Reports of Cases

JUDGMENT OF THE COURT (First Chamber)

6 December 2012*

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* Language of the case: English.

(Appeals — Competition — Abuse of dominant position — Market in anti-ulcer medicines — Abuse of procedures relating to supplementary protection certificates for medicinal products and of marketing authorisation procedures for medicinal products — Misleading representations — Deregistration of marketing authorisations — Obstacles to the marketing of generic medicinal products and to parallel imports)

In Case C-457/10 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 15 September 2010,

AstraZeneca AB, established in Södertälje (Sweden),

AstraZeneca plc, established in London (United Kingdom),

represented by M. Brealey QC, M. Hoskins QC, D. Jowell, Barrister, and F. Murphy, Solicitor,

appellants,

the other parties to the proceedings being:

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

defendant at first instance,

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

intervener at first instance,

THE COURT (First Chamber),

composed of A. Tizzano, acting as President of the First Chamber, M. Ilešič (Rapporteur), E. Levits, J.-J. Kasel and M. Safjan, Judges,

Advocate General: J. Mazák,

Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 12 January 2012,

after hearing the Opinion of the Advocate General at the sitting on 15 May 2012,

gives the following

Judgment

1 By their appeal, AstraZeneca AB and AstraZeneca plc seek to have set aside the judgment of the General Court of the European Union in Case T-321/05 *AstraZeneca* v *Commission* [2010] ECR II-2805 ('the judgment under appeal'), whereby that court largely dismissed their action 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 contested decision'). By that decision, the European Commission had imposed a fine of a total amount of EUR 60 million on those companies for having abused the patents system and the procedures for marketing pharmaceutical products in order to prevent or delay the arrival of competing generic medicinal products on the market and to impede parallel trade.

2 The application to have the judgment under appeal set aside and the contested decision annulled is supported by the European Federation of Pharmaceutical Industries and Associations (EFPIA) ('the EFPIA'), which has lodged a cross-appeal to that effect.

3 A cross-appeal has also been lodged by the Commission seeking to have set aside the judgment under appeal in so far as it annulled in part and varied the contested decision.

Legal context

Directive 65/65/EEC

4 The first paragraph of Article 3 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), in the version applicable to the facts, provides that '[n]o medicinal product may be placed on the market of a Member State unless a marketing authorisation ["MA"] has been issued by the competent authorities of that Member State'.

5 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 an MA. Point 8 of the third paragraph of Article 4 of that directive required the production of the following:

'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) [either] by detailed references to published scientific literature ... that the constituent or constituents of the medicinal product have a well established medicinal use, with recognised efficacy and an acceptable level of safety;

(iii) or that the medicinal product is essentially similar to a medicinal 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 … Furthermore, a Member State may also extend this period to 10 years by a single Decision covering all the medicinal 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.

…'

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

7 Directive 65/65 was replaced by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67).

Regulation (EEC) No 1768/92

8 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), applicable to the facts, introduced a supplementary protection certificate ('SPC') for medicinal products subject to a MA procedure. That certificate, which may be obtained by the holder of a national or European patent, extends the protection conferred by that patent for an additional maximum period of five years so that the holder will have the benefit of a maximum period of 15 years of exclusivity from the first MA of the medicinal product concerned in the European Union. The reason for introducing that certificate is, in particular, that the period that elapses between the filing of an application for a patent for a new medicinal product and obtaining of a MA for that product makes the period of effective protection under the patent insufficient to cover the investment put into the research.

9 Article 3 of that regulation, entitled 'Conditions for obtaining a certificate', provided:

'A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

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

(b) a valid [MA for the product] as a medicinal product has been granted in accordance with [Directive 65/65] …, as appropriate;

…'.

10 Pursuant to Article 7(1) of that regulation, the application for a certificate must be lodged within six months of the date on which the MA referred to in Article 3(b) of the same regulation for the product as a medicinal product was granted.

11 In accordance with Article 8(1)(a)(iv) of Regulation No 1768/92, the application for a certificate must contain a request for the grant of a certificate, stating in particular the number and date of the first MA for the product, as referred to in Article 3(b) of that request and, if this authorisation is not the first MA for the product in the Community, the number and date of that authorisation.

12 According to Article 13(1) of Regulation No 1768/92, the certificate took 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 MA for the product in the Community, reduced by a period of five years.

13 Article 19(1) of that regulation was one of the transitional provisions and provided:

'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 [MA for the product] 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.

...'

14 Regulation No 1768/92 was replaced by a codified version, namely Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1).

Background to the dispute and the contested decision

15 AstraZeneca AB and AstraZeneca plc belong to a pharmaceutical group ('AZ') which is active worldwide in the sector of the invention, development and marketing of pharmaceutical products. Its business is focused, in that field, in particular on gastrointestinal conditions. In that regard, one of the main products marketed by AZ is known as 'Losec', a brand name used in most European markets. This omeprazole-based medicinal product, used in the treatment of gastrointestinal conditions linked with hyperacidity and, in particular, to proactively inhibit acid secretion into the stomach, was the first on the market to act directly on the proton pump, that is to say, the specific enzyme inside the parietal cells along the stomach wall, which pumps acid into the stomach.

16 On 12 May 1999, Generics (UK) Ltd and Scandinavian Pharmaceuticals Generics AB complained to the Commission of AZ's conduct aimed at preventing them from introducing generic versions of omeprazole on a number of markets in the European Economic Area (EEA).

17 By the contested decision, the Commission found that AstraZeneca AB and AstraZeneca plc had committed two abuses of a dominant position, thereby infringing Article 82 EC and Article 54 of the Agreement on the European Economic Area, of 2 May 1992 ('the EEA Agreement').

18 According to Article 1(1) of that decision, the first abuse consisted in misleading representations to patent offices in Belgium, Denmark, Germany, the Netherlands, the United Kingdom and Norway and also before the national courts in Germany and Norway. The Commission considered in that regard that those representations formed part of an overall strategy designed to keep manufacturers of generic products away from the market by obtaining or maintaining SPCs for omeprazole to which AZ was not entitled or to which it was entitled for a shorter duration. The Commission distinguished two stages in that first abuse, the first of which concerned representations made when, on 7 June 1993, instructions were sent to the patent agents through whom SPC applications were filed in seven Member States, and the second of which referred to representations subsequently made to several patent offices and before national courts.

19 Under Article 1(2) of the contested decision, the second abuse consisted in the submission of requests for deregistration of the MAs for Losec capsules in Denmark, Sweden and Norway, combined with the withdrawal of Losec capsules from the market and the launch of Losec MUPS tablets ('Multiple Unit

Pellet System'; a system of tablets with multiple microgranules) in those three countries. In the Commission's submission, those steps were taken in order to ensure that the abridged registration route provided for in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 would not be available to producers of generic omeprazole and they also had the consequence that parallel importers were likely to lose their parallel import licences. It took issue, in particular, with the appellants' strategic implementation of the regulatory framework in order to artificially protect from competition products that were no longer protected by a patent and for which the period of data exclusivity had expired.

20 In respect of those two abuses, the Commission imposed on the appellants jointly and severally a fine of EUR 46 million and on AstraZeneca AB a separate fine of EUR 14 million.

Procedure before the General Court and the judgment under appeal

21 By application lodged at the Registry of the Court of First Instance (now the General Court) on 25 August 2005, the appellants brought an action for annulment of the contested decision. That action called into question the lawfulness of that decision with respect to the definition of the relevant market, the assessment of dominance, the first and second abuses of a dominant position and the amount of the fines. During the procedure, the EFPIA intervened in support of the form of order sought by the appellants.

22 By the judgment under appeal, the General Court upheld the action in part and annulled Article 1(2) of the contested decision relating to the second abuse in so far as it found that the appellants had infringed Article 82 EC and Article 54 of the EEA Agreement by requesting the deregistration of the Losec capsule MAs 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. The General Court therefore reduced the amount of the fine imposed jointly and severally on the appellants to EUR 40 250 000 and the fine imposed separately on AstraZeneca AB to EUR 12 250 000 and dismissed the action for the remainder.

Forms of order sought by the parties before the Court of Justice

23 The appellants claim that the Court should:

— set aside the judgment under appeal and annul the contested decision;

— in the alternative, reduce the amount of the fine imposed on the appellants by Article 2 of the contested decision; and

— order the Commission to pay the costs at first instance and on appeal.

24 The EFPIA claims that the Court should set aside the judgment under appeal and annul the contested decision and order the Commission to pay the costs at first instance and on appeal, including those relating to the EFPIA's intervention.

25 The Commission contends that the Court should:

— dismiss the appeal;

— allow the Commission's cross-appeal; and

— order the appellants to pay the costs.

Main appeal

26 In support of their appeal, the appellants put forward four groups of grounds of appeal, relating to errors of law allegedly made by the General Court in respect of the definition of the relevant product market, the first and second abuses, and the fines.

Definition of the relevant product market

Judgment under appeal

27 At paragraphs 28 to 222 of the judgment under appeal, the General Court dealt with and then rejected the two pleas in law put forward by the appellants challenging the definition of the relevant product market adopted in the contested decision, according to which that market was made up of only one category of medicinal products, known as 'proton pump inhibitors' ('PPIs'), such as AZ's product 'Losec', and did not include other categories of medicinal product used for the treatment of gastrointestinal conditions linked with hyperacidity, such as histamine receptor antagonists ('H2 blockers'), which block only one of the stimulants of the proton pump and therefore, unlike PPIs, act only indirectly on the proton pump.

28 The General Court considered, in particular, on the basis of an overall appraisal of the evidence on which the Commission based its assessment – namely 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 particular circumstances observed in Germany and the United Kingdom – that that evidence constituted, in the present case, a body of relevant data that was sufficient to substantiate the conclusion that H2 blockers did not exercise a significant competitive constraint on PPIs during the reference period between 1993 and 2000.

29 On the basis of an examination carried out at paragraphs 61 to 107 of the judgment under appeal, the General Court thus rejected the first plea in law relating to market definition, alleging a manifest error of assessment as to the relevance of the gradual increase in the use of PPIs at the expense of H2 blockers. In that context, the General Court held, in particular, 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 their concerns about its side effects, which gave no grounds for a presumption that there was a causal link between the gradual nature of the increase in sales of PPIs and a competitive constraint exercised by H2 blockers over PPIs. The General Court further considered that no specific evidence in the case before it permitted the conclusion that such a causal link existed.

30 The second plea put forward with respect to market definition, alleging various inconsistencies and errors of assessment in the contested decision and asserting, in particular, that insufficient account was taken of therapeutic use, that excessive attention was paid to price indicators and that excessive importance was attached to the particular circumstances observed in Germany and the United Kingdom, was examined at paragraphs 147 to 222 of the judgment under appeal. As regards, in particular, the complaints relating to the Commission's assessment of the price indicators, the General Court found, at paragraphs 157 to 199 of the judgment under appeal, a number of errors and lacunae in the contested decision, but held that they did not affect the soundness of the Commission's conclusions.

First ground of appeal

– Arguments of the parties

31 By their first ground of appeal, the appellants claim that the General Court made an error of law in failing correctly to examine the relevance of the gradual nature of the increase in the use of PPIs at the expense of H2 blockers. This ground is divided into two parts.

32 The first part alleges that the General Court failed to have regard to the development over time of the facts before it. Thus, the judgment under appeal, and in particular paragraphs 66 to 82 thereof, does not recognise the need to examine the development of the competitive relationship between PPIs and H2 blockers during the relevant infringement periods and does not take account of the changes which occurred on the relevant geographic markets. It is wrong as a matter of law to adjudicate on the situation, in 1993, of a product market in a particular country on the basis of the state of competition on that same market in 2000. Furthermore, the fact that the relationship between PPIs and H2 blockers changed over time is clear from the statements of the medical experts on which the General Court relied.

33 In the second part, the appellants take issue with the General Court for having failed to recognise the relevance of the inertia that characterised prescribing practices, which was the reason for the gradual replacement of H2 blockers by PPIs. The General Court was wrong to reject, at paragraphs 83 to 107 of the judgment under appeal, the appellants' argument that H2 blockers necessarily exercised considerable competitive constraint on PPIs, since sales of PPIs increased only gradually at the expense of H2 blockers and therefore less rapidly than would have been expected given the therapeutic superiority of PPIs. The appellants submit, in particular, that the General Court artificially compartmentalised the various advantages and disadvantages of H2 blockers and PPIs, which were none the less interlinked. If a doctor decides to prescribe a H2 blocker because he has concerns about the side effects of PPIs, the fact remains that that decision is also based on an evaluation of the quality and therapeutic profile of H2 blockers, including the fact that they present fewer risks for the health of the patient.

34 The EFPIA, which supports this first ground of appeal, claims that the General Court, at paragraph 92 of the judgment under appeal, reversed the burden of proof by requiring that the appellants show that the gradual replacement of H2 blockers by PPIs is relevant to market definition.

35 The Commission contends that this first ground of appeal is ineffective, because it challenges only one of the elements of the General Court's reasoning. The gradual nature of the substitution trends is only one aspect of the overall assessment of the relevant market and any error of law in relation to that aspect would not undermine that assessment. It further claims that a large part of this ground of appeal is inadmissible in that it requests the Court to reappraise findings of fact. In any event, this ground of appeal is unfounded.

– Findings of the Court

36 As a preliminary point it must be stated that, contrary to what the Commission claims, the first ground of appeal is not ineffective. Although, admittedly, the General Court carried out an overall evaluation of the evidence on which the Commission based its assessment, the fact remains that, had that court misconstrued the relevance of the gradual nature of the increase in the use of PPIs at the expense of H2 blockers and the development of the competitive relationship between those two products during the period at issue, namely that between 1993 and 2000, that error would be such as to call into question that assessment in its entirety and the conclusions which the General Court drew from it.

37 In so far as it is common ground, as it was observed in particular at paragraphs 63 and 84 of the judgment under appeal, that the respective sales of PPIs and H2 blockers underwent significant evolution between 1993 and 2000, characterised by a gradual substitution of PPIs for H2 blockers, the General Court could not have correctly confirmed the definition of the relevant market in respect of all of that period by basing its analysis only on the state of competition as it was in 2000, that is to say, at the end of that period. Furthermore, as the Advocate General observed in point 22 of his Opinion, given that the first abuse the appellants are alleged to have committed started, in most of the Member States concerned, in 1993 and ended in some of those States from 1994 onwards, it is all the more important, having regard to that evolution, that the relevant product market be correctly established with respect to the entire relevant period and in particular the start of that period.

38 This first ground of appeal must, however, be rejected. First, the General Court examined the competitive interaction between PPIs and H2 blockers throughout the period at issue, taking into account the evolution of the sales of those two products and the gradual nature of the increase in the use of PPIs at the expense of H2 blockers during that period. Secondly, the arguments put forward by the appellants do not show that the General Court committed any error of law in that examination.

39 It must be observed in this connection that, in order to ascertain whether the Commission had committed a manifest error of assessment in rejecting the appellants' argument that the gradual nature of the increase in the sales of PPIs at the expense of those of H2 blockers meant that the latter exercised a significant competitive constraint over PPIs and, therefore, that H2 blockers should, for that reason, be included in the product market at issue, the General Court examined, first, at paragraphs 66 to 82 of the judgment under appeal, the differentiated therapeutic use of PPIs and H2 blockers and, secondly, at paragraphs 83 to 106 of that judgment, the relevance of that gradual nature both on the theoretical level and in the specific situation in the case.

40 It is clear from paragraphs 66 to 106 of the judgment under appeal that the General Court analysed items of evidence relating not only to the end of the reference period, namely the year 2000, but also to a period between 1991 and 2000, thereby even including a time frame before the alleged abuses began.

41 Thus, the General Court observed, in particular at paragraph 69 of the judgment under appeal, that it was apparent from the statements of the medical experts produced by the appellants during the administrative procedure that, although between 1991 and 2000 PPIs and H2 blockers were administered to treat the same conditions, PPIs were generally prescribed to treat severe forms of gastrointestinal conditions linked with hyperacidity while H2 blockers were generally prescribed more to treat their mild or less serious forms. The General Court thus took account of the entirety of the period between 1991 and 2000 to conclude, at paragraph 72 of the judgment in particular, that during that period PPIs and H2 blockers were used differently.

42 In addition, contrary to what the appellants submit, it is not in any way apparent from paragraph 76 of the judgment under appeal that the General Court restricted its assessment to information relating to the year 2000. The reference by the General Court in this paragraph to information relating to that year is explained by the straightforward fact that in this paragraph it is responding to the appellants' argument, summarised at paragraph 37 of that judgment, that at the end of the reference period H2 blockers were still prescribed in a significant proportion of cases for the treatment of major gastrointestinal conditions, even for severe forms of those conditions.

43 Moreover, the General Court carried out a detailed analysis of the evolution of the substitution process observed between 1991 and 2000, finding, in particular at paragraph 84 of the judgment under appeal, that several tables attached as an annex to the contested decision showed 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 Belgium and Norway in 1996, in Denmark and Germany in 1997, and in the Netherlands and the United Kingdom in 1998. In the same paragraph of

that judgment, it pointed out that other tables in the annex to the contested decision showed 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, the Netherlands, the United Kingdom and Norway in 1995 and in Germany in 1996. At paragraph 101 of that judgment it also held that it was apparent from some of those tables 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.

44 In addition, the General Court specifically ruled, at paragraph 96 of the judgment under appeal, on the start of the period of the infringement (1993), confirming the fact, relied upon by the appellants, that sales of PPIs had been much lower than those of H2 blockers that year.

45 Consequently, the appellants' submission in support of the first part of the first ground of appeal, according to which the General Court failed to conduct an analysis of the relevant product market over time, has no factual basis.

46 As regards the second part of that ground of appeal, it is apparent from paragraphs 83 to 106 of the judgment under appeal that the General Court – while accepting that the gradual or 'inert' nature of the increase in sales of a new product which is being substituted for an existing product is important for the purposes of the definition of the market since it can, in some circumstances, indicate that the existing product exercises a significant competitive constraint over the new product – held that that was not the case in this instance.

47 In this latter respect, the General Court held, at paragraphs 98 to 102 of the judgment under appeal, that it was apparent from the evidence in the file that the 'inertia' characterising prescribing practices depended more on the accumulation and dissemination of information on the properties and potential side-effects of PPIs than on the quality of H2 blockers. It observed in this context that that finding was borne out by the fact that the PPIs were deemed to be the only effective treatment for severe forms of gastrointestinal conditions, that PPIs and H2 blockers therefore had different therapeutic uses and that the growth in PPIs was very largely not at the expense of H2 blockers.

48 Contrary to what seems to be the appellants' view, the gradual nature of the increase in sales of a new product being substituted for an existing product does not necessarily mean that that latter product exercised on the former a significant competitive constraint. It is possible that, even in the absence of an earlier product such as H2 blockers, the sales of PPIs as a new product would have evolved overall in the same gradual manner on account of the prescribing doctors' fears as regards the possible carcinogenic effects of PPIs. Consequently, the General Court was fully entitled to hold, at paragraphs 91 to 93 of the judgment under appeal, that it cannot be assumed that there is, in principle, a causal link between the gradual nature of the increase in sales of PPIs and a competitive constraint exercised by H2 blockers over PPIs.

49 Concerning the EFPIA's argument that the General Court, at paragraph 92, reversed the burden of proof, that argument is based on a misreading of that paragraph. While the General Court found in that paragraph that the appellants had adduced no evidence permitting the inference that the gradual increase in sales of PPIs was caused by a significant competitive constraint exercised by H2 blockers, that statement was made to justify its conclusion that the appellants were seeking to establish that there was a presumption of such a causal link. It follows, moreover, from paragraphs 66 to 106 of the judgment under appeal that the General Court based its findings on the correct premiss, namely that the burden of proof lay with the Commission, in examining whether it could, without committing a manifest error of assessment, conclude on the basis of the information in the file that H2 blockers did not exercise a significant competitive constraint over PPIs.

50 Moreover, the manner in which the General Court assessed the 'inertia' on the part of the prescribing doctors in the context, first, of the market definition and, secondly, of the dominant position is not at all inconsistent, as claimed by the appellants. Although those assessments by the General Court

admittedly produced different results, those differences are, as the Advocate General observed in point 32 of his Opinion, entirely justified in the light of the General Court's specific findings of fact. Thus, so far as concerns market definition, the General Court concluded, as recalled at paragraph 47 of this judgment, that H2 blockers did not exercise a significant competitive constraint over PPIs and were therefore not part of the same market, since the inertia which characterised the prescription of PPIs was a result not of the therapeutic qualities of the H2 blockers, which were far inferior to those of the PPIs, but of uncertainty concerning the side-effects of PPIs. On the other hand, in the context of the assessment of the appellants' dominant position on the PPI market, and therefore in relation to products which were therapeutically similar, the General Court found, at paragraph 278 of the judgment under appeal, that the status of AZ as producer of the first PPI on the market, enjoying a solid brand image and reputation, was further supported by the fact that doctors generally require time in order to learn about a new medicinal product and thus that they will hesitate to prescribe PPIs of other producers entering that market.

51 Lastly, in so far as the appellants call into question the findings made by the General Court on the basis of the information in the file, namely, inter alia, that the PPIs and H2 blockers had differentiated therapeutic uses during the reference period and that the gradual nature of the increase in sales of PPIs was not caused by a significant competitive constraint exercised by H2 blockers, it is sufficient to point out that the Court of Justice has consistently held that it has no jurisdiction to establish the facts or, in principle, to examine the evidence which the General Court accepted in support of those facts. Provided that the evidence has been properly obtained and the general principles of law and the rules of procedure in relation to the burden of proof and the taking of evidence have been observed, it is for the General Court alone to assess the value which should be attached to the evidence produced to it. Save where the clear sense of the evidence has been distorted, which is not claimed in the present case, that appraisal does not therefore constitute a point of law which is subject as such to review by the Court of Justice (see judgments in Case C-535/06 P *Moser Baer India* v *Council* [2009] ECR I-7051, paragraph 32, and in Joined Cases C-191/09 P and C-200/09 P *Council and Commission* v *Interpipe Niko Tube and Interpipe NTRP* [2012] ECR, paragraph 65).

52 It follows from all the above considerations that the first ground of appeal must be rejected as in part inadmissible and in part unfounded.

Second ground of appeal

– Arguments of the parties

53 By their second ground of appeal, the appellants, supported by the EFPIA, take issue with the General Court for having failed to examine the general cost of treatment based on PPIs by comparison with the cost of treatment with H2 blockers when it evaluated the price factors on which the Commission relied in order to issue the contested decision. They maintain in that regard that although the cost of a daily dose of PPIs is higher than the cost of a daily dose of H2 blockers, the general cost of treatment is virtually identical because PPIs treat patients more rapidly. Although the General Court recognised that fact at paragraphs 188 and 193 of the judgment under appeal, it held at paragraphs 189 and 190 of that judgment that, since quantification of cost-effectiveness is likely to be particularly complex and uncertain, the Commission did not make a manifest error of assessment in taking into account the price of the medicines for an identical period of treatment. That approach by the General Court is legally incorrect, in that it reverses the burden of proof. Thus, when the Commission seeks to rely on complex and uncertain factors, such as price indicators, it should either analyse those factors in a satisfactory manner or refrain from relying on them if it is unable to prove them because of their complexity.

54 The Commission contends that this ground of appeal is ineffective, as it does not challenge the finding made at paragraph 191 of the judgment under appeal. It is also in part inadmissible and in part unfounded. The fact that the decision in issue is based on a course of treatment of 28 days cannot be considered a manifest error of assessment, as it is impossible to determine the precise duration of each treatment. The Commission maintains in this context that the appellants' view of the assessment of cost-effectiveness is over-simplistic and does not take account of the multitude of conditions and individual treatments possible.

– Findings of the Court

55 As the Commission, and the Advocate General in point 37 of his Opinion, have observed, this second ground of appeal, which is directed solely against the findings made at paragraphs 189 and 190 of the judgment under appeal, is ineffective.

56 After having observed, at paragraph 188 of the judgment under appeal, that the appellants were 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, on which the contested decision is based, the General Court admittedly held, at paragraphs 189 and 190 of that judgment, that, in so far as quantification of cost-effectiveness was likely to be particularly complex and uncertain given that the length of treatment depends considerably on the type of condition in question and is liable to vary from one patient to another, it could not be considered that the Commission had committed a manifest error of assessment in taking into account the price of the medicines for an identical period of treatment.

57 However, the General Court also observed, at paragraph 191 of the judgment under appeal, that it was apparent in any event from the findings made at paragraphs 171 to 175, 177 and 178 of that judgment 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.

58 Even if, contrary to what was held by the General Court, the Commission had committed a manifest error of assessment by taking into account the price of medicinal products over an identical period of treatment and, moreover, the general cost of PPI-based treatment, as the appellants claim, did not in actual fact exceed that of H2 blocker-based treatment, the fact remains that H2 blockers were not liable to exercise a significant competitive constraint over PPIs having regard, in particular, to the weight given by doctors and patients to the therapeutic superiority of PPIs.

59 It must also be added that the General Court's conclusion, at paragraph 220 of the judgment under appeal, that the evidence constituted a body of relevant data that was sufficient to establish the market definition upheld by the Commission was reached after an overall appraisal of all the evidence on which the Commission based its assessment, which includes other price indicators, such as the fact that the strongest impact on the demand for omeprazole produced by AZ was caused by the price of the generic versions of omeprazole and, to a lesser extent, that of the other PPIs, and factors not relating to price, such as the greater efficacy of PPIs, the differentiated therapeutic use of PPIs and H2 blockers, the asymmetrical substitution trend that characterised the growth in sales of PPIs and the corresponding decrease or the stagnation in sales of H2 blockers and the particular circumstances observed in Germany and the United Kingdom. The error of law allegedly committed by the General Court at paragraphs 189 and 190 of that judgment, which relates specifically to the appraisal of only one of those items of evidence, is not, in any event, such as to call in question the result of that overall appraisal.

60 Consequently the second ground of appeal must also be rejected.

First abuse of a dominant position concerning the SPCs

Judgment under appeal

61 At paragraphs 295 to 613 of the judgment under appeal, the General Court dealt with the two pleas in law relied upon by the appellants to dispute the Commission's finding relating to the first abuse.

62 The first of those pleas, alleging certain errors of law on the Commission's part, was examined at paragraphs 352 to 382 of the judgment under appeal. The General Court, inter alia, confirmed at paragraphs 355 and 361 of that judgment the Commission's interpretation of Article 82 EC, according to which 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, such as the SPC, to which the undertaking is in actual fact not entitled, or to which it is only entitled for a shorter period, constitutes a practice falling outside the scope of competition on the merits and therefore an abuse of a dominant position.

63 The General Court added, at paragraphs 356 and 359 of the judgment under appeal, that it followed from the objective nature of the concept of abuse that the misleading nature of representations made to public authorities had to 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 was not required, but could none the less constitute a relevant factor.

64 The General Court upheld that plea in part, however, in so far as it alleged an error of law on the part of the Commission in its assessment of the date on which the alleged first abuse of a dominant position began in certain countries: the General Court considered, at paragraphs 370, 372 and 381 of the judgment under appeal, that that abuse began not when AZ sent instructions to patent attorneys but when it filed SPC applications with the national patent offices.

65 In order to assess the second plea put forward with respect to the finding of the first abuse, alleging lack of evidence, the General Court, at paragraphs 474 to 613 of the judgment under appeal, first observed that the burden of proof was borne by the Commission and then carried out a detailed analysis of the first and second stages of the abuse, described at paragraph 18 of this judgment. It concluded, at paragraph 598 of the judgment under appeal, that the appellants adopted a consistent and linear approach, characterised by the communication to the patent offices of misleading representations for the purposes of obtaining the issue of SPCs to which they were not entitled, or to which they were entitled for a shorter period.

66 The General Court pointed out, at paragraph 599 of the judgment under appeal, that the numerous items of evidence in the documents before the Court and the extent of the conduct in question, which lasted from June 1993 to June 1999, and its more or less consistent implementation with varying degrees of success in nine Member States of the Community and of the EEA, permitted the conclusion that the Commission was right to find that AZ had deliberately tried to mislead the patent offices.

67 At paragraph 600 of the judgment under appeal, the General Court held that, in view of all the documentary evidence on which the Commission relied in order to issue the contested decision, those considerations could not be called in question by the statements submitted by the appellants in support, inter alia, of their claim that AZ acted in good faith. According to the General Court, apart from the fact that those statements tended, in certain respects, to corroborate the correctness of the

contested decision, they did 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 supported the Commission's findings.

68 After having rejected at paragraphs 601 to 607 of the judgment under appeal the appellants' argument concerning the alleged lack of effect of the misleading representations in certain countries, namely Belgium, Denmark, Germany, the Netherlands, the United Kingdom and Norway, the General Court concluded, at paragraph 608 of that judgment, that the misleading representations made by AZ constituted a practice based exclusively on methods falling outside the scope of competition on the merits and that 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. It therefore held, at paragraphs 609 and 610 of that judgment, that the Commission had not erred in finding that the appellants had abused their dominant position and, as a result, rejected the second plea.

Third ground of appeal

– Arguments of the parties

69 By their third ground of appeal, the appellants take issue with the General Court for having taken a legally flawed approach to competition on the merits. The General Court was wrong, when assessing whether the appellants' representations to the patent offices were objectively misleading, to have dismissed as irrelevant the reasonableness of their interpretation of Article 19 of Regulation No 1768/92 and their *bona fides* in that regard.

70 The appellants claim that the General Court misinterpreted the concept of 'competition on the merits' by deciding that the appellants' non-disclosure of their interpretation of that article to the national patent offices and therefore, in particular, the fact that the reference to the first authorisation on which they relied in support of their SPC applications was not the authorisation under Directive 65/65 but the reference to the subsequent authorisation linked with the publication of prices, did not fall within the scope of such competition. A 'lack of transparency' cannot suffice for an abuse. In dismissing as irrelevant the fact that, at the time of submission of the applications, it was reasonable, given the ambiguity of Article 19 of Regulation No 1768/92, to consider that the appellants were entitled to the SPCs, the General Court wrongly promoted to the rank of an abuse the mere fact that an undertaking in a dominant position seeks a right from which it thinks it can benefit without disclosing the elements on which it bases its opinion. The General Court's reasoning is based on the premiss that the appellants were not entitled to the SPC and is therefore made with the benefit of hindsight, taking account of the clarification provided by the judgment in Case C-127/00 *Hässle* [2003] ECR I-14781.

71 The appellants maintain that there are compelling political and legal reasons why deliberate fraud or deceit should be a requirement for a finding of abuse in circumstances such as those of the present case. Thus, an interpretation of the concept of abuse as severe as that applied by the General Court will be likely to impede and delay applications for intellectual property rights in Europe, particularly if it is combined with the Commission's strict approach to market definition. In support of their view, the appellants point out, by way of comparison, that in United States law only patents obtained fraudulently can be challenged under competition law, in order not to chill patent applications.

72 The EFPIA adds that, if the General Court's interpretation of 'competition on the merits' is to be followed, an 'objectively misleading' representation in reality means an 'objectively wrong' representation. If that standard were to be applied, dominant undertakings would have to be infallible in their dealings with regulatory authorities. Thus, even an error that was made unintentionally and immediately rectified could give rise to liability under Article 82 EC. The EFPIA maintains, in

particular, that it is legally indefensible to apply that concept to patent applications, since a number of such applications would have to be rejected each year on the ground that those applications were not objectively correct, as their objective did not satisfy the patentability criteria.

73 The Commission takes the view that this ground of appeal is inadmissible in so far as it seeks to obtain a fresh assessment of the facts at the origin of the first abuse and, in any event, that it must be declared unfounded.

– Findings of the Court

74 As a preliminary point, it must be noted that it is settled case-law that the concept of 'abuse' is an objective concept referring to the conduct of a dominant undertaking which is such as to influence the structure of a market where the degree of competition is already weakened precisely because of the presence of the undertaking concerned, and which, through recourse to methods different from those governing normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition (judgments in Case 85/76 *Hoffman-La Roche* v *Commission* [1979] ECR 461, paragraph 91; Case C-62/86 *AKZO* v *Commission* [1991] ECR I-3359, paragraph 69; Case C-52/07 *Kanal 5 and TV 4* [2008] ECR I-9275, paragraph 25; and Case C-52/09 *TeliaSonera Sverige* [2011] ECR I-527, paragraph 27).

75 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 70, and Case C-202/07 P *France Télécom* v *Commission* [2009] ECR I-2369, paragraph 106).

76 In the light of the arguments put forward by the appellants in support of their third ground of appeal, it must be established whether the General Court misinterpreted the concept of 'competition on the merits' by holding that the conduct criticised in the context of the first abuse fell outside the scope of such competition.

77 In this connection, it must be observed that the General Court held, at paragraphs 306, 478 to 500 and 591 of the judgment under appeal, that there were two stages to the first abuse, of which the first consisted in notifying to the patent offices in Belgium, Denmark, Germany, Ireland, Luxembourg, the Netherlands and the United Kingdom the date of 'March 1988' as that of the first MA in the Community, without informing them either of the legal basis underpinning the choice of that date, namely the alternative interpretation which AZ wished to adopt of the concept of 'MA' for the purposes of Article 19 of Regulation No 1768/92, or of the existence of the MA issued in France on 15 April 1987, which constituted the first MA issued under Directive 65/65 ('the technical authorisation') in the Community.

78 It is common ground that had AZ notified to those patent offices the date of that first technical authorisation issued in France, it would have been impossible for it, on account of the transitional rule referred to in the second subparagraph of Article 19(1) of Regulation No 1768/92, to obtain a SPC for omeprazole in particular in Denmark and in Germany, the first MA in the Community having been obtained prior to 1 January 1988.

79 As the General Court observed at paragraphs 479 to 484, 492 and 509 of the judgment under appeal, it is apparent from a number of its internal memoranda that AZ, and in particular its patent department, was conscious of that fact and had in fact identified the technical authorisation issued in France as being the first MA for the purposes of Regulation No 1768/92. That department nevertheless

indicated, before even having adopted its alternative interpretation of the concept of the MA, that for the purposes of the SPC applications in Denmark and in Germany, it would maintain before the patent offices that the first MA in the Community had not been issued before 1 January 1988.

80 According to that alternative interpretation, the concept of 'MA' for the purposes of Article 19 of Regulation No 1768/92 did not refer to the technical authorisation but to the publication of the prices, since those were, according to the appellants, necessary in certain Member States, such as France and Luxembourg, in order for the medicinal product to be actually marketed. The General Court observed, at paragraph 488 of the judgment under appeal, that the date of publication of the price as the date of the alleged effective marketing was used only for omeprazole and omeprazole sodium, while for six other products, AZ had communicated the date of the technical authorisation or that of the first publication of that authorisation, each of those dates being later than 1 January 1988.

81 As the General Court found at paragraphs 492 and 493 of the judgment under appeal, it is common ground that both the patent offices and the patent attorneys construed that concept as referring to the technical authorisation and 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, by failing to specify the interpretation which it intended to adopt of Regulation No 1768/92 which underlay the choice of the dates provided in relation to the French Republic and the Grand Duchy of Luxembourg, the patent offices would be prompted to construe those representations as indicating that the first technical authorisation in the Community had been issued in Luxembourg in 'March 1988'.

82 It is apparent from paragraphs 490 to 492 of the judgment under appeal that AZ nevertheless chose not to notify the patent attorneys and national patent offices of the fact that, in the instructions of 7 June 1993 given to the patent attorneys in respect of the SPC applications concerning omeprazole, the dates indicated in respect of the French Republic and the Grand Duchy of Luxembourg did not correspond to the issue of the technical authorisation, but to the alleged date of publication of the price of the medicinal product.

83 In addition, nothing in the presentation of the information communicated in connection with those instructions was such as to imply that the dates indicated in respect of those two Member States did not relate to the technical authorisations. On the contrary, the fact, first, that the dates indicated in respect of seven other countries related to the issuing of the technical authorisation, secondly, that the numbers corresponding to the French and Luxembourg technical authorisations were retained and, lastly, that, in order to meet the requirements of Article 8(1)(c) of Regulation No 1768/92, AZ referred to the Luxembourg legislation relating not to the price publication but to the technical authorisation, suggested that the dates stated in respect of the French Republic and the Grand Duchy of Luxembourg corresponded to those authorisations.

84 The General Court also observed, at paragraph 495 of the judgment under appeal, that the appellants' claim that AZ intended to discuss with the patent offices the relevant date for the purposes of Regulation No 1768/92 is not supported by the facts and that 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 the first abuse.

85 As regards that second stage, it follows from paragraphs 307, 478 and 501 of the judgment under appeal that that stage included, first, misleading representations made in 1993 and 1994 before the patent offices in reply to their questions on the SPC applications filed by AZ, secondly, misleading representations made in December 1994 during the second round of SPC applications in three EEA countries, namely Austria, Finland and Norway, and, lastly, 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.

86 In this connection, the General Court observed, inter alia, at paragraphs 495, 505, 506, 514, 515, 523, 574, 592 and 593 of the judgment under appeal, that, following the explanations requested by the patent offices as regards the vague reference to 'March 1988' as the MA date in Luxembourg and except in its exchanges with the United Kingdom and Irish patent offices, AZ remained silent, first, regarding the existence of the French technical authorisation of 15 April 1987 and, secondly, as regards the interpretation of Regulation No 1768/92 which underlay the dates indicated in respect of the French Republic and the Grand Duchy of Luxembourg.

87 The failure to disclose the French technical authorisation prompted the Belgian, Luxembourg and Netherlands patent offices to consider that the date of 16 November 1987 – corresponding to the issue of the technical authorisation in Luxembourg and which had been notified by AZ at the express request of those offices, or inserted, in the case of the Luxembourg patent office, by that office itself – had to be taken into account as date of the first MA in the Community. Those offices therefore granted SPCs on the basis of that latter date, while in Germany a SPC was granted on the basis of the date of 21 March 1988 after a clarification to that effect was provided by AZ.

88 As the General Court noted at paragraphs 508, 527, 530 and 594 of the judgment under appeal, AZ did not subsequently intervene in order to rectify the SPCs issued to it, even though (i) its internal documents show that it was aware of their incorrect basis and, in particular, that the date of the first MA was incorrect, and (ii) the Netherlands patent attorney had expressly suggested to it that it might so intervene.

89 The General Court observed, at paragraph 539 of that judgment, that it was apparent from such an internal document, drawn up in 1994 by the head of AZ's patent department, that, in order to ensure that the SPCs for Losec lasted as long as possible in the various European countries, its services were arguing that the definition of MA was not clear and were trying to get the date of 21 March 1988 accepted as the relevant one, since it ensured the longest SPC term and the possibility of receiving or maintaining a SPC in Denmark and in Germany.

90 In addition, the General Court pointed out, at paragraphs 508 and 530 of that judgment, that it was apparent from other internal documents that AZ had, since 1993, evaluated the risk linked with the failure to disclose the French technical authorisation of 15 April 1987 and had taken the view that, in respect of the countries other than the Kingdom of Denmark and the Federal Republic of Germany, it would consist, in the worst cases, in the loss of the supplementary six months of protection which had been granted to it on the basis of the technical authorisation issued in Luxembourg on 16 November 1987. Thus, in the countries in relation to which the transitional provisions of Regulation No 1768/92 did not pose a problem, but in respect of which AZ had made use of the Luxembourg authorisation 'for the sake of consistency', it would have been possible for it, in the event of disputes relating to the SPCs, to revert to the French technical authorisation date.

91 As the General Court found at paragraphs 595 and 596 of the judgment under appeal, even after having disclosed, following questions put by the Irish and United Kingdom patent offices, the existence of the French technical authorisation, AZ 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, namely in Austria, Finland and Norway. Those representations in fact prompted those patent offices to issue SPCs on the basis of that date.

92 Lastly, it follows from paragraphs 576 to 590 and 597 of the judgment under appeal that, before the German, Finnish and Norwegian courts, AZ attempted to defend the validity of the SPCs granted in those countries by making incorrect representations concerning the relevance of the date of 21 March 1988, despite possessing consistent information indicating that, even on the basis of its own interpretation of Article 19 of Regulation No 1768/92 and its 'effective marketing theory', that date

was not the relevant date, since the true position was that it did not correspond to the date of the publication of the price in Luxembourg and marketing of Losec in that country had actually taken place prior to that date.

93 Clearly, as the General Court held at paragraphs 493, 495, 507, 598, 599, 608 and 609 of the judgment under appeal, AZ's consistent and linear conduct, as summarised above, which was characterised by the notification to the patent offices of highly misleading representations and by a manifest lack of transparency, inter alia as regards the existence of the French technical authorisation, and by which AZ deliberately attempted to mislead the patent offices and judicial authorities in order to keep for as long as possible its monopoly on the PPI market, fell outside the scope of competition on the merits.

94 That finding is not called into question by the appellants' argument as to the allegedly reasonable nature of their alternative interpretation of Article 19 of Regulation No 1768/92 and their good faith in this respect.

95 Even if AZ – despite the fact that it itself had taken the view, at least initially, that the technical authorisation issued in France on 15 April 1987 constituted the authorisation to which Regulation No 1768/92 refers – had ultimately considered that its alternative interpretation was reasonable and had a serious chance of being followed both by the national courts and by the Court of Justice in the event of competitors calling into question SPCs issued on the basis of the date of 21 March 1988 or 16 November 1987, the onus was on AZ to disclose to the patent offices all the relevant information and in particular the existence of that French technical authorisation in order to allow them to decide, with full knowledge of the facts, which of those authorisations they wished to accept for the purposes of issuing the SPC.

96 Thus, by making misleading representations to those patent offices, by concealing the existence of that French technical authorisation and deliberately leading them to believe that the date of 21 March 1988 corresponded to the Luxembourg technical authorisation and that that latter was the first MA in the Community, AZ knowingly accepted that those offices granted it SPCs which they would not have issued had they known of the existence of the French technical authorisation and which would have been shown to be unlawful in the event that the alternative interpretation proposed by AZ was not followed by the national courts or the Court of Justice.

97 It is moreover common ground that, as pointed out at paragraph 92 of the present judgment, even on the basis of its alternative interpretation, the date of 21 March 1988 notified to the patent offices was not relevant for the purposes of the issue of SPCs. That date in fact related to a list of the Grand Duchy of Luxembourg entitled 'Ministère de la Santé – Spécialités pharmaceutiques – Liste des spécialités pharmaceutiques admises à la vente dans le Grand-Duché de Luxembourg' ('Ministry of Health – Proprietary medicinal products – List of proprietary medicinal products approved for sale in the Grand Duchy of Luxembourg'), and did not in fact correspond to the date of publication of the price in Luxembourg. The General Court observed in this regard, at paragraphs 497, 498 and 580 to 582 of the judgment under appeal, that that list by its appearance did not lend itself to being regarded as the publication of the price and that, furthermore, AZ's conduct during the second stage of the abuse tended to discredit the claims regarding its good faith as to the relevance of that date.

98 Regarded in the light of the facts found by the General Court, which the appellants have expressly stated that they are not calling into question, the third ground of appeal raised by them is tantamount to an argument that where an undertaking in a dominant position considers that it can, in accordance with a legally defensible interpretation, lay claim to a right, it may use any means to obtain that right, and even have recourse to highly misleading representations with the aim of leading public authorities into error. Such an approach is manifestly not consistent with competition on the merits and the specific responsibility on such an undertaking not to prejudice, by its conduct, effective and undistorted competition within the European Union.

99 Lastly, contrary to what the EFPIA submits, the General Court did not hold that undertakings in a dominant position had to be infallible in their dealings with regulatory authorities and that each objectively wrong representation made by such an undertaking constituted an abuse of that position, even where the error was made unintentionally and immediately rectified. It is sufficient to note in this connection that, first, that example is radically different from AZ's conduct in the present case, and that, secondly, the General Court pointed out, at paragraphs 357 and 361 of the judgment under appeal, that the assessment of whether representations made to public authorities for the purposes of improperly obtaining exclusive rights are misleading must be made *in concreto* and may vary according to the specific circumstances of each case. It thus cannot be inferred from that judgment that any patent application made by such an undertaking which is rejected on the ground that it does not satisfy the patentability criteria automatically gives rise to liability under Article 82 EC.

100 It follows from all of the foregoing considerations that the third ground of appeal must be rejected as unfounded.

Fourth ground of appeal

– Arguments of the parties

101 By their fourth ground of appeal, the appellants maintain that the General Court erred in law in holding that the mere fact of applying for an SPC was sufficient to constitute an abuse. By doing so, it created an 'abuse in itself' without considering whether competition was affected or whether the impugned conduct had a tendency to restrict competition. They take the view that competition can only be affected from the time that the exclusive right sought has been granted, that AZ's competitors knew of that right's existence and that that right is liable to affect the conduct of those competitors. That approach has the merit of being consistent with that followed in United States law.

102 They submit, in that regard, that the SPC applications were filed between five and six years before they entered into force and that, up to that point, AZ's rights were protected by patents over substances and, in certain cases, also by patents over formulations. Furthermore, in Denmark the SPC application was withdrawn while in the United Kingdom the SPC was granted on the basis of the 'correct' date. In Germany, the SPC was revoked before the expiry of the patent which underlay it and in Norway it was revoked a few months after that expiry. Lastly, if the SPCs issued in Belgium and the Netherlands effectively conferred on AZ unwarranted protection during five and six months respectively, there is no evidence proving that that protection had the effect of restricting competition. Moreover, AZ was not in a dominant position at that time. In order to constitute an abuse, it must be possible for the effect of the conduct to be perceptible at the time when the undertaking holds such a position.

103 The EFPIA also takes issue with the General Court for having held that a misleading representation may constitute an abuse even if it had no external effect because the error was corrected by a patent office or by third parties using correction mechanisms such as opposition procedures or invalidity litigation.

104 The Commission takes the view that that ground of appeal is unfounded.

– Findings of the Court

105 As is apparent, inter alia, from paragraph 357 of the judgment under appeal, the General Court examined in the present case whether, in the light of the context in which the practice in question had 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. It held in this connection that 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 could be relevant factors to be taken into consideration for the purposes of determining whether the practice in question was liable to raise regulatory obstacles to competition.

106 Contrary to what the appellants submit, that examination by the General Court is not in any way based on the assumption that the practice in question constitutes an 'abuse in itself', regardless of its anti-competitive effect. On the contrary, the General Court expressly pointed out, at paragraph 377 of the judgment under appeal, that 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.

107 As the General Court found, in particular at paragraphs 591 to 598 of the judgment under appeal, that was the case here, which is indeed confirmed by the fact that AZ's misleading representations actually enabled it to obtain SPCs either to which it was not entitled, as was the case in Germany, in Finland and in Norway, or to which it was entitled only for a shorter period, as was the case in Belgium, in Luxembourg, in the Netherlands and in Austria.

108 As regards, in particular, those countries where the misleading representations enabled AZ to obtain unlawful SPCs, the appellants cannot deny the anti-competitive effect of those representations on the ground that the applications for the SPCs were filed between five and six years before the entry into force of those SPCs and that, until that time, AZ's rights were protected by lawful patents. Not only do such unlawful SPCs lead, as the General Court observed at paragraphs 362, 375 and 380 of the judgment under appeal, to a significant exclusionary effect after the expiry of the basic patents, but they are also liable to alter the structure of the market by adversely affecting potential competition even before that expiry.

109 In the light of those anti-competitive effects, the General Court was also fully entitled, at paragraph 605 of the judgment under appeal, to regard as irrelevant the fact that, in Germany, following legal proceedings brought by a manufacturer of generic products, the SPC was annulled before the expiry of the basic patent.

110 Nor, in contrast to what is submitted by the appellants, was it necessary for AZ still to have been in a dominant position after the basic patents expired, since the anti-competitive nature of its acts must be evaluated at the time when those acts were committed. Consequently, the General Court was correct to reject, at paragraphs 379 and 606 of the judgment under appeal, the argument that the additional period of supplementary protection obtained in Belgium and the Netherlands on the basis of the misleading representations extended to a period during which AZ did not hold a dominant position in those Member States.

111 So far as concerns the fact that the misleading representations did not enable AZ to obtain SPCs in Denmark and that in Ireland and the United Kingdom the SPCs were ultimately issued on the basis of the correct date, it must be stated that the General Court did not err in law in holding, at paragraphs 602 to 604 of the judgment under appeal, that that fact does not mean that AZ's conduct in those countries was not abusive, since it is established that those representations were very likely to result in the issue of unlawful SPCs. In addition, as the Commission has pointed out, in so far as the impugned conduct forms part of an overall strategy seeking to unlawfully exclude manufacturers of generic products from the market by means of obtaining SPCs in breach of the regulatory framework which established them, the existence of an abuse is not affected by the fact that that strategy did not succeed in some countries.

112 Lastly, as regards the circumstances which, according to the appellants, must be present in order to be able to find that the misleading representations were such as to restrict competition, it is sufficient to note that in actual fact they amount to a requirement that current and certain anti-competitive effects

be shown. However, it follows from the Court's case-law that, although the practice of an undertaking in a dominant position cannot be characterised as abusive in the absence of any anti-competitive effect on the market, such an effect does not necessarily have to be concrete, and it is sufficient to demonstrate that there is a potential anti-competitive effect (see, to that effect, *TeliaSonera Sverige*, paragraph 64).

113 Consequently, the fourth ground of appeal must be rejected as unfounded.

Second abuse of a dominant position

Judgment under appeal

114 The two pleas relied upon with regard to the finding of the second abuse were dealt with at paragraphs 614 to 864 of the judgment under appeal.

115 In its assessment of the first of those pleas, alleging errors in law, the General Court first observed, at paragraphs 666 to 669 of that judgment, that, after the expiry of a period of exclusivity of six or ten years which starts to run from the grant of the first MA, Directive 65/65 no longer confers on the owner of an original 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 MAs for essentially similar products under the abridged procedure provided for in point 8(a)(iii) of the third paragraph of Article 4 of that directive. That choice by the legislature results from the balancing of, on the one hand, the interests of the innovative undertakings with, on the other hand, those of the manufacturers of essentially similar products and the interest in avoiding the repetition of tests on humans or animals where not necessary.

116 The General Court pointed out that the Court of Justice, in its judgment in Case C-223/01 *AstraZeneca* [2003] ECR I-11809, paragraphs 49 to 54, nevertheless considered that the interest of safeguarding public health required, in order for an application for MA of a generic medicinal product to be dealt with by way of the abridged procedure provided for in that provision, that the reference MA still be in force in the Member State concerned at the date when that application is lodged, and therefore precluded the use of that abridged procedure after the withdrawal of the reference MA.

117 The General Court inferred, at paragraph 670 of the judgment under appeal, that the deregistration of the MA of the original medicinal product had the effect of preventing the applicant for a MA 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 the product in question. Thus, in this case, although the legislation no longer conferred on AZ the exclusive right to make use of the results of those tests and trials, the strict public health protection requirements which informed the Court of Justice's interpretation of Directive 65/65 enabled it to prevent or make more difficult, by the deregistration of its MAs, the acquisition, by way of the abridged procedure, of MAs for essentially similar medicinal products, to which the manufacturers of generic products were none the less entitled.

118 The General Court found, at paragraphs 675 and 676 of the judgment under appeal, that such conduct, which was designed to prevent manufacturers of generic products from making use of their right to benefit from the results of those tests and trials, was not based in any way on the legitimate protection of an investment which came within the scope of competition on the merits. It observed, inter alia, that it was apparent that AZ's deregistration of the MAs was only such as to prevent applicants for MA in respect of essentially similar medicinal products from being able to make use of the abridged procedure and thus to obstruct or delay the market entry of generic products. It stated

that such deregistration might also be such as to prevent parallel imports. It added, at paragraph 677 of that judgment, that the fact that AZ was entitled to request the withdrawal of those authorisations in no way caused that conduct to escape the prohibition laid down in Article 82 EC.

119 At paragraphs 678 to 684 of the judgment under appeal the General Court then rejected the argument that the compatibility with Article 82 EC of the impugned conduct had to be assessed according to the criteria set out in the case-law on 'essential facilities'. Lastly, at paragraphs 685 to 694 of that judgment, it rejected the appellants' argument, put forward for the first time during the procedure before that Court, that in this case the pharmacovigilance obligations to which AZ was subject in Denmark, Sweden and Norway constituted an objective ground of justification of the applications for deregistration of the MAs in those countries.

120 The second plea, relating to the second abuse, whereby the appellants called in question the Commission's assessment of the facts surrounding the impugned conduct and the conclusions which the Commission drew from those facts, was examined at paragraphs 757 to 865 of the judgment under appeal.

121 At paragraphs 806 to 812 of that judgment, the General Court held that the deregistration of the Losec capsule MAs did not constitute conduct coming within the scope of competition on the merits. It was held that, on the other hand, AZ could not be criticised for having launched Losec MUPS or for having withdrawn Losec capsules from the market, as those acts, unlike the deregistration of MAs, were not capable of delaying or preventing the introduction of generic products and parallel imports.

122 At paragraphs 824 to 863 of the judgment under appeal the General Court considered whether the Commission had shown to the requisite legal standard that, in view of the objective context in which the impugned conduct was implemented, that conduct was capable of restricting competition by preventing or delaying the introduction of generic products and parallel imports.

123 As regards, in the first place, the introduction of generic products, it was held at paragraph 828 of that judgment that the deregistration of the MAs had made the abridged procedure unavailable and was therefore such as to delay the grant of authorisations for the marketing of generic products in Denmark, Sweden and Norway. In that regard, the General Court held at paragraphs 829 to 835 of that judgment that the appellants' assertion that AZ's competitors would have been able to obtain MAs by means of alternative procedures, which were longer and more costly, did not suffice to render the deregistration of those MAs non-abusive since that deregistration had the sole aim of excluding from the market, at least temporarily, competing manufacturers of generic products.

124 As regards, in the second place, parallel imports, the General Court held, at paragraphs 838 to 863 of the judgment under appeal, that, although the Commission had demonstrated that, in Sweden, the deregistration of the MA for Losec capsules was capable of excluding parallel imports of those products, it had not so demonstrated in the case of the Kingdom of Denmark or the Kingdom of Norway. The General Court therefore upheld that plea in part in so far as it related to a restriction of parallel imports in those two countries and rejected it for the remainder.

The fifth ground of appeal

– Arguments of the parties

125 By their fifth ground of appeal, the appellants claim that the General Court misinterpreted the concept of 'competition on the merits' in considering that the mere exercise of a right conferred by Union law was incompatible with such competition. The right to withdraw a MA cannot logically be both prohibited and, at the same time, granted by the European Union. They maintain in that context that the European Union regulation of pharmaceutical matters confers on the holder of a MA the right to

request the withdrawal of that authorisation, just like the right not to renew it upon its expiry. The Commission itself, and Advocates General La Pergola and Geelhoed in their respective Opinions preceding the judgments of the Court in Case C-94/98 *Rhône-Poulenc Rorer and May & Baker* [1999] ECR I-8789 and Case C-172/00 *Ferring* [2002] ECR I-6891, expressly recognised that the owner may exercise that right at any time without having to provide any reasons and without having to take account of the interests of manufacturers of generic products and parallel importers. Those principles also follow from the judgment in *Ferring*.

126 The appellants emphasise that the existence of a MA imposes stringent pharmacovigilance obligations on its holder, involving permanent costs, which it is lawful to dispose of if the authorised product is no longer marketed. For a company in a dominant position to be deprived of a right of withdrawal and be required to maintain in force an authorisation which it no longer needs and thus to be forced to incur effort and costs and to assume public health liability for the accuracy of the information which it supplies, without any compensation on the part of their competitors, stretches too far the special responsibility of companies in a dominant position.

127 The appellants further take issue with the General Court for having provided insufficient reasons, at paragraph 677 of the judgment under appeal, for its conclusion that the illegality of abusive conduct under Article 82 EC is unrelated to its compliance with other legal rules. Thus, the General Court ought to have explained how the exercise by AZ of a legitimate right constituted an abuse in this case. In addition, the European Union regulations governing pharmaceutical matters themselves seek to reconcile the encouragement of innovation with the protection of competition. The appellants further contend that the General Court characterised as abuse a different set of conduct from that identified by the Commission and in doing so exceeded its jurisdiction.

128 The Commission takes the view that this ground of appeal is unfounded.

– Findings of the Court

129 As a preliminary point it must be stated that, as the General Court observed at paragraph 804 of the judgment under appeal, the preparation by an undertaking, even in a dominant position, of a strategy whose object it is to minimise the 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.

130 However, contrary to what the appellants submit, conduct like that impugned in the context of the second abuse – consisting in the deregistration, without objective justification and after the expiry of the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials granted by Directive 65/65, of the MAs for Losec capsules in Denmark, Sweden and Norway, by which AZ intended, as the General Court held at paragraph 814 of the judgment under appeal, to hinder the introduction of generic products and parallel imports – does not come within the scope of competition on the merits.

131 In this connection, it must in particular be stated that, as the General Court observed at paragraph 675 of that judgment, after the expiry of the period of exclusivity referred to above, conduct designed, inter alia, to prevent manufacturers of generic products from making use of their right to benefit from those results 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 those results.

132 Furthermore, the General Court was correct to hold, at paragraph 677 of that judgment, that the fact, relied on by the appellants, that under Directive 65/65 AZ was entitled to request the withdrawal of its MAs for Losec capsules in no way causes that conduct to escape the prohibition laid down in Article 82 EC. As that court pointed out, the illegality of abusive conduct under Article 82 EC is unrelated to its compliance or non-compliance with other legal rules and, in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law.

133 Moreover, as the Advocate General observes in point 78 of his Opinion, the primary purpose of Directive 65/65 is to safeguard public health while eliminating disparities between certain national provisions which hinder trade in medicinal products within the Union, and it therefore does not, as claimed by the appellants, pursue the same objectives as Article 82 EC in such a way that the application of the latter is no longer required for the purposes of ensuring effective and undistorted competition within the internal market.

134 It is important to point out, in this context, that an undertaking which holds a dominant position has a special responsibility in that latter regard (see Case C-202/07 P *France Télécom* v *Commission* [2009] ECR I-2369, paragraph 105) and that, as the General Court held at paragraphs 672 and 817 of the judgment under appeal, it cannot therefore 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.

135 As regards the appellants' argument that maintaining an MA would impose onerous pharmacovigilance obligations on it, it must be noted that such obligations may in fact constitute an objective justification for the deregistration of a MA.

136 However, as the General Court observed at paragraphs 686 and 688 of the judgment under appeal, that argument was raised for the first time at the stage of the proceedings before that Court and the burden arising from those obligations was never mentioned in AZ's internal documents relating to its commercial strategy, which casts doubt on the fact that the deregistration of the MAs was due in this case to those obligations.

137 The General Court, moreover, found at paragraph 689 of that judgment that, in so far as AZ had not requested the deregistration of its MAs in Germany, Spain, France, Italy, the Netherlands and Austria, the appellants had failed to demonstrate that the additional burden on AZ, had it not deregistered its MAs in Denmark, Sweden and Norway, would have been so significant that it would have constituted an objective ground of justification.

138 In the light of that finding by the General Court, based on a detailed analysis, at paragraphs 690 to 693 of that judgment, of AZ's pharmacovigilance obligations in relation to its MAs in those latter countries, which has not been called into question by the appellants, it must be concluded that the argument derived from such obligations has no factual basis.

139 In so far as the appellants are seeking to rely on arguments derived from the Opinions in the cases which gave rise to the judgments in *Rhône-Poulenc Rorer and May & Baker* and *Ferring*, or from the judgment in that latter case, suffice it to state that those cases did not address the issue of whether the deregistration of a MA by an undertaking in a dominant position which is such as to prevent or delay the introduction of generic products and parallel imports constitutes an infringement of Article 82 EC and no conclusions may be drawn from them in that regard.

140 Lastly, contrary to what the appellants claim, the General Court did not in any case exceed its jurisdiction in holding, at paragraphs 806 to 811 of the judgment under appeal, that, although the Commission defined the second abuse as resulting from the combination of the deregistrations of the

MAs for Losec capsules with the conversion of sales of those capsules to Losec MUPS, the central element of that abuse consists in those deregistrations, as the Commission indeed confirmed during the proceedings, that conversion constituting the context in which those deregistrations were carried out, and that it is the deregistration alone which is liable to produce the anti-competitive effects challenged by the Commission and thus to be regarded as an abuse.

141 It follows from all of the foregoing considerations that the fifth ground of appeal must be rejected as unfounded.

Sixth ground of appeal

– Arguments of the parties

142 By their sixth ground of appeal, the appellants maintain that the General Court erred in law in considering that the conduct impugned in the context of the second abuse tended to restrict competition. They argue that the mere exercise of a right lawfully afforded by Union law could at the most amount to an 'abuse' only in exceptional circumstances, namely where there is an elimination of all effective competition, a mere propensity to distort competition not being sufficient for that purpose. An analogy should be drawn with compulsory licensing cases, such as that dealt with in Case C-418/01 *IMS Health* [2004] ECR I-5039. That analogy is justified by virtue of the 'effective expropriation' of the right to request deregistration of the MA and by virtue of the fact that the prohibition on deregistration is a form of compulsory licensing. The appellants claim, furthermore, that, contrary to the General Court's assertion at paragraph 830 of the judgment under appeal, AZ still held exclusive rights in the clinical data, which remained confidential, after the expiry of the exclusivity period conferred by Directive 65/65, that directive not providing for any obligation for companies supplying that confidential information to share it with their competitors.

143 The appellants consequently take the view that, contrary to what the General Court held, inter alia, at paragraphs 824 to 827 and 829 of the judgment under appeal, the Commission should have demonstrated in the present case not only that the deregistration of the MAs rendered competition 'more difficult', but that the deregistration had a disproportionate effect on competition. Were that criterion to be applied, the deregistration of the MAs could not be characterised as an abuse, since in the present case competition would have been eliminated neither so far as concerns generic products nor at the level of parallel imports.

144 With regard to generic products, the appellants submit that, first, deregistration of the MAs did not deprive the manufacturers of those products who were already present on the market of the right to continue marketing their products. Secondly, the manufacturers who were not yet active on the market had options other than the abridged procedure provided for in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65, even if such alternatives were 'less advantageous'.

145 With regard to parallel imports, the appellants submit that the Commission's decision should have been annulled also in so far as it concerned the Kingdom of Sweden, not only because competition was only impeded rather than eliminated, but also on the ground that that impediment was caused by the incorrect application of European Union law by the Swedish authority, the Court of Justice having held that Articles 28 EC and 30 EC preclude the withdrawal of the MA for a pharmaceutical product from entailing in itself the withdrawal of the parallel import licence in the absence of a risk to health (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).

146 The Commission contends that this ground of appeal is inadmissible since, in their arguments concerning compulsory licences, the appellants are merely reiterating arguments already put forward at first instance, without stating in what way the examination of those arguments by the General Court was flawed. In any event, this ground of appeal is unfounded.

– Findings of the Court

147 Contrary to the Commission's submission, this ground of appeal is not inadmissible. It is sufficient to state in this connection that, provided that the appellant challenges the interpretation or application of Community law by the General Court, the points of law examined at first instance may be discussed again in the course of an appeal. Indeed, if an appellant could not thus base his appeal on arguments already relied on before the General Court, an appeal would be deprived of part of its purpose (see Case C-425/07 P *AEPI* v *Commission* [2009] ECR I-3205, paragraph 24, and Case C-54/09 P *Greece* v *Commission* [2010] ECR I-7537, paragraph 43).

148 It must be stated, however, that this ground of appeal is unfounded. The situation which characterises the second abuse is not in any way comparable to a compulsory licence or to the situation which gave rise to the judgment in *IMS Health*, relied upon by the appellants, which concerned the refusal by an undertaking in a dominant position, which was the owner of an intellectual property right in a 'brick structure', to grant its competitors a licence for the use of that structure.

149 In fact, the possibility provided for in Directive 65/65 of deregistering a MA is not equivalent to a property right. Consequently, the fact that, in the light of its special responsibility, an undertaking in a dominant position cannot make use of such a possibility in such a way as to prevent or render more difficult the entry of competitors on the market, unless it can, as an undertaking engaged in competition on the merits, rely on grounds relating to the defence of its legitimate interests or on objective justifications, does not constitute either an 'effective expropriation' of such a right or an obligation to grant a licence, but a straightforward restriction of the options available under European Union law.

150 The fact that the exercise of such options by an undertaking in a dominant position is limited or made subject to conditions in order to ensure that competition already weakened by the presence of that undertaking is not subsequently undermined is in no way an exceptional case and does not justify a derogation from Article 82 EC, unlike a situation in which the unfettered exercise of an exclusive right awarded for the realisation of an investment or creation is limited.

151 As regards the appellants' argument that AZ still held exclusive rights over the clinical data in the file which were still confidential, that argument fails to have regard to the fact that, as the General Court observed at paragraph 681 of the judgment under appeal, Directive 65/65 in any event created a limitation to those alleged rights by establishing, in point 8(a)(iii) of the third paragraph of Article 4 thereof, an abridged procedure which, after the expiry of a period of exclusivity of six or ten years, allows the national authorities to rely on that data and the manufacturers of essentially similar medicinal products to benefit from its existence for the purposes of being granted a MA. The General Court was therefore fully entitled to find, at paragraphs 670, 674, 680 and 830 of the judgment under appeal, that Directive 65/65 no longer gave AZ the exclusive right to make use of the results of the pharmocological and toxicological tests and clinical trials included in the file.

152 Moreover, in so far as the national authorities do not disclose that data to applicants in the context of the abridged procedure, the finding of the second abuse, as the Commission points out, does not result in competitors being granted access to the clinical data and does not prejudice its confidentiality.

153 The General Court therefore did not commit any error of law in rejecting, at paragraphs 678 to 684 of the judgment under appeal, the appellants' argument that the compatibility with Article 82 EC of the conduct impugned in the context of the second abuse should be assessed in accordance with the criteria applied, inter alia, in *IMS Health*, or in holding, at paragraphs 824 and 826 of the judgment under appeal, that, for the purposes of characterising that conduct as an abuse of a dominant position, it is sufficient to demonstrate that it is such as to restrict competition and, in particular, to constitute an impediment to generic products entering the market and to parallel imports.

154 The General Court was also fully entitled, in ascertaining whether the Commission had actually proved this in respect of generic products, to hold, at paragraphs 829 to 835 of the judgment under appeal, that the fact that the regulatory framework offers alternative means, which are longer and more costly, to obtain a MA did not prevent the conduct of an undertaking in a dominant position from being abusive where that conduct, considered objectively, has the sole purpose of rendering the abridged procedure provided for by the legislator in point 8(a)(iii) of the third paragraph of Article 4 of Directive 65/65 unavailable and therefore of excluding the producers of generic products from the market for as long as possible and of increasing the costs incurred by them in overcoming barriers to entry to the market, thereby delaying the significant competitive pressure exerted by those products.

155 Furthermore, as regards parallel imports in Sweden, it is common ground that, as the General Court observed at paragraphs 862 and 863 of the judgment under appeal, the deregistration of the MA for Losec capsules actually had the effect of impeding parallel imports, as the Swedish pharmaceutical products agency withdrew the parallel import licences with effect on 1 January 1999 and 30 June 1999 respectively, being of the view that those licences could only be granted where there were valid MAs. It is moreover apparent, inter alia from paragraph 814 of the judgment under appeal and the documents referred to there, that that consequence was envisaged and even intended by AZ. The mere fact that the Court held, in *Paranova Läkemedel and Others* and *Paranova*, a number of years later, that withdrawal of MAs for reasons other than the protection of public health does not justify the automatic cessation of authorisation of parallel imports where the protection of public health can be guaranteed by alternative means, such as collaboration with the national authorities of other Member States, does not alter the fact that the withdrawal of the MAs was, at the time when the application for that withdrawal was lodged, such as to impede parallel imports.

156 It follows from the foregoing that the sixth ground of appeal must be rejected as unfounded.

The fine

Judgment under appeal

157 At paragraphs 884 to 914 of the judgment under appeal, the General Court examined and rejected the four complaints put forward by the appellants by which they criticised the lawfulness of the fine imposed on them by the Commission. Those complaints related, respectively, to a time bar in respect of some of the impugned actions, the gravity of the infringements, their duration and the existence of mitigating circumstances. However, the General Court reduced the amount of the fine in view of the error found on the Commission's part in relation to the second abuse, mentioned at paragraph 124 of this judgment.

Arguments of the parties

158 By their seventh ground of appeal, which is divided into two parts, the appellants claim that the amount of the fine imposed on them is excessive.

159 In the context of the first part, they maintain that the General Court ought to have reduced the amount of the fine on the ground that the abuses were novel. In the present case, the competition rules relating to those abuses had never been established before, which, in accordance with paragraph 163 of the judgment in *AKZO* v *Commission*, justifies the imposition of a symbolic fine. For the reasons set out in the context of the third ground of appeal, the appellants dispute the General Court's analysis, according to which the practices constituting the first abuse were manifestly contrary to competition on the merits, so that a reduction of the fine to take account of their novelty was excluded. The case-law on which the General Court based that analysis is inapplicable, as it relates to a completely different scenario. As regards the second abuse, the appellants claim that the fact that AZ's request to withdraw its MAs was permitted under Union law ought to be regarded as a mitigating circumstance that would justify a reduction of the fine.

160 In the context of the second part of the seventh ground of appeal, the appellants maintain that the absence of anti-competitive effects is a factor that the General Court ought to have taken into account when it re-examined the amount of the fine. They rely in that regard on Case C-8/08 *T-Mobile Netherlands and Others* [2009] ECR I-4529 and Case T-137/94 *ARBED* v *Commission* [1999] ECR II-303. Thus, as regards the first abuse, there were no anti-competitive effects in Denmark and the United Kingdom because SPCs were not granted there. In Germany, although an SPC was granted, it was revoked long before it entered into force and cannot therefore have affected competition. Nor is there any evidence that competition was actually restricted in Belgium, the Netherlands and Norway. As regards the second abuse, the appellants submit that the incorrect application of European Union law by the Swedish authority is a factor weighing in favour of a reduction of the fine.

161 The Commission takes the view that that ground of appeal is inadmissible since its purpose is to secure a general re-examination of the fine and, in any event, considers it unfounded.

Findings of the Court

162 As a preliminary point, it should be remembered that it is not for the Court of Justice, when ruling on questions of law in the context of an appeal, to substitute, on grounds of fairness, its own assessment for that of the General Court exercising its unlimited jurisdiction to rule on the amount of fines imposed on undertakings for infringements of European Union law (Case C-219/95 P *Ferriere Nord* v *Commission* [1997] ECR I-4411, paragraph 31, and Case C 185/95 P *Baustahlgewebe* v *Commission* [1998] ECR I-8417, paragraph 129).

163 Nevertheless, as the Advocate General observed in point 105 of his Opinion, the appellants are not, by the present ground of appeal, merely seeking a general re-examination of the fines imposed but claim that, for the purpose of calculating the fines, the General Court failed to assess in a legally correct manner the novelty of the infringements in question and the effects of those infringements. This ground of appeal is therefore admissible.

164 As regards the first part of that ground of appeal, concerning the novelty of the two abuses of a dominant position, it must be stated that those abuses, as the General Court pointed out at paragraph 900 of the judgment under appeal, had the deliberate aim of keeping competitors away from the market. It is therefore common ground that even though the Commission and the Courts of the European Union had not yet had the opportunity to rule specifically on conduct such as that which characterised those abuses, AZ was aware of the highly anti-competitive nature of its conduct and should have expected it to be incompatible with competition rules under European Union law. In addition, as it has already been explained in the assessment of the third and fifth grounds of appeal, the General Court was fully entitled to find that that conduct was manifestly contrary to competition on the merits.

165 So far as concerns the second part of that ground of appeal, concerning, inter alia, the lack of concrete anti-competitive effects of the first abuse in Denmark, Germany and the United Kingdom, suffice it to note that the appellants cannot take advantage, in the context of the calculation of the fine, of the fact that, thanks to the intervention of a third party, their highly anti-competitive conduct, which was likely to have a significant effect on competition, did not always produce the effects expected. Likewise, the appellants cannot benefit from the fact that the conduct impugned in the context of the second abuse in fact led the Swedish authorities, as AZ had envisaged, to withdraw the parallel import licences in breach of Articles 28 EC and 30 EC and thus generated exactly the anti-competitive effects intended by AZ. The General Court was also fully entitled to hold, at paragraph 902 of the judgment under appeal, 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.

166 The General Court consequently did not err in law in concluding, at paragraphs 901 to 903 and 914 of the judgment under appeal, that the novelty of the abuses and the fact that they did not always produce the effects expected by AZ did not justify either changing the classification of those abuses as serious infringements or a finding that there were mitigating circumstances and therefore a reduction in the fine for those reasons.

167 Accordingly, the seventh ground of appeal in law must be rejected as unfounded.

168 Since none of the grounds of appeal have been upheld, the appeal must be dismissed in its entirety.

Cross-appeal lodged by the EFPIA

169 The arguments put forward by the EFPIA in support of its cross-appeal, in so far as they have not already been set out in the context of the main appeal, relate to the finding by the General Court of the existence of a dominant position. In relation to that finding, the General Court held, on the basis of an assessment made at paragraphs 239 to 294 of the judgment under appeal, that the Commission did not commit any manifest error in concluding that AZ, over certain specified periods, held such a position on a number of national markets during the reference period.

First ground of appeal

Arguments of the parties

170 By its first ground of appeal, the EFPIA complains that the General Court erred in law in failing to take proper account of the role of the State. The General Court failed to consider whether AZ's high market share allowed it to act independently of its competitors and customers or, on the contrary, whether the role of the State as a buyer of prescription medicines with monopsonist power and as price regulator excluded or at least mitigated AZ's alleged market power.

171 The General Court restricted itself, at paragraph 257 of the judgment under appeal, to merely confirming the conclusions of the Commission, which do not however suffice to substantiate the conclusion that AZ was able to act independently while it was active within a market which was heavily regulated in terms of pricing and on which there was fierce competition in terms of innovation. Nor did the General Court consider the extent to which the pharmaceutical undertakings' bargaining power gave them leverage over the State's bargaining power.

172 It follows, moreover, from the General Court's finding at paragraphs 191 and 262 of the judgment under appeal, according to which (i) the sensitivity of doctors and patients to price differences was limited owing to the importance of the role played by therapeutic efficacy and (ii) the costs of medicines were fully or largely covered by social security systems, that price had a limited impact on

the number of Losec prescriptions and hence on AZ's market share. Contrary to the General Court's finding at paragraph 261 of that judgment, therefore, no meaningful conclusion with respect to market power can be derived from the fact that AZ was able to maintain higher shares than its competitors while charging higher prices.

173 The Commission contends that this ground of appeal is inadmissible, since the EFPIA merely requests the Court to reassess the findings of fact made by the General Court. In any event, it submits, this ground of appeal is unfounded.

Findings of the Court

174 Contrary to what the Commission argues, this ground of appeal is admissible since the EFPIA is not disputing the findings of the General Court as regards the facts, but criticises it, first, for having failed to examine the effect of the role of the State for the purposes of establishing whether AZ held a dominant position during the reference period and, secondly, for having confirmed the Commission's conclusions on the basis of inadequate findings.

175 In order to assess whether this ground of appeal is well founded, it should be noted 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 *Hoffmann-La Roche* v *Commission*, paragraphs 38 and 39).

176 The Court has already clarified that, although the importance of the market shares may vary from one market to another, the possession, over a long period, of a very large market share constitutes in itself, save in exceptional circumstances, proof of the existence of a dominant position (*Hoffman-La Roche* v *Commission*, paragraph 41) and that market shares of more than 50% constitute very large market shares (Case *AKZO* v *Commission*, paragraph 60).

177 As the General Court pointed out at paragraphs 245 to 253, 279, 288 and 290 of the judgment under appeal, it is common ground that AZ, during the reference period and on all the geographical markets in question, held very large market shares which were well above those of its competitors, its position on those markets sometimes being even overwhelmingly strong. The General Court was therefore fully entitled to hold, at paragraphs 244, 245, 253 and 278 of that judgment, that the Commission, in its detailed analysis of the competitive conditions which took into account a range of factors, could rely specifically on AZ's generally very large market shares as an indicator of its market power, which was out of all comparison to those of the other market players.

178 In addition, contrary to what the EFPIA claims, the General Court did not omit to examine whether AZ's large market share allowed it to behave independently of its competitors and its customers and whether AZ's market power was excluded or mitigated on account of the State's role as price regulator and buyer with a monopsonist power in respect of medicinal products issued on prescription. On the contrary, it carried out, at paragraphs 256 to 268 of the judgment under appeal, a particularly detailed analysis in that regard.

179 In that context, the General Court held, inter alia, at paragraphs 256 to 260 of that judgment, that, although the price or reimbursement level are the result of a decision adopted by the public authorities, the capacity of a pharmaceutical undertaking to obtain a higher price or reimbursement

level varies according to the added and innovative value of the product, which enabled AZ, as the first producer to offer a PPI whose therapeutic value was much higher than that of H2 blockers, to obtain from the public authorities a higher price as against existing products and 'me-too' products.

180 The General Court furthermore observed, at paragraphs 262 and 264 of that judgment, that the health systems which characterise markets for pharmaceutical products tend in particular to reinforce the market power of pharmaceutical companies offering new products with an added value, since costs of medicines are fully or largely covered by social security systems, which to a significant extent makes demand inelastic. It explained in this connection that, vis-à-vis undertakings which enjoy first-mover status, the reimbursements paid by social security systems, first, are set at relatively high levels in comparison with 'me-too' products, despite the attempts by public authorities to reduce health costs with a view to compensating for the limited sensitivity of prescribing doctors and patients to the high prices of medicinal products and, secondly, 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.

181 Accordingly, the General Court was fully entitled to hold, at paragraphs 261 and 266 of the judgment under appeal, that the fact that AZ was able to maintain much higher market shares than those of its competitors while charging prices higher than those charged for other PPIs was 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.

182 It follows from all the foregoing that this ground of appeal must be dismissed as unfounded.

Second ground of appeal

Arguments of the parties

183 By the second ground of appeal, the EFPIA maintains that the General Court erred in law in considering that AZ's intellectual property rights, its first-mover status and its financial strength constituted evidence of its dominant position. Those three characteristics are typically shared by many innovative companies that successfully engage in research for new products and do not allow a meaningful distinction to be drawn between dominant and non-dominant undertakings. The General Court thus misapplied the case-law of this Court, and in particular the judgments in Joined Cases C-241/91 P and C-242/91 P *RTE and ITP* v *Commission* ('*Magill*') [1995] ECR I-743 and in *IMS Health*, which confirmed that the mere possession of intellectual property rights is not sufficient to establish the existence of a dominant position.

184 The Commission contends that this ground of appeal is inadmissible in so far as it is based merely on the assertion that AZ's financial situation and human resources are irrelevant for the purposes of the assessment of the existence of a dominant position. As to the remainder, this ground of appeal is unfounded.

Findings of the Court

185 It must first be stated that, in so far as this ground of appeal is directed against the finding at paragraphs 283 and 286 of the judgment under appeal, according to which the Commission did not commit a manifest error of assessment in taking into account, among other factors, AZ's first-mover status on the PPI market and its financial strength for the purposes of assessing its competitive position on the market, it is inadmissible since, as the Advocate General observed at paragraph 130 of his Opinion, the EFPIA does not indicate how that finding is vitiated by legal error.

186 As regards, next, the arguments put forward by the EFPIA criticising the General Court's finding, at paragraph 275 of the judgment under appeal, that the Commission did not commit any such error in including in that assessment the existence and use of AZ's intellectual property rights, the General Court was fully entitled to hold, at paragraph 270 of that judgment, that, 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*, paragraphs 46 and 47).

187 As the General Court observed in this connection at paragraph 271 of the judgment under appeal, Losec, as the first PPI to be introduced on the market, 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 and to dictate to a large extent market-entry terms to them. Moreover, the existence and use of intellectual property rights was only one of the various factors on which the Commission based the finding in this case that AZ held a dominant position on a number of national markets during the reference period.

188 Lastly, contrary to what the EFPIA submits, the taking into account of intellectual property rights for the purposes of finding that an undertaking has a dominant position does not mean that companies introducing innovative products on the market should refrain from acquiring a comprehensive portfolio of intellectual property rights or from enforcing those rights. It is sufficient to point out in that regard that a dominant position is not prohibited, only its abuse, and a finding that an undertaking has such a position is not in itself a criticism of the undertaking concerned (see, to that effect, Joined Cases C-395/96 P and C-396/96 P *Compagnie maritime belge transports and Others* v *Commission* [2000] ECR I-1365, paragraph 37, and *TeliaSonera Sverige*, paragraph 24).

189 Consequently, this ground must be rejected as in part inadmissible and in part unfounded.

190 Inasmuch as neither of the two grounds of the cross-appeal lodged by the EFPIA has been upheld, that cross-appeal must be dismissed in its entirety.

Cross-appeal lodged by the Commission

191 The Commission's cross-appeal is directed against the General Court's arguments, set out at paragraphs 840 to 861 of the judgment under appeal, in which it held that the Commission had demonstrated for the Kingdom of Sweden, but not for the Kingdom of Denmark or the Kingdom of Norway, that the deregistration of the MA for Losec capsules was capable of excluding parallel imports of those products.

Arguments of the parties

192 The Commission submits that the General Court misapplied the rules on the burden and standard of proof by requiring that the Commission show that the national authorities were inclined to withdraw, or indeed did habitually withdraw, parallel import licences following deregistration of the MA. In reality, the General Court focused on the actual effects of the practice instead of applying the legal test which it had set for itself. The General Court's reasoning is contradictory and has paradoxical consequences. Thus, the Kingdom of Denmark was specifically the only country in which AZ's deregistration strategy proved to be wholly effective, and yet the General Court found that there was no abuse in that country, which illustrates that the causality test applied was too narrow. The mere fact that other factors might have contributed to the exclusion of all parallel trade is no justification for the conclusion that deregistration was not also apt to have that effect. Furthermore, in so far as the legal context in the three countries was exactly the same, it is contradictory to arrive at different

results. In addition, the General Court failed, at paragraph 850 of the judgment under appeal, to assess crucial evidence and, at paragraphs 839 and 846 of that judgment, made a manifestly flawed application of the presumption of innocence.

193 In addition, the General Court's finding, at paragraphs 848 and 849 of the judgment under appeal, that the AZ documents referred to by the Commission reflected only the personal opinion, or the expectations, of AZ employees and could at the very most show that AZ had the intention of excluding parallel imports by deregistering the Losec capsules MA, constitutes a manifest distortion of the clear sense of the evidence. Those documents show that AZ had carried out its own research into the practices of the national authorities and had concluded that its strategy was likely to succeed in the three countries concerned. In those circumstances, the Commission submits, the General Court was wrong to require that the Commission investigate, *ex post facto*, years after the events, what an authority's attitude might have been, when AZ's research into the authorities' attitude was particularly reliable. Nor is the Commission to be criticised for not having ascertained a practice that did not exist, owing to the fact that the 'switch and deregistration' operation was unprecedented. Furthermore, the rejection by the General Court, at paragraph 849 of that judgment, of the relevance of the evidence of AZ's intention to restrict competition by means falling outside the scope of competition on the merits was contrary to the test which it had set for itself and to the case-law of the Court of Justice.

Findings of the Court

194 In order to assess whether the Commission's argument is well founded, it is necessary to examine the grounds on which the General Court in the present case held that, in the light of the appellant's argument that the reduction in parallel imports was due to the success of Losec MUPS, that institution had not shown to the requisite legal standard that the withdrawal, in Denmark and in Norway, of the MA for Losec capsules was liable to prevent parallel imports of those products.

195 So far as concerns, first of all, the Kingdom of Denmark, the General Court observed, at paragraphs 840, 843 and 847 of the judgment under appeal, on the one hand, that the contested decision did not include any evidence indicating that, before the delivery of *Paranova Läkemedel and Others* and *Paranova*, the content of which was recalled at paragraph 155 of this judgment, it was the Danish authorities' practice to automatically withdraw parallel import licences following the withdrawal of the MAs for the relevant product for reasons unrelated to public health and, on the other hand, that that decision did not even establish that those authorities had revoked the parallel import licences for Losec capsules.

196 The General Court was therefore fully entitled to hold, at paragraph 846 of the judgment under appeal, that it was 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 MAs for the relevant product. Even if the judgments in *Paranova Läkemedel and Others* and *Paranova* were not delivered until a number of years after the deregistration by AZ of the MAs for Losec capsules in Denmark, it cannot be assumed, in the absence of such evidence, that the Danish authorities were likely to react to that deregistration in the way AZ wished, in breach of Articles 28 EC and 30 EC, and that that deregistration was thus such as to restrict competition.

197 Nor did the General Court distort, at paragraphs 847 and 848 of the judgment under appeal, AZ's memorandum of 22 October 1997, 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 MAs, by holding that that document only reflected the expectations of AZ employees regarding the reaction of 'several of the Scandinavian authorities', without however establishing that the Danish authorities were actually inclined to withdraw the parallel import licences in the present case, and that that document showed, at the very most, AZ's

intention to exclude parallel imports by deregistering the Losec capsule MA. Furthermore, contrary to what the Commission seems to be submitting, AZ's expectations do not suffice to prove that deregistration of the MA in Denmark was objectively such as to lead to the withdrawal of the parallel import licences in that country.

198 As regards the Commission's argument that, at paragraphs 850 and 851 of the judgment under appeal in which it examined a document of AZ's board in Denmark referred to in recital 311 of the contested decision, the General Court failed to take into consideration other items of evidence, inter alia the Norwegian post-patent strategy document referred to in recital 302 of that decision, it must be stated that not only does recital 311 of the contested decision refer to recital 302 thereof, but that the Norwegian post-patent strategy document does not in any way rule out the ceasing of parallel imports of Losec capsules in Denmark being due, as the appellants submit, to consumers migrating towards Losec MUPS and not to a withdrawal of parallel import licences. Thus, as the General Court observed at paragraph 788 of that judgment, that document stated simply that, following the deregistration of the Losec capsule MAs 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'.

199 Consequently, the General Court was fully entitled to conclude, at paragraph 852 of the judgment under appeal, that, in the absence of any indication in this respect in the contested decision and in view of the fact that it was not even established that the Danish authorities had revoked the parallel import licences for Losec capsules, a presumption of a causal link between the deregistration of the Losec capsule MA 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.

200 So far as concerns, next, the Kingdom of Norway, the General Court observed, at paragraphs 856 to 858 of the judgment under appeal, that the Norwegian authority had allowed parallel imports of Losec capsules to continue by reference to AZ's MA for Losec MUPS, which was itself based on the MA for Losec capsules and that the course of action adopted by that authority was consistent with the regulatory practice allowed by the Court of Justice in its judgment in *Rhône-Poulenc Rorer and May & Baker*.

201 The fact that a significant drop in parallel imports of Losec in Norway was registered from 1998 onwards, despite the fact that the Norwegian authority maintained parallel import licences for Losec capsules, tends to suggest that the drop in those imports was not due to the deregistration of the MAs and could, on the contrary, indicate that that drop was caused by a reduction in the demand for Losec capsules following the introduction of Losec MUPS.

202 In addition, for the reasons set out at paragraph 196 of this judgment and as the General Court found at paragraphs 859 and 860 of the judgment under appeal, the Commission could not, without tangible evidence, presume that, although the parallel import licences had in the present case been maintained, the deregistration of the MA for Losec capsules in Norway was at the very least liable to lead the Norwegian authorities to withdraw the parallel import licences.

203 It follows from the foregoing that the cross-appeal lodged by the Commission must be rejected as unfounded.

Costs

204 Under Article 184(2) of the Rules of Procedure of the Court of Justice, where the appeal is unfounded, the Court is to make a decision as to the costs. In accordance with Article 138(1) of those rules, which apply to the procedure on appeal by virtue of Article 184(1) of those rules, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

205 Since the Commission has applied for an order that the appellants and the EFPIA pay the costs and those parties have been unsuccessful, the appellants must be ordered to pay the costs of the appeal and the EFPIA must be ordered to pay the costs of its cross-appeal and to bear its own costs relating to its intervention in support of the main appeal.

206 The Commission is to bear its own costs relating to its cross-appeal.

On those grounds, the Court (First Chamber) hereby:

1. **Dismisses the main appeal and cross-appeals;**

2. **Orders AstraZeneca AB and AstraZeneca plc to pay the costs relating to the main appeal;**

3. **Orders the European Federation of Pharmaceutical Industries and Associations (EFPIA) to pay the costs of its cross-appeal and to bear its own costs relating to the main appeal;**

4. **Orders the European Commission to bear its own costs relating to its cross-appeal.**

[Signatures]