the marketing authorisation, and it is not necessary that the reference medicinal product be actually marketed (*AstraZeneca*, paragraph 617 above, paragraph 27). Thus, the fact that the reference medicinal product has been withdrawn from the market does not preclude the use of the abridged procedure provided for in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65. Similarly, the launch of Losec MUPS cannot preclude the use of the abridged procedure in respect of pharmaceutical products which are essentially similar to Losec capsules.

810 Furthermore, with respect to parallel imports, the Court observes that, in the contested decision, the Commission did not consider that the withdrawal from the market of Losec capsules and the introduction on the market of Losec MUPS was such as to lead the national authorities to revoke the parallel import licences for Losec capsules. On the other hand, the Commission observed, in recital 264 of the contested decision, that parallel import licences have traditionally relied on the existing market authorisations of the proprietary medicinal product in question. Consequently, only deregistration of marketing authorisations could, by hypothesis, be such as to induce national authorities to withdraw parallel import licences. It is apparent from the contested decision that that was the case in Finland and Sweden, where the national authorities revoked the parallel import licences as a result of the deregistration of the marketing authorisations.

811 Thus, in view of the fact that, in the present case, the conduct that may be classified as an abuse of a dominant position consists essentially in deregistration of the marketing authorisations, which is, by hypothesis, the sole element which could be capable of producing the anticompetitive effects alleged by the Commission, the applicants' arguments are irrelevant inasmuch as they assert, in essence, that, first, Losec MUPS was introduced on the market because it was a better product and, second, Losec capsules were withdrawn from the market because the local marketing companies considered, inter alia as a result of several market studies and a study on consumer preferences, that it was preferable to maintain just one product on the market. In the present case, there is no reason to reproach AZ either for launching Losec MUPS or for withdrawing Losec capsules from the market, since those acts were not such as to raise the legal barriers to entry complained of by the Commission that were capable of delaying or preventing the introduction of generic products and parallel imports.

812 By contrast, the deregistration of the Losec capsule marketing authorisations cannot be regarded as within the scope of competition on the merits. As was established in

paragraph 675 above, that conduct was not based on the legitimate protection of an investment designed to contribute to competition on the merits, since AZ no longer had the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials. Furthermore, the applicants adduce no evidence to permit the inference that those deregistrations were necessary, or even useful, for the introduction on the market of Losec MUPS, or for the conversion of sales of Losec capsules to Losec MUPS. Thus, without prejudice to the question whether the Commission has established to the requisite legal standard that the objective context in which the impugned conduct took place permitted the inference that that conduct was such as to restrict competition, the deregistration of the Losec capsule marketing authorisations was the sole aspect of the conduct identified by the Commission which would be capable of creating obstacles to the market entry of generic products and to parallel imports.

813 The applicants repeatedly claim that there is no documentary evidence expressly indicating that AZ applied a 'malevolent' or 'intentional' strategy in Denmark, Norway and Sweden seeking to deregister the marketing authorisations in order to delay the market entry of generic products and to prevent parallel imports. In this respect, it is sufficient to note that the concept of abuse of a dominant position is an objective concept and does not require that an intention to cause harm be established (see, to that effect, *Aéroports de Paris* v *Commission*, paragraph 309 above, paragraph 173). It is common ground that AZ carried out those deregistrations in Denmark, Norway and Sweden. The alleged absence of any malevolent intention underlying that conduct cannot therefore preclude the Commission's classification of that conduct as an abuse of a dominant position where it is established that, in view of the objective context in which that conduct took place, the conduct was such as to delay or prevent the introduction of generic products and parallel imports.

814 In any event, it is quite clear from the documents on which the Commission relied that AZ intended, by means of those deregistrations, to obstruct the introduction of generic products and parallel imports. It is apparent inter alia from the document of 3 October 1997 setting out the MUPS strategy (see paragraph 776 above), and from the memorandum of 22 October 1997 on the consequences of the MUPS strategy (see paragraph 780 above), that AZ was aware of the utility that the deregistration of the Losec capsule marketing authorisations might have for the purposes of raising barriers to entry of a regulatory nature, with regard both to the introduction on the market of generic products and to parallel imports. Those documents also show that AZ was aware that the envisaged action might be caught by the European rules on competition and free movement of goods. The Commission further observed, in recital 302 of the contested decision, that the Norwegian LPP Strategy document indicates that AZ intended to deregister the Losec capsule marketing authorisations in order to bring an end to parallel imports and to make them 'virtually non existing from February 1, 1999' (see paragraph 788 above).

815 The applicants further claim that an obligation must not be imposed on AZ to protect the interests of companies marketing generics or of parallel importers by maintaining the marketing authorisations.

816 However, the Court observes that the fact that an undertaking in a dominant position is under no obligation to protect the interests of competitors does not make practices implemented solely to exclude competitors compatible with Article 82 EC. The mere desire of an undertaking in a dominant position to protect its own commercial interests and to guard against competition from generic products and parallel imports does not justify recourse to practices falling outside the scope of competition on the merits.

817 As was stated in paragraph 672 above, in the absence of grounds connected with the legitimate interests of an undertaking engaged in competition on the merits and in the absence of objective justification, an undertaking in a dominant position cannot use regulatory procedures solely in such a way as to prevent or make more difficult the entry of competitors on the market.

— The centralised nature of the strategy from which the abuse of a dominant position stems

818 The applicants contest the Commission's view that the abusive conduct results from a decision taken centrally at AZ's management level. In this respect, the Court would point out, first of all, that it is common ground that the marketing companies concerned are wholly owned by AZ (see recital 8 and footnote 10 of the contested decision). Under Community competition law different companies belonging to the same group form an economic unit and therefore an undertaking within the meaning of Articles 81 EC and 82 EC if those companies do not independently determine their own conduct on the market (*Michelin* v *Commission*, paragraph 334 above, paragraph 290).

819 To the extent that, by that argument, the applicants seek to dispute the existence of an abuse of a dominant position, the Court observes that, even if it were established, the applicants' assertion that the deregistrations of the marketing authorisations in Denmark, Norway and Sweden stem from a decentralised decision-making process would not, by definition, have any effect on the Commission's classification of the conduct at issue as an abuse of a dominant position. It is not necessary, in order that conduct can be classified as an abuse within the meaning of Article 82 EC, that it be implemented as a result of a strategy prepared at the management level of the group, or that it was adopted with the established intention of restricting competition.

Conduct implemented by one of the companies in the economic unit constituted by that group is also capable of infringing Article 82 EC.

820 Furthermore, as the Commission maintains, as the marketing companies are wholly owned by AZ, it is not necessary to examine whether AZ was able to exert decisive influence over the policy of its subsidiaries, since those subsidiaries necessarily follow a policy laid down by the same executive bodies as those which determine that parent company's policy (see, to that effect, *AEG-Telefunken* v *Commission*, paragraph 719 above, paragraph 50; 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 Maatschappij and Others* v *Commission* [1999] ECR II-931, paragraphs 961 and 984).

821 For the sake of completeness, the Court would point out that although the Commission has not established, on the basis of the documentary evidence, that the marketing authorisations in Denmark, Norway and Sweden were deregistered on the basis of specific instructions to that effect from AZ's management, the fact remains that those deregistrations are entirely consistent with the strategy prepared by AZ centrally. In this respect, all the documents to which the Commission referred emanate from AZ's central management and indicate that AZ's management bodies were heavily involved. Thus, the LPP Strategy of 29 April 1997 was prepared centrally and the specific issues regarding its implementation were also studied at that level. That is apparent, inter alia, from the minutes of the meeting of 18 September 1997, headed 'Losec MUPS i Europa — "Brain Storming"' (see paragraph 771 above), which emanates from the patent department in Sweden, from the document of 3 October 1997 on the MUPS Strategy (see paragraph 773 above) by Astra Hässle in Sweden, from the memorandum of 22 October 1997, headed 'Consequences of MUPS strategy — interim report' (see paragraph 779 above), whose author is a member of AZ's legal affairs department, and from the document of 12 May 1999 headed 'The Gastrointestinal

Franchise Plan' (see paragraph 784 above) by Astra Hässle. Those four documents show that the possibility of deregistering the Losec capsule marketing authorisations had been envisaged centrally by AZ and that the consequences of such deregistration on the introduction of generic products and on parallel imports had been examined at that level (see more specifically paragraphs 776, 779 and 780 above).

822 Moreover, it cannot be denied that the fax of 29 May 1998 from the managing director of the Swedish marketing company (who was also part of AZ's central management as 'regional director for the Nordic countries') to the managing directors of the Danish, Finnish and Norwegian marketing companies (see recital 815 of the contested decision) shows that AZ's management kept a close watch over the implementation of the defence strategy against generic products. The author of that document expresses his concern about the lack of dynamism and coordination displayed by the local marketing companies in implementing the LPP Strategy. The applicants' claim that that fax related only to legal actions designed to defend patents cannot be accepted in the absence of any supporting evidence, in view of the context in which that fax was sent, as shown by all the documentary evidence examined by the Commission.

823 The coordination drive between the marketing companies is, moreover, also evidenced by Astra Norway's letter of 22 October 1998 to the managing director of the Swedish marketing company, which refers to a 'Nordic … patent strategy' and which submits a third issue of the document setting out the Norwegian strategy. As the Commission maintains, that letter demonstrates the interactive nature of the relationship between the central and local levels in implementing the strategy at the local level.

Whether the conduct was restrictive of competition

824 The Court would point out, first of all, that, as regards conduct such as that at issue in the present case — in which regulatory procedures are used without any basis in competition on the merits — evidence that, in view of its economic or regulatory context, that conduct is capable of restricting competition is sufficient to classify it as an abuse of a dominant position.

825 In the present case, it was established in paragraphs 675 and 812 above that the deregistration of the Losec capsule marketing authorisations was not based on the legitimate protection of an investment which was part of competition on the merits and, moreover, was not required by the conversion of AZ's sales of Losec capsules to Losec MUPS.

826 Consequently, in so far as it is established that in Denmark, Norway and Sweden the deregistrations of the marketing authorisations were capable of constituting an obstacle to the market entry of generic products and to parallel imports, the applicants' arguments disputing the effects of those deregistrations in practice cannot affect the classification of the conduct in question as an abuse of a dominant position.

827 However, those arguments are capable of calling in question the merits of that classification in so far as the applicants maintain that the Commission has failed to establish to the requisite legal standard that, in view of the objective context in which that conduct was implemented, that conduct was such as to delay or prevent the

introduction on the market of generic products and parallel imports. It is therefore necessary to examine that point in the light of the applicants' grounds of complaint.

828 As regards, in the first place, the ability of the deregistration of the Losec capsule marketing authorisations to impair the introduction on the market of generic versions of omeprazole capsules, it should be recalled that the Court of Justice has held that, in order for an application for marketing authorisation of a generic medicinal product to be dealt with by way of the abridged procedure provided for in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65, the marketing authorisation of the reference medicinal product must be in force, at the very least, on the date when that application is lodged (*AstraZeneca*, paragraph 617 above, paragraph 49). AZ's conduct therefore made the abridged procedure referred to in that provision unavailable and was, consequently, such as to delay the grant of authorisations for the marketing of generic products in Denmark, Norway and Sweden.

829 The applicants assert however that potential competitors could have followed the procedure provided for in point 8(a)(ii) of the third paragraph of Article 4 of Directive 65/65, which enables the applicant to demonstrate, just by detailed references to published scientific literature, that the proprietary medicinal product for which a marketing authorisation has been applied has recognised efficacy and an acceptable level of safety. In this respect, the Court would point out, as the Commission observes, that the fact that the regulatory framework offers an alternative route to obtaining a marketing authorisation does not remove the abusive nature of the conduct of an undertaking in a dominant position where that conduct, considered objectively, has the sole object of making the abridged procedure provided for by the legislature in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 unavailable and, accordingly, of keeping producers of generic products away from the market for as long as possible and increasing their costs in overcoming barriers to market entry.

830 In this respect, it should be recalled, once again, that the basis for AZ's deregistering its marketing authorisations was not the legitimate protection of an investment designed to contribute to competition on the merits, since AZ no longer had the exclusive right to use the results of the pharmacological and toxicological tests and clinical trials which it had carried out and those deregistrations were not required by the conversion of AZ's sales of Losec capsules to Losec MUPS.

831 Moreover, the Court would point out that the fact that the Commission was not able to evaluate precisely the delay caused to competitors in gaining access to the market does not affect the finding that the conduct at issue was such as to restrict competition, since it is established that that deregistration resulted in the unavailability of the abridged procedure provided for in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65.

832 Furthermore, the fact that Article 7 of Directive 65/65 provides for a maximum period of 210 days in respect of procedures for granting authorisations to place proprietary medicinal products on the market does not mean that the delay caused to competitors in entering the market cannot be greater than that period. As the Commission observed in recital 854 of the contested decision, unless they were informed in advance about AZ's deregistrations of the marketing authorisations, producers of generic products could have been aware of them only once they had taken place. There is every reason to consider that it is only once the competitors became aware of those deregistrations that they would begin their research into collecting the published scientific literature for the purposes of obtaining the marketing authorisations in accordance with the procedure referred to in point 8(a)(ii) of the third paragraph of Article 4 of Directive 65/65. Before the procedure referred to in point 8(a)(iii) of the third paragraph of Article 4 of that directive was made unavailable, manufacturers of generic products had no reason to envisage using the published literature procedure.

833 The Court would also point out, as the Commission maintains, that the procedures other than that referred to in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65, such as the published literature procedure or the hybrid procedure (an intermediate procedure between the full marketing authorisation procedure and the procedure referred to in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65), require conditions to be satisfied — such as the submission of additional data — that go beyond those required by the procedure referred to in point 8(a)(iii) of the third paragraph of Article 4 of that directive. Those other procedures are therefore more burdensome for manufacturers of generic products and necessarily take more time than the abridged procedure referred to in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65.

834 The deregistrations of the marketing authorisations were therefore such as to enable AZ to delay, at least temporarily, the significant competitive pressure that generic products were to exert on it. It is apparent from the internal documents of AZ examined by the Commission that such a delay could be very useful for AZ, so as to ensure that prices were as high as possible pending the introduction on the market of esomeprazole at an advantageous price (see paragraphs 765 and 767 above). In addition, in view of the sales volumes at stake, any delay in the entry of generic products onto the market was worthwhile for AZ (see paragraph 764 above).

835 It follows from the foregoing that the fact, relied on by the applicants, that AZ's competitors could have obtained marketing authorisations by means of the published literature procedure does not suffice to make the deregistration of the Losec capsule marketing authorisations non-abusive, since that conduct solely served to exclude from the market, at least temporarily, competing manufacturers of generic products.

836 Furthermore, the fact, relied on by the applicants, that, first, AZ held a formulation patent in Sweden until 2007, and SPCs in respect of omeprazole sodium and the omeprazole substance until 4 February 2003 and, second, obtained injunctions against its competitors on the basis of its formulation patents or its SPCs in Denmark, Norway and Sweden, is irrelevant to the issue whether the deregistration of the marketing authorisations was anticompetitive. The fact that AZ had at its disposal various regulatory or judicial means — some of which were legitimate when viewed from the perspective of competition on the merits — to create obstacles to the introduction on the market of generic products and, therefore, that the conduct objected to was not the only course of conduct able to produce, or which did produce, the intended restriction of competition in no way makes that conduct non-abusive, since it is established that that conduct was in any event such as to restrict competition.

837 In addition, the fact that the complainants could have obtained the marketing authorisations on the basis of the abridged procedure referred to in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65, to the extent that they had filed their applications before the deregistrations of AZ's marketing authorisations became effective, is clearly incapable of making the conduct objected to non-abusive. Indeed, AZ is charged specifically with making that abridged procedure unavailable to any manufacturer of generic omeprazole capsules wishing to file an application for marketing authorisation after the effective deregistration of AZ's marketing authorisations.

838 As regards, in the second place, the ability of the deregistrations of the marketing authorisations to restrict parallel imports, the applicants dispute that those deregistrations are the cause of the decline in parallel imports of Losec capsules and maintain that the decline in those parallel imports is due to the success of Losec MUPS. It is necessary to examine the merits of that argument in relation to Denmark, Norway and Sweden respectively.

839 It should be borne in mind, in this respect, as was stated, in essence, in paragraphs 474 and 475 above, that it is incumbent on the Commission to adduce evidence capable of demonstrating the existence of the circumstances constituting an infringement of Article 82 EC (*Microsoft* v *Commission*, paragraph 32 above, paragraph 688), and any doubt of the Court must benefit, in proceedings for annulment of a decision finding an infringement and imposing a fine, the undertaking to which that decision is addressed (see, by analogy, *Coats Holdings and Coats* v *Commission*, paragraph 476 above, paragraphs 68 and 69).

840 With respect to Denmark, the Court observes that, in recital 311 of the contested decision, the Commission merely noted that an internal AZ Denmark board document indicated that the introduction on the market of Losec MUPS and the withdrawal from the market of Losec capsules 'meant exclusion of all omeprazole parallel import'. In the contested decision, the Commission does not therefore specify whether the parallel import licences for Losec capsules were revoked in Denmark by the public authorities.

841 The Commission maintains however that it is reasonable to take the view that there is a causal link between the deregistration of the marketing authorisation for Losec capsules in Denmark and the exclusion of parallel trade in that country.

842 In this respect, the Court would point out that, in reply to requests for preliminary rulings submitted to it by the Finnish and Swedish courts, the Court of Justice held that the withdrawal of marketing authorisations for reasons other than public health did not justify the automatic cessation of the parallel import licence where the protection of public health which pharmacovigilance seeks to ensure can be secured by alternative means, such as cooperation with the national authorities of the other Member States. Consequently, Articles 28 EC and 30 EC preclude the withdrawal of the marketing authorisation of a pharmaceutical product from entailing, of itself, the withdrawal of the parallel import licence granted for the medicinal product in question, if there is no risk to human health from maintaining that medicinal product on the market of the Member State of importation (Case C-15/01 *Paranova Läkemedel and Others* [2003] ECR I-4175, paragraphs 25 to 28 and 33, and Case C-113/01

Paranova [2003] ECR I-4243, paragraphs 26 to 29 and 34; see, also, *Ferring*, paragraph 659 above, paragraphs 38 to 40).

843 The Court would point out that the contested decision does not contain any indication that, before those judgments were delivered by the Court of Justice, it was the Danish authorities' practice to automatically withdraw parallel import licences following the withdrawal of the marketing authorisations for the relevant product for reasons unrelated to public health. In those circumstances, the Commission's argument that it is reasonable to take the view that there is a causal link between the deregistration of the marketing authorisations for Losec capsules in Denmark and the exclusion of parallel trade in that country amounts to postulating a presumption that the Danish authorities had withdrawn the parallel import licences, possibly in violation of European Union law.

844 In this respect, in reply to the Court's questions, the Commission maintains that the deregistration of the marketing authorisation created a situation of legal uncertainty as regards the validity of the parallel import licences for Losec capsules, and that it must therefore be found that that deregistration was capable of producing restrictive effects on competition. According to the Commission, it is clear that, had the marketing authorisations not been deregistered, the national authorities would undoubtedly have allowed parallel trade in Losec capsules to continue.

845 The Court would however point out, as was held in paragraph 824 above, that the classification as an abuse of a dominant position of conduct such as that at issue in the present case, which consists in the use of regulatory procedures without any basis in competition on the merits, requires at the very least evidence that, in view of the

economic or regulatory context surrounding that conduct, that conduct is such as to restrict competition.

846 In accordance with the judgment in *Coats Holdings and Coats* v *Commission*, paragraph 476 above, paragraphs 68 and 69, it is therefore incumbent on the Commission to adduce tangible evidence showing that, in the present case, in view of the regulatory context in question, the national authorities were liable to withdraw or did usually withdraw parallel import licences following the deregistration, at the request of their holder, of the marketing authorisations for the relevant product.

847 However, in relation to Denmark, the Commission has not adduced any evidence showing to the requisite legal standard that the Danish authorities were likely to withdraw, in violation of Articles 28 EC and 30 EC, the parallel import licences following AZ's deregistration of its marketing authorisations. Furthermore, the Court would point out that, in the contested decision, the Commission did not even establish that the Danish authorities had revoked the parallel import licences for Losec capsules.

848 In this respect, the Court would point out that, in view of the regulatory context in the present case, the memorandum of 22 October 1997 (see paragraphs 779 and 780 above), in which AZ's in-house counsel expressed the opinion that 'several of the Scandinavian authorities generally would take' the position that the parallel import licences could not be upheld after deregistration of the marketing authorisations (see recital 283 of the contested decision), cannot constitute sufficient evidence. That document reflects only the personal opinion, or the expectations, of AZ employees regarding the reaction of 'several of the Scandinavian authorities', but does not establish that the Danish authorities were actually inclined to withdraw, potentially in violation of Articles 28 EC and 30 EC, the parallel import licences as a result of AZ's deregistration of its marketing authorisation for reasons unrelated to public health.

Furthermore, that document is insufficient to establish that the cessation of parallel imports in Denmark is caused by AZ's deregistration of the Losec capsule marketing authorisation.

849 At the very most, there are grounds for considering that that document shows AZ's intention to exclude parallel imports by deregistering the Losec capsule marketing authorisation. However, the Court would point out that, although the intention of an undertaking in a dominant position to restrict competition by methods falling outside the scope of competition on the merits may be taken into consideration in the identification of an abuse of a dominant position, that identification must first and foremost be based on the objective finding of conduct which, in the context in which it is implemented, is such as to restrict competition.

850 Moreover, the reference to an AZ Denmark board document (recital 311 of the contested decision), in which it is stated that '[i]n March 1998, Losec MUPS was introduced and in April Losec capsules [were] withdrawn from the market[, which] meant exclusion of all omeprazole parallel import', cannot establish to the requisite legal standard that the deregistration of the Losec capsule marketing authorisations was capable of resulting in the cessation of those parallel imports. In that document, no link is established between the deregistration of the Losec capsule marketing authorisation and the exclusion of parallel imports.

851 At most, that document indicates a link between, on the one hand, the swing of AZ's sales of Losec capsules towards Losec MUPS and, on the other, the exclusion of parallel imports of Losec capsules. However, the applicants specifically claim that the decline in, or cessation of, parallel imports of Losec capsules is due to consumers migrating towards Losec MUPS and, therefore, to the decline in consumption of Losec

capsules. As is apparent from the documents before the Court, that was the effect sought by AZ in its strategy of tilting its activities towards the sale of Losec MUPS.

852 Accordingly, in the absence of any indication in this respect in the contested decision and in view of the fact that it is not even established that the Danish authorities revoked the parallel import licences for Losec capsules, a presumption of a causal link between the deregistration of the Losec capsule marketing authorisation in Denmark and the cessation of the parallel imports of that product in that country is incompatible with the principle that doubt must operate to the advantage of the addressee of the decision finding the infringement, as held by the Court in *Coats Holdings and Coats* v *Commission*, paragraph 476 above (paragraphs 68 to 70). Similarly, in view of the judgments in *Paranova Läkemedel and Others*, *Paranova*, paragraph 842 above, and *Ferring*, paragraph 659 above, the Commission was not entitled to find, in the absence of any evidence on that point, that the deregistration of the marketing authorisation was such as to lead to the withdrawal of the parallel import licences in Denmark.

853 The Commission further claims that the applicants admit that the deregistration of the marketing authorisation resulted in the prohibition on parallel trade by the public authorities. The Court finds however that such an explicit admission by the applicants cannot be identified in their pleadings and that such an admission cannot be inferred *a contrario* without creating the risk of distortion or misrepresentation of their arguments.

854 The Court must also reject the Commission's claim that the applicants do not contest, in their pleadings, that the Commission established a causal link between the deregistrations of the Losec capsule marketing authorisations in Denmark, Norway and Sweden and the decline in parallel imports in those countries. In their pleadings, the applicants do indeed dispute that the Commission established that causal link.

855 The Court therefore considers that the Commission has failed to establish to the requisite legal standard that the deregistration in Denmark of the Losec capsule marketing authorisation was capable of excluding parallel imports of those products.

856 As regards Norway, the Court observes that, in recital 321 of the contested decision, the Commission noted that parallel imports of Losec had fallen sharply from 1998 onwards, but had not entirely disappeared. The Commission found that the Norwegian authority had allowed parallel imports of Losec capsules to continue by reference to AZ's marketing authorisation for Losec MUPS, which was itself based on the marketing authorisation for Losec capsules.

857 In this respect, the Court observes that, in its judgment in *Rhône-Poulenc Rorer and May & Baker*, paragraph 622 above (paragraph 48), the Court of Justice held that, in circumstances similar to those at issue in the present case, the national authority of a Member State of importation was entitled to grant an import licence for the first version of a pharmaceutical product in respect of which the reference marketing authorisation had been withdrawn in that State, where a marketing authorisation for the second version of that pharmaceutical product had been granted in that Member State of importation. Thus, in the present case, the Norwegian authority's allowing parallel imports of Losec capsules to continue by reference to AZ's marketing authorisation for Losec MUPS is consistent with the regulatory practice allowed by the Court of Justice.

858 Although, as the Commission observes in recital 321 of the contested decision, parallel imports fell sharply in Norway, it cannot be presumed in the present case, for the reasons set out in paragraphs 842 and 846 above, that the deregistration of the Losec capsule marketing authorisation in those countries caused that fall. The fact that the Norwegian authority upheld the parallel import licences for Losec capsules also tends

to show that the fall in parallel imports was not necessarily caused by the deregistration of the marketing authorisations.

859 Thus, for the reasons set out in paragraph 852 above, namely that it is incumbent on the Commission to establish evidence capable of demonstrating the existence of an abuse of a dominant position, the Commission was not entitled, in the present case, without evidence, to take the view that the deregistration of the Losec capsule marketing authorisation in Norway for reasons unrelated to public health was such as to lead to the withdrawal of the parallel import licences for that product in that country, or presume that the sharp fall in parallel imports of Losec capsules had been caused by the deregistration of the marketing authorisation pertaining to that product.

860 In order to assess the anticompetitive nature of the conduct in question with respect to parallel imports, it was therefore incumbent on the Commission to establish, at the very least, what the practice of the Norwegian authorities was in relation to the conditions for granting parallel import licences.

861 The Court therefore considers that the Commission has also failed to establish to the requisite legal standard that the deregistration in Norway of the Losec capsule marketing authorisation was capable of excluding parallel imports of Losec capsules.

862 As regards Sweden, on the other hand, it is not disputed that the Swedish Medical Products Agency considered that parallel import licences could be granted only if valid marketing authorisations were in place (recital 315 of the contested decision). Furthermore, it is also established that that agency withdrew the parallel import licences as a result of the deregistration of the Losec capsule marketing authorisation, although an extension of six months of an authorisation was granted to a parallel

importer (see paragraph 798 above). It is unambiguously clear from this that the deregistration of the marketing authorisations was such as to impede parallel imports.

863 The fact that the Commission is not in a position to evaluate precisely the effect that that deregistration had on parallel imports does not affect the abusive nature of that conduct, since it is established that that conduct was capable of impeding parallel imports and that, moreover, it did indeed impede them in the present case.

Conclusion

864 In the light of all the foregoing, the Court holds that the Commission did not err in finding that AZ's deregistration of the Losec capsule marketing authorisations in Denmark, Norway and Sweden, in conjunction with the swing in AZ's sales from Losec capsules towards Losec MUPS in those countries, amounted to an abuse of a dominant position, inasmuch as it was such as to restrict access to the market of generic products in those countries. Similarly, the Commission did not err in taking the view that that conduct constituted an abuse of a dominant position in Sweden, inasmuch as it was such as to restrict parallel imports of Losec capsules in that country.

865 The second plea must however be upheld to the extent that it alleges an error by the Commission inasmuch as it considered that the conduct objected to constituted an abuse of a dominant position in Denmark and in Norway in so far as it restricted parallel trade in Losec capsules. The Commission has failed to establish to the requisite legal standard that the deregistration of the Losec capsule marketing authorisations was capable of restricting parallel imports of Losec capsules in those two countries.

E — *Fines*

1. *Arguments of the parties*

866 The applicants are requesting the Court to annul the fines totalling EUR 60 million, or reduce them significantly.

867 They state that Article 1 of Regulation (EEC) No 2988/74 of the Council of 26 November 1974 concerning limitation periods in proceedings and the enforcement of sanctions under the rules of the European Economic Community relating to transport and competition (OJ 1974 L 319, p. 1) and Article 25 of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 [EC] and 82 [EC] (OJ 2003 L 1, p. 1) limit the power of the Commission to impose fines for an infringement of Article 82 EC to actions which have taken place within five years of an action taken in the investigation which was notified to AZ. However, AZ first became aware of the Commission's investigation of

this case on 24 February 2000. Accordingly, the Commission may impose fines only for conduct which is shown to have been engaged in after February 1995.

868 With regard the first alleged abuse of a dominant position, the applicants state that, according to the Commission, the conduct at issue took place between 7 June 1993 and 31 December 2000 in Belgium and the Netherlands, 7 June 1993 and 30 November 1994 in Denmark, 7 June 1993 and 31 December 1997 in Germany, 21 December 1994 and 31 December 2000 in Norway and 7 June 1993 and 16 June 1994 in the United Kingdom. As regards the second abuse of a dominant position, the conduct objected to occurred over the periods between 19 March 1998 and 31 December 1999 in Denmark, 1 November 1998 and 31 December 2000 in Norway and 20 August 1998 and 31 December 2000 in Sweden.

869 In the applicants' submission, with respect to the first abuse of a dominant position, there are therefore, between the cessation of the alleged infringement and the first action taken by the Commission in the course of the investigation, time differences of five years and three months in Denmark and five years and eight months in the United Kingdom, which preclude the Commission from fining AZ for its conduct in those countries. Moreover, the conduct complained of in Germany and Norway, which is alleged to have occurred after February 1995, in relation to the third stage of the abuse of a dominant position, consisting of misrepresentations to the courts, has not been substantiated by any evidence.

870 According to the applicants, the Commission characterises the alleged abuses as a single and continuous infringement in order to ensure that the limitation rules do not preclude the imposition of fines for the alleged offences in Denmark and the United Kingdom. They point out, in that regard, that a single and continuous infringement requires that the different acts pursue an identical anticompetitive object, that similar

instruments and mechanisms are used in the different cases and that the company in question was, in all cases, aware of all the constituent elements of the infringement (Commission Decision of 26 May 2004 relating to a proceeding under Article 81 EC against The Topps Company Inc, Topps Europe Limited, Topps International Limited, Topps UK Limited and Topps Italia SRL (COMP/C-3/37.980 — Souris/Topps), recital 130, a summary of which is published in the Official Journal of 13 December 2006 (OJ 2006 L 353, p. 5), and Joined Cases C-204/00 P, C-205/00 P, C-211/00 P, C-213/00 P, C-217/00 P and C-219/00 P *Aalborg Portland and Others* v *Commission* [2004] ECR I-123, paragraph 258).

871 However, AZ's conduct in relation to the alleged first and second abuses of a dominant position was not pursued with an identical anticompetitive object. In that regard, the applicants make clear that they do not claim that the fact that the alleged abuse of a dominant position occurs in different countries precludes a finding of identical anticompetitive conduct. Moreover, the relevant AZ companies did not have knowledge of all the constituent elements of the abuses, since their conduct did not result from communication with other companies in the group or from instructions from the head office whose purpose was to implement anticompetitive behaviour. In addition, the applicants point out that the Commission admitted that the infringements in question were novel and were not clear cut (recital 908 of the contested decision). The Commission admitted that the constituent elements of the second abuse of a dominant position, namely the development of Losec MUPS tablets, their launch and the withdrawal of Losec capsules, the requests for deregistration of the marketing authorisations for a pharmaceutical product (recital 792 of the contested decision) and allowing a marketing authorisation to lapse, do not normally constitute abuses of a dominant position. In addition, the Commission does not take issue with AZ's interpretation of the regulatory frameworks relevant to the two abuses of a dominant position (recitals 666 and 830 of the contested decision). In those circumstances, the Commission cannot maintain that AZ was aware of all the constituent elements of the two alleged abuses of a dominant position.

872 In the reply, the applicants further argue that the issue of whether the alleged abuses of a dominant position constitute a single and continuous infringement is key to determining whether the Commission is entitled to impute responsibility for those actions and to impose a fine accordingly, on the basis of participation in the infringement considered as a whole.

873 The applicants also submit that, in the light of the novelty of the alleged abuses of a dominant position in this case, which is accepted by the Commission in recital 922 of the contested decision, the latter should have refrained from imposing a fine.

874 In the applicants' submission, the alleged abuses of a dominant position cannot be considered to be serious. In that regard, they again point out, inter alia, that the Commission has admitted that the alleged abuses of a dominant position were novel (recitals 904, 908 and 922 of the contested decision) and were not clear cut (recital 908 of the contested decision), that it does not dispute AZ's interpretation of the law (recital 803 of the contested decision), and that the impact of the infringements on the market cannot be precisely assessed (recitals 911 and 913 of the contested decision). The applicants refer to Commission Decision 2001/892/EC of 25 July 2001 relating to a proceeding under Article 82 [EC] (COMP/C-1/36.915 — Deutsche Post AG — Interception of cross-border mail) (OJ 2001 L 331, p. 40), in which the novel nature of the abuse of a dominant position in question was taken into consideration. They submit that the fact that there are 'precedents' in United States law is irrelevant, since the decisive factor is that the alleged abuses of a dominant position are novel under Community law.

875 The applicants dispute the Commission's contention that the novelty of the abuses of a dominant position was taken into account, in the contested decision, inasmuch as the infringements were classified as 'serious' rather than 'very serious', and point out that recital 913 of the contested decision does not mention the novel nature of the

abuses and makes no reference to the classification of the infringements as 'very serious', from which a downgrading is claimed to have taken place.

876 The applicants state that the Commission did not identify the basic amount for each company and for each of the alleged abuses of a dominant position, thus preventing AZ from assessing the amounts corresponding to the duration of each of the abuses and to the aggravating and mitigating circumstances. Since the Commission concluded that AZ had committed a serious infringement, the fine imposed should not exceed EUR 20 million (Guidelines on the method of setting fines imposed pursuant to Article 15(2) of Regulation No 17 and Article 65(5) of the ECSC Treaty (OJ 1998 C 9, p. 3, 'the Guidelines on the method of setting fines') point 1.A). On the assumption that the Commission imposed that maximum basic amount for each of the alleged abuses of a dominant position, it is disproportionate having regard to their novelty.

877 Moreover, the Commission cannot claim, as it does in recital 904 of the contested decision, that the purpose of AZ's conduct was to restrict competition, since it used only legal means and it was accepted, in recitals 666 and 830 of the contested decision, that its interpretation of the legal and regulatory regimes was held in good faith. Similarly, the applicants dispute the allegation that AZ was aware of the alleged infringements after the merger in April 1999. They refer, in that regard, to paragraphs 18 to 21 of the witness statement of Mr G., the author of the notes on the meeting of January 2000, relied upon by the Commission in recitals 886 and 890 of the contested decision, to paragraph 63 of the witness statement of Mr P. and to paragraphs 18 to 20 of the witness statement of Dr N. The applicants submit that that evidence cannot be disregarded by the Commission and point out that the Guidelines on the method of setting fines provide that 'infringements committed as a result of negligence or unintentionally' are an attenuating circumstance.

878 With regard to the duration of the infringement, the applicants also complain that the Commission provided an incomplete statement of reasons. They maintain that it appears that the Commission considered each of the alleged abuses of a dominant position differently under duration, in contrast to what was the case as regards gravity (recitals 917, 918 and 946 of the contested decision).

879 In recital 918 of the contested decision, the Commission maintained that the first alleged abuse of a dominant position could deploy its main effects only when the patents expired. However, the SPCs were granted only in Belgium, the Netherlands, Luxembourg and Norway and only came into force in April 1999. The abuses of a dominant position could not, therefore, have taken place before that date. Moreover, by that date, Astra's dominance had ceased in the first three abovementioned countries and, in the case of Norway, the SPC took effect for only two months, at a time when competition was, in any event, precluded by the existence of a formulation patent.

880 The applicants note that, in recital 918 of the contested decision, the Commission considered that, for the pre-1998 phase, an additional percentage of 5% for each full year and 2.5% for any period of between six months and one year should apply, and that, for the post-1998 phase, an additional percentage of 10% for each full year and 5% for any period of between six months and one year should apply. Consequently, in the applicants' submission, the Commission's calculations are incorrect. In their view, the total amount of the fine for the alleged abuse of a dominant position concerning SPCs before 1998 is EUR 9 million, the total amount of the fine for the alleged abuse of a dominant position concerning SPCs after 1998 is EUR 12 million and the total amount of the fine for the alleged abuse of a dominant position concerning MUPS after 1998 is EUR 10 million. Consequently, the total for the duration of the infringements is EUR 31 million. Moreover, accepting the Commission's conclusion, set out in recitals 919 and 920 of the contested decision, that an increase of 50% for AstraZeneca AB and 15% for AstraZeneca plc should be applied after 6 April 1999,

the total payable by AstraZeneca plc would be EUR 12 million. Accordingly, the applicants arrive at a grand total of EUR 43 million for the duration of the alleged infringements. They therefore do not understand how the Commission concluded that the final amount was EUR 60 million.

881 The applicants further submit that the Commission should have conceded that there were mitigating circumstances. They observe, in that regard, that, in relation to the first abuse of a dominant position, the Commission did not take issue with AZ's interpretation of Regulation No 1768/92 (recital 666 of the contested decision). Nor, in relation to the second abuse of a dominant position, did the Commission take issue with AZ's interpretation of the legal and regulatory regimes or dispute that Directive 65/65 does not impose on the holder of a marketing authorisation an obligation to maintain that authorisation (recital 832 of the contested decision). The Commission further conceded that the market launch and market withdrawal of a pharmaceutical product, or the request for deregistration of its marketing authorisation are not normally regarded as abusive in themselves (recitals 792 and 793 of the contested decision). Finally, the Commission conceded that both alleged abuses of a dominant position are novel (recitals 908 and 922 of the contested decision).

882 In addition, the applicants dispute that AZ refused for one year to respond to a request for information and claim that AZ provided information which had not been requested. AZ's cooperation with the investigation therefore justifies the application of a mitigating circumstance.

883 The Commission contests the merits of the applicants' arguments.

2. *Findings of the Court*

884 The Court notes, as a preliminary point, that, although in the body of the arguments set out in their application and in their reply, the applicants are also asking the Court to reduce the amount of the fines, the applicants did not, in the form of order sought, formally seek an order that their amount should be reduced. That omission by the applicants does not however preclude the Court's exercising its unlimited jurisdiction in relation to fines. Even in the absence of any formal submission, the Court is authorised to reduce the amount of an excessive fine since such a result would not be *ultra petita*, but would on the contrary amount to a partial acceptance of the application (Case 8/56 *ALMA* v *High Authority* [1957 and 1958] ECR 95, at 100; see, also, to that effect, Joined Cases T-202/98, T-204/98 and T-207/98 *Tate & Lyle and Others* v *Commission* [2001] ECR II-2035, paragraphs 22 and 164).

885 The applicants dispute the level of the fines by means of four complaints relating to (i) the argument that a time bar exists in respect of some of the actions objected to, (ii) the gravity of the infringements, (iii) their duration and (iv) mitigating circumstances.

886 As regards, first, the complaint that there is a time bar in respect of some of the actions alleged against AZ, the Court would point out, first of all, that, under Article 1 of Regulation No 2988/74, the power of the Commission to impose fines for infringements of the competition rules is subject to a limitation period of five years, and that, in the case of continuing or repeated infringements, that period is to begin to run on the day on which the infringement ceases. According to Article 2 of that regulation, any action taken by the Commission for the purpose of the preliminary investigation or proceedings in respect of an infringement interrupts the limitation period in proceedings, that interruption taking effect from the date on which the action is notified to at least one undertaking which has participated in the infringement.

887 The applicants assert — and the Commission does not dispute — that they first became aware of the Commission's investigation on 24 February 2000. According to the applicants, the Commission is not therefore entitled to impose a fine on AZ for an infringement which ended on 23 February 1995 at the latest. It is therefore necessary to examine whether the infringements in question ended before 24 February 1995.

888 In this respect, the Court observes that the Commission found, in recital 916 of the contested decision, that the first abuse of a dominant position had 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. In recital 917 of the contested decision, the Commission found that the second abuse of a dominant position had lasted until the end of 1999 in Denmark and until the end of 2000 in Norway and Sweden.

889 Consequently, the Court would point out that, since it was only AZ's actions in respect of the first abuse of a dominant position in Denmark and the United Kingdom which ended before 24 February 1995, namely on 3 November and 16 June 1994 respectively, the applicants' plea that there is a time bar in respect of AZ's actions can be relevant only in relation to AZ's actions in Denmark and the United Kingdom in the context of the first abuse of a dominant position.

890 In the contested decision, the Commission found that the single and continuous nature of the first abuse of a dominant position followed from the high degree of centralisation and coordination which characterised the abusive behaviour. The Commission observed, moreover, that the misleading representations made by AZ in the various countries were interdependent since AZ's conduct in one Member State of the EEA affected, at least potentially, its SPC protection and its chances of obtaining SPCs in other EEA Member States. The Commission thus observed that the SPC protection obtained by AZ in Belgium, Norway and the Netherlands depended on the outcome of the proceedings before the German courts (see recital 775 of the contested decision). The Commission also observed that the Belgian, Danish, Dutch and Norwegian pharmaceutical authorities set prices of pharmaceutical products on the

basis of comparison of the prices in force in the various States. Consequently, prices in one country were liable to affect those in the other countries (recital 776 of the contested decision).

891 The applicants dispute however that the first abuse of a dominant position is of a single and continuous nature and submit that the Commission was not entitled to impose a fine for AZ's conduct in Denmark and the United Kingdom.

892 The Court would point out, in this respect, that the concept of a single and continuous infringement relates to a series of actions which form part of an 'overall plan' because their identical object distorts competition within the common market (*Aalborg Portland and Others* v *Commission*, paragraph 870 above, paragraph 258). For the purposes of characterising various instances of conduct as a single and continuous infringement, it is necessary to establish whether they complement each other inasmuch as each of them is intended to deal with one or more consequences of the normal pattern of competition and, by interacting, contribute to the realisation of the objectives intended within the framework of that overall plan. In that regard, it will be necessary to take into account any circumstance capable of establishing or casting doubt on that complementary link, such as the period of application, the content (including the methods used) and, correlatively, the objective of the various actions in question (Joined Cases T-101/05 and T-111/05 *BASF and UCB* v *Commission* [2007] ECR II-4949, paragraphs 179 and 181).

893 In the present case, and as is apparent from paragraphs 591 to 599 above, AZ adopted a consistent course of conduct over time, characterised by the communication to the patent offices of misleading representations for the purposes of obtaining the issue of SPCs to which it was not entitled or to which it was entitled for a shorter period. It is apparent from the examination of the first abuse of a dominant position that AZ's

conduct stemmed from a strategy prepared by its central bodies, which, having established that the acquisition of SPCs in Germany and Denmark was probably impossible, initiated an information-collection exercise and ultimately decided to ask the patent attorneys to make misleading representations to the national patent offices as to the date of first marketing authorisation of omeprazole (see paragraphs 479 to 489 above and, more specifically, Hässle's decision of 6 May 1993). It is also apparent from the various documents in the case-file, including the fax of 11 October 1996 from the head of the patent department to the Dutch marketing company (see paragraph 528 above) and the minutes of a meeting of 15 November 1994 in Copenhagen (see paragraph 551 above), that AZ deliberately applied a strategy of misleading the national patent offices as to the date of issue of the first marketing authorisation for omeprazole, in order to obtain SPCs in Germany and Denmark.

894 It is also clear from the examination of the second plea raised in the context of the first abuse of a dominant position that, first, AZ made misleading representations in all the countries concerned, including those in which there was no obstacle to obtaining SPCs, in order to give a semblance of consistency to its misrepresentations. Second, AZ chose not to argue its case in Denmark so as not to jeopardize its arguments for the proceedings in Germany. Indeed, AZ withdrew its SPC application in Denmark in order to avoid a rejection decision, which would constitute a precedent which might prejudice its chances of maintaining its SPC in Germany (see paragraphs 552 to 554 above). Moreover, the fact that the head of the patent department felt the need to send the letters of 8 May 1998 in identical terms to the patent offices of the Benelux countries and of Finland in order to inform them of the proceedings pending in Germany corroborates the finding that AZ considered that the outcome of those proceedings was important also with regard to its SPCs in the other Member States (see also recital 227 of the contested decision).

895 In view of all those factors, the Court considers that the Commission did not err in its classification of the facts in finding that AZ's actions in Germany, Belgium, Denmark, Norway, the Netherlands and the United Kingdom were part of a single and continuous infringement. In those countries, the purpose of those actions was to obtain SPCs to which AZ was not entitled or to which it was entitled for a shorter period. The misleading representations made to the various national authorities were moreover, to a certain extent, interdependent, in that the reactions of the patent office or the judicial authorities of one country were capable of influencing the conduct of the authorities in the other countries and, therefore, of affecting AZ's proprietorship of SPCs in those countries.

896 Moreover, the applicants do not put forward any arguments calling in question those findings. Thus, first of all, their arguments are irrelevant to the extent that they seek to contest the single and continuous nature of the second abuse of a dominant position, since, as is apparent from paragraph 889 above, the expiry of the limitation period would not in any event be capable of hindering the imposition of a fine for the acts coming within the scope of that second abuse.

897 Next, the applicants' assertion that the AZ companies did not have knowledge of all the constituent elements of the infringement would be irrelevant even if it were established, since it has been demonstrated that the patent department and Hässle devised the strategy based on the misleading representations with knowledge of the facts and closely followed the course of events in the relevant countries.

898 Lastly, as the Commission maintains, in so far as, in their reply, the applicants dispute the single and continuous nature of the infringement in order to call in question the imputation of liability for the infringement considered as a whole, that argument not

only lacks clarity but also amounts to a new argument and must, on this ground, be declared inadmissible pursuant to Article 48(2) of the Rules of Procedure.

899 In the light of the foregoing, the Court must reject the applicant's first complaint, namely that a time bar exists in respect of some of the actions alleged against AZ.

900 As regards, second, the complaint that the infringement was not serious, the Court would point out, first of all, that both abuses of a dominant position had the stated aim of keeping competitors away from the market.

901 In so far as it consisted in misleading representations made deliberately in order to obtain exclusive rights to which AZ was not entitled or to which it was entitled for a shorter period, the first abuse of a dominant position quite clearly constitutes a serious infringement. The fact that that abuse is novel cannot call that finding into question, given that such practices are manifestly contrary to competition on the merits. Moreover, as the Commission observes, the fact that conduct with the same features has not been examined in past decisions does not exonerate an undertaking (see, to that effect, *Nederlandsche Banden-Industrie-Michelin* v *Commission*, paragraph 30 above, paragraph 107). With respect to the second abuse of a dominant position, it is also established that the purpose of the deregistrations of the marketing authorisations was to create obstacles to the market entry of generic products in Denmark, Norway and Sweden and to parallel imports in Sweden, thus resulting in partitioning of the common market.

902 Although the practices objected to in the first abuse of a dominant position did not always produce the effects anticipated by AZ, and although the Commission was not able to identify precisely the extent to which the second abuse of a dominant position affected competition on the relevant markets, the fact remains that those practices were highly anticompetitive, in that they were capable of having a significant effect on competition. The Court would point out, in this respect, 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 effects (Case T-141/94 *Thyssen Stahl* v *Commission* [1999] ECR II-347, paragraph 636, and *Michelin* v *Commission*, paragraph 334 above, paragraph 259).

903 In the light of the foregoing, and in view of the considerable income generated by Losec in the relevant countries — which, as the Commission observes in recital 914 of the contested decision, was the best-selling medicinal product in the world for several years — there is no reason to alter the classification of the abuses of a dominant position at issue as serious infringements. The fact that, in recital 908 of the contested decision, the Commission took into account that the abuses of a dominant position at issue were novel and that they did not constitute clear-cut abuses does not alter that position.

904 As regards the starting amount for gravity of the two abuses of a dominant position at issue, the Commission set that amount at EUR 40 million (recital 915 of the contested decision, in which the starting amount is erroneously referred to as the 'basic amount'). In cases of serious infringements, the Guidelines on the method of setting fines provide for a likely fine of EUR 20 million per infringement. Although the Commission did not make it explicitly clear, there is no doubt that it doubled that amount to reflect the fact that two abuses of a dominant position were identified.

905 However, since the Court has found, in paragraphs 840 to 861 above, that the Commission failed to establish to the requisite legal standard that the deregistrations of the marketing authorisations at issue in the second abuse of a dominant position were capable of preventing or restricting parallel imports in Denmark and Norway, it is appropriate to reduce the starting amount. Since the Commission set a basic amount of EUR 20 million in respect of the second abuse of a dominant position, the Court considers, in the exercise of its unlimited jurisdiction, that it would be fair to reduce the fine by setting the starting amount for the second abuse of a dominant position at EUR 15 million. It is therefore necessary to set the total starting amount of the fine in respect of the two abuses of a dominant position at EUR 35 million, instead of the EUR 40 million set by the Commission.

906 In any event, the applicants cannot complain that the Commission did not specify the starting amount imposed on each company for each of the abuses of a dominant position at issue. It should be borne in mind, in this respect, that the Commission is not bound to break down the amount of the fine between the various aspects of the abuse, or to state specifically how it took into account each of the components of the abuse for the purposes of setting the fine (judgments of 6 October 1994 in Case T-83/91 *Tetra Pak* v *Commission*, paragraph 671 above, paragraph 236, and *Michelin* v *Commission*, paragraph 334 above, paragraph 265). In addition, the Commission cannot divest itself of its own power of assessment by mechanical recourse to arithmetical formulas alone (Case C-291/98 P *Sarrió* v *Commission* [2000] ECR I-9991, paragraph 76).

907 As regards, thirdly, the complaint concerning the duration of the infringements, the Court would point out that the Commission took the view that, between 1993 and 1998, only the first abuse of a dominant position had been implemented and that it could not normally produce any effects until a later date, when the patents expired, although it was not inconceivable that effects might have arisen before that time. It therefore decided to apply an increase of 5% per year and 2.5% per period of between six months and one year in respect of the period prior to 1998. For the remainder of the period concerned (from 1998 to 2000), the Commission decided to apply a rate of

10% per full year and 5% per period of between six months and one year. Moreover, it took account of the fact that AstraZeneca plc should be held liable for the infringements only from 6 April 1999 onwards. Thus, to the starting amount of EUR 40 million imposed on AstraZeneca AB and AstraZeneca plc, the Commission applied an increase of 50% for AstraZeneca AB and 15% for AstraZeneca plc (see recitals 918 to 920 of the contested decision).

908 As the Commission confirms in its defence, it follows that a rate of increase of 5% was applied in respect of 1994, 1995, 1996 and 1997, which results in a cumulative increase of 20% for the period 1994-1997. A rate of 10% was then applied in respect of 1998, 1999 and 2000, which leads to a cumulative increase of 30% for the period 1998-2000. A total increase of 50% is therefore applied for the period between 1994 and 2000. Since AstraZeneca plc was held liable only from 6 April 1999 onwards, the increase applicable to it covers the period between April 1999 and 31 December 2000 and therefore amounts to 15%. The remaining 35% must therefore be borne exclusively by AstraZeneca AB.

909 Since 15% of EUR 40 million amounts to EUR 6 million, the Commission imposed the sum of EUR 46 million on the two applicants jointly and severally. Moreover, EUR 14 million, which corresponds to 35% of EUR 40 million, was imposed exclusively on AstraZeneca AB.

910 Although the Commission did not explain in so much detail in the contested decision how it arrived at the amounts of EUR 46 million and EUR 14 million, the Court does not consider that the Commission overlooked its obligation to provide a statement of reasons, since the material in the contested decision makes it possible to

understand how the Commission arrived at the final amounts of EUR 46 million and EUR 14 million.

911 The Court takes the view that is not necessary to change the methodology used by the Commission, which takes account of the fact that the second abuse of a dominant position commenced only in March 1998. The applicants' arguments, which seek to apply different calculation methods, must therefore be rejected. Moreover, with respect to the arguments that the Commission took insufficient account of the fact that the first abuse of a dominant position did not produce any effects, it should be borne in mind, once again, 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 effects (*Thyssen Stahl* v *Commission*, paragraph 902 above, paragraph 636, and *Michelin* v *Commission*, paragraph 334 above, paragraph 259).

912 The Court observes, moreover, that the Commission's error of law in finding that the first abuse of a dominant position started on the date on which the instructions to file the SPC applications at the patent offices were transmitted to the patent attorneys (see paragraphs 370 to 372 above) has no effect on the rate of increase applied for the duration of the infringements. Indeed, it is apparent that the period between 7 June and 31 December 1993 was not in any event taken into account by the Commission for the purposes of calculating the rate of increase.

913 Accordingly, given that the Court has decided to reduce the starting amount of the fine to EUR 35 million to reflect the fact that the Commission has failed to establish to the requisite legal standard that the deregistrations of the marketing authorisations at issue in the second abuse of a dominant position were capable of preventing or restricting parallel imports in Denmark and Norway, it is necessary to apply to that amount the rates of increase referred to in paragraph 908 above. The Court therefore

considers that it is appropriate to impose on the two applicants jointly and severally a fine of EUR 40 250 000 and on AstraZeneca AB exclusively a fine of EUR 12 250 000.

914 As regards, fourthly, the complaint concerning mitigating circumstances, the Court observes that the applicants reiterate once more the arguments taken into consideration at the stage of examining the abuses of a dominant position or assessing the gravity of the infringement. Furthermore, the applicants do not substantiate their claim that their cooperation during the administrative procedure would justify the application of a mitigating circumstance. The Court must therefore reject that last complaint.

Costs

915 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Article 87(3) of those regulations provides that where each party succeeds on some and fails on other heads, or where the circumstances are exceptional, the Court may order that the costs be shared or that each party bear its own costs.

916 The Commission requests the Court to order the applicants to bear all the costs, whatever the outcome of the proceedings before the Court. In its submission, first of all, the pleadings have been unnecessarily long, secondly, the Commission has had to examine a large number of 'witness statements' that were possibly inadmissible as evidence and, lastly, the applicants have distorted both the contested decision and the defence.

917 In this respect, although the applicants' pleadings might have been less voluminous in the present case, the Court finds that the applicants did not make the proceedings before it unreasonably burdensome (see, to that effect, *Atlantic Container Line and Others* v *Commission*, paragraph 243 above, paragraphs 1646 and 1647). In those circumstances, the Court must reject the Commission's head of claim on this point.

918 In the present case, the applicants have been unsuccessful in their claim that the contested decision should be annulled in its entirety and the Commission has been unsuccessful in its claim that the entirety of the application should be dismissed.

919 In the main action, it is appropriate, in those circumstances, to order that the costs be shared. The applicants shall bear 90% of their own costs and pay 90% of the Commission's costs, with the exception of the costs which the Commission has incurred in connection with the intervention of the EFPIA. The Commission shall bear 10% of its own costs and pay 10% of the applicants' costs.

920 The EFPIA shall bear its own costs. As the Commission did not request that the EFPIA be ordered to pay the costs which the Commission incurred in connection with its intervention, the EFPIA shall not bear those costs.

On those grounds,

THE GENERAL COURT (Sixth Chamber, Extended Composition)

hereby:

1. **Annuls Article 1(2) of Commission Decision C(2005) 1757 final of 15 June 2005 relating to a proceeding under Article 82 [EC] and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 — AstraZeneca) in so far as it finds that AstraZeneca AB and AstraZeneca plc infringed Article 82 EC and Article 54 of the EEA Agreement by requesting the deregistration of the Losec capsule marketing authorisations in Denmark and Norway in combination with the withdrawal from the market of Losec capsules and the launch of Losec MUPS tablets in those two countries, inasmuch as it was found that those actions were capable of restricting parallel imports of Losec capsules in those countries;**

2. **Sets the fine imposed by Article 2 of that decision jointly and severally on AstraZeneca AB and AstraZeneca plc at EUR 40 250 000 and the fine imposed by that article on AstraZeneca AB at 12 250 000 euros;**

3. **Dismisses the remainder of the application;**

4. **Orders AstraZeneca AB and AstraZeneca plc to bear 90% of their own costs and to pay 90% of the costs of the European Commission, with the exception of the Commission's costs incurred in connection with the intervention of the European Federation of Pharmaceutical Industries and Associations (EFPIA);**

5. **Orders the EFPIA to bear its own costs;**

6. **Orders the Commission to bear its own costs incurred in connection with the intervention of the EFPIA, 10% of the remainder of its own costs and to pay 10% of the costs of AstraZeneca AB and AstraZeneca plc.**

Meij Vadapalas Wahl

Truchot Frimodt Nielsen

Delivered in open court in Luxembourg on 1 July 2010.

[Signatures]

Table of contents

Background to the dispute . . . . . II - 2832

Procedure and forms of order sought by the parties . . . . . II - 2835

Law . . . . . II - 2837

A — Relevant product market . . . . . II - 2839

1. Preliminary observations . . . . . II - 2840

2. First plea in law, alleging a manifest error of assessment as to the relevance of the gradual nature of the increase in use of PPIs at the expense of H2 blockers . . . . . II - 2842

(a) Arguments of the applicants and of the EFPIA . . . . . II - 2842

(b) Arguments of the Commission . . . . . II - 2848

(c) Findings of the Court . . . . . II - 2852

The differentiated therapeutic use of PPIs and H2 blockers . . . . . II - 2854

The relevance of the gradual nature of substitution of PPIs for H2 blockers . . . . . II - 2861

3. The second plea in law, alleging various inconsistencies and errors of assessment . . . . . II - 2870

(a) Arguments of the applicants and of the EFPIA . . . . . II - 2870

(b) Arguments of the Commission . . . . . II - 2878

(c) Findings of the Court . . . . . II - 2887

The account taken of the therapeutic use of the relevant products . . II - 2888

The importance attached to price indicators . . . . . II - 2891

The 'natural events' . . . . . II - 2904

B — Dominance ..... II - 2912

1. Arguments of the parties ..... II - 2912

2. Findings of the Court ..... II - 2917

(a) AZ's market share ..... II - 2919

(b) Price levels ..... II - 2922

(c) The existence and use of intellectual property rights ..... II - 2928

(d) AZ's first-mover status ..... II - 2931

(e) AZ's financial strength ..... II - 2933

(f) AZ's dominant position in Germany ..... II - 2934

C — The first abuse of a dominant position, relating to supplementary protection certificates ..... II - 2937

1. Regulatory framework and behaviour objected to ..... II - 2937

2. First plea in law, alleging an error of law ..... II - 2943

(a) Arguments of the applicants ..... II - 2943

Applicable legal principles ..... II - 2943

The errors of law allegedly made by the Commission ..... II - 2948

(b) Arguments of the Commission ..... II - 2952

Applicable legal principles ..... II - 2952

The errors of law allegedly made by the Commission ..... II - 2959

(c) Findings of the Court ..... II - 2963

The classification of the behaviour in question as an abuse of a dominant position ..... II - 2963

The start of the alleged abusive practice ..... II - 2969

The anticompetitive nature of the behaviour objected to and its effects on competition . . . . . II - 2971

3. The second plea in law, alleging failure to prove the abuse of a dominant position . . . . . II - 2974

(a) Arguments of the applicants . . . . . II - 2974

The allegation of fraud . . . . . II - 2974

The first stage of the abuse . . . . . II - 2978

The second stage of the abuse . . . . . II - 2986

— The nature of the allegations relating to the second stage of the abuse of a dominant position . . . . . II - 2986

— The instructions to the patent attorneys . . . . . II - 2988

— The representations before the Luxembourg patent office (June 1993) . . . . . II - 2989

— The representations before the Belgian patent office (September to November 1993) . . . . . II - 2991

— The representations before the Netherlands patent office (November and December 1993) . . . . . II - 2993

— Representations before the United Kingdom patent office (January to June 1994) . . . . . II - 2996

— The withdrawal of the SPC application in Denmark (November 1994) . . . . . II - 3000

— AZ's representations in the second round of SPC applications . . . . . II - 3001

— Applications in the EEA countries . . . . . II - 3001

— Representations before the Irish patent office (October 1995) . . . . . II - 3003

— Representations before the patent offices in the Benelux countries and Finland (May 1998) . . . . . II - 3004

— Representations during the court proceedings in Germany II - 3005

— Representations during the court proceedings in Norway . . . II - 3007

— Representations during the court proceedings in Finland . . . . II - 3008

— Existence of a strategy designed to mislead AZ's patent attorneys, the national patent offices and the national courts II - 3008

(b) Arguments of the Commission . . . . . II - 3009

(c) Findings of the Court . . . . . II - 3010

The burden of proof . . . . . II - 3010

The first stage of the abuse of a dominant position . . . . . II - 3011

The second stage of the abuse of a dominant position . . . . . II - 3021

— The representations before the Luxembourg patent office (June 1993) . . . . . II - 3022

— The representations before the Belgian patent office (September to November 1993) . . . . . II - 3026

— The representations before the Dutch patent office (November and December 1993) . . . . . II - 3028

— The representations before the United Kingdom patent office (January to June 1994) . . . . . II - 3033

— The withdrawal of the SPC application in Denmark (November 1994) . . . . . II - 3037

— Applications in the EEA countries (December 1994) . . . . . II - 3040

— The representations before the Irish patent office (October 1995) . . . . . II - 3043

— Representations before the patent offices in the Benelux countries and Finland (May 1998) . . . . . II - 3044

— Representations during the court proceedings in Germany II - 3045

— Representations during the court proceedings in Norway and Finland . . . . . II - 3049

Conclusion on the first abuse of a dominant position . . . . . II - 3052

D — The second abuse of a dominant position: selective deregistrations of marketing authorisations for Losec capsules . . . . . II - 3058

1. Regulatory framework and conduct objected to . . . . . II - 3058

2. First plea in law, alleging an error of law . . . . . II - 3062

(a) Arguments of the applicants . . . . . II - 3062

Regulatory and factual framework . . . . . II - 3062

The Commission's legal analysis . . . . . II - 3063

No abuse of a dominant position in any event . . . . . II - 3068

(b) Arguments of the Commission . . . . . II - 3071

Regulatory and factual framework . . . . . II - 3071

The Commission's legal analysis . . . . . II - 3074

The alleged absence of abuse of a dominant position in any event . . . II - 3078

(c) Findings of the Court . . . . . II - 3082

Regulatory context . . . . . II - 3082

The legal approach adopted by the Commission . . . . . II - 3084

The alleged absence of abuse of a dominant position in any event . . . II - 3089

3. Second plea in law, alleging errors of fact . . . . . II - 3093

(a) Arguments of the applicants . . . . . II - 3093

Reasons for the development and marketing of Losec MUPS . . . . . II - 3094

Challenging of evidence . . . . . II - 3098

Effects . . . . . II - 3111

(b) Arguments of the Commission . . . . . II - 3114

(c) Findings of the Court . . . . . II - 3116

Factual context of the second abuse of a dominant position identified by the Commission . . . . . II - 3117

— Minutes of the MAC meeting of 9 August 1996 . . . . . II - 3117

— Memorandum of 20 December 1996 on the LPP Strategy . II - 3117

— LPP Strategy document of 29 April 1997 . . . . . II - 3118

— Speech by the head of the AZ patent department in October 1999 and slides of May 1997 . . . . . II - 3121

— 'Losec® MUPS STEPSUM' document submitted by memorandum of 26 February 1997 . . . . . II - 3122

— Minutes of the 'Losec MUPS i Europa — "Brain Storming"' meeting of 18 September 1997 . . . . . II - 3122

— Memorandum of 25 September 1997 . . . . . II - 3123

— MUPS Strategy of 3 October 1997 . . . . . II - 3123

— Memorandum of 22 October 1997 headed 'Consequences of MUPS strategy — interim report' . . . . . II - 3126

— 'Losec/H199 scenario' document of 29 April 1998 ..... II - 3128

— Draft paper of 30 November 1998 for the GITA team meeting of 4 December 1998 ..... II - 3128

— Document concerning the 'The Gastrointestinal Franchise Plan' of 12 May 1999 ..... II - 3129

— National strategy documents ..... II - 3130

— Effective implementation of the LPP Strategy ..... II - 3131

— Effects of the deregistrations of the marketing authorisations ..... II - 3132

The abusive nature of AZ's conduct ..... II - 3136

— The LPP Strategy ..... II - 3136

— The abusive nature of the conduct objected to ..... II - 3137

— The centralised nature of the strategy from which the abuse of a dominant position stems ..... II - 3142

Whether the conduct was restrictive of competition ..... II - 3145

Conclusion ..... II - 3157

E — Fines ..... II - 3158

1. Arguments of the parties ..... II - 3158

2. Findings of the Court ..... II - 3165

Costs ..... II - 3175