European Court of Justice, 5 December 1996, Merck en Beecham

TRADEMARK LAW

The principle of free movement of goods in Spain and Portugal

- **The principle of free movement of goods and that it is settled case-law that such deroga-tions are to be interpreted strictly The provisions in question must therefore be interpreted in a way that the transitional periods expire on the date which ensures the earliest application, in the field concerned**

In so doing, it is important to bear in mind that Articles 47 and 209 of the Act of Accession introduced a derogation from the principle of free movement of goods and that it is settled case-law that such derogations are to be interpreted strictly (see, to this effect, **Case C-191/90 Generics and Harris Pharmaceuticals [1992] ECR I-5335, paragraph 41**). The provisions in question must therefore be interpreted in a way that the transitional periods expire on the date which ensures the earliest application, in the field concerned, of the principle of free movement of goods in Spain and Portugal. Consequently, the answer to the first two questions must be that the transitional periods provided for in Article 47 and 209 of the Act of Accession expired on 6 October 1995 in the case of the Kingdom of Spain and on 31 December 1994 in the case of the Portuguese Republic.

- **Treaty preclude application of national legislation which grants the holder of a patent for a pharmaceutical product the right to oppose importation by a third party of that product from another Member State in circum-stances where the holder first put the product on the market in that State after its accession to the European Community but before the product could be protected by a patent in that State, unless the holder of the patent can prove that he is under a genuine, existing legal ob-ligation to market the product in that Member State.**

In view of the foregoing, the answer to be given to the third question must be that Articles 30 and 36 of the Treaty preclude application of national legislation which grants the holder of a patent for a pharmaceutical product the right to oppose importation by a third party of that product from another Member State in circumstances where the holder first put the product on the market in that State after its accession to the European Community but before the product could be protected by a patent in that State, unless the holder of the patent can prove that he is under a genuine, existing legal obligation to market the product in that Member State.

Source: **Eur-Lex**

European Court of Justice, 5 December 1996
((Rodríguez Iglesias, Mancini, Murray, Sévon, Kakouris, Gulmann, Edward, Puissochet, Ragnemalm, Fennelly)

Parties

In Joined Cases C-267/95 and C-268/95,
REFERENCES to the Court under Article 177 of the EC Treaty by the High Court of Justice of England and Wales, Chancery Division, Patents Court, for a preliminary ruling in the proceedings pending before that court between
Merck & Co. Inc., Merck Sharp & Dohme Ltd, Merck Sharp & Dohme International Services BV
and
Primecrown Ltd, Ketan Himatlal Mehta, Bharat Himatlal Mehta, Necessity Supplies Ltd,
and between
Beecham Group plc
and
Europharm of Worthing Ltd,
on the interpretation of Article 47 and Article 209 of the Act concerning the Conditions of Accession of the Kingdom of Spain and the Portuguese Republic and the Adjustments to the Treaties (OJ 1985 L 302, p. 23), and of Articles 30 and 36 of the EC Treaty,
THE COURT,
composed of: G.C. Rodríguez Iglesias, President, G.F. Mancini, J.L. Murray and L. Sevón (Presidents of Chambers), C.N. Kakouris, C. Gulmann (Rapporteur), D.A.O. Edward, J.-P. Puissochet and H. Ragnemalm, Judges,
Advocate General: N. Fennelly,
Registrar: L. Hewlett, Administrator,
after considering the written observations submitted on behalf of:
- Merck & Co. Inc., Merck Sharp & Dohme Ltd and Merck Sharp & Dohme International Services BV, by Romano Subiotto, Solicitor, and Dirk Vandermeersch, of the Brussels Bar, and Mario Siragusa, of the Rome Bar,
- Beecham Group plc, by David Kitchin QC and Justin Turner, Barrister, instructed by Mark Hodgson, Tony Woodgate, Ciaran Walker and Lyndall Squire, Solicitors,
- Primecrown Ltd, Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd, by Martin Howe and Nicholas Shea, Barristers, instructed by R.R. Sanghvi & Co., Solicitors,
- the United Kingdom Government, by Lindsey Nicoll, of the Treasury Solicitor's Department, acting as Agent, and Geoffrey Hobbs QC and Michael Silverleaf, Barrister,
- the Belgian Government, by Jan Devadder, Director in the Legal Service of the Ministry of Foreign Affairs, acting as Agent,

- the Greek Government, by Vasileios Kontolaimos, Assistant Legal Adviser to the State Legal Council, Kyriaki Grigoriou, representative at law of the same Council, and Lydia Pnevmatikoy, special scientific collaborator in the Department for Contentious Community Affairs of the Ministry of Foreign Affairs, acting as Agents,
- the Spanish Government, by Alberto José Navarro González, Director General for Community Legal and Institutional Affairs, and Rosario Silva de Lapuerta, Abogado del Estado, of the State Legal Service, acting as Agents,
- the Italian Government, by Oscar Fiumara, Avvocato dello Stato, acting as Agent,
- the Commission of the European Communities, by Richard Wainwright, Principal Legal Adviser, acting as Agent,

having regard to the Report for the Hearing,
after hearing the oral observations of Merck & Co. Inc., Merck Sharp & Dohme Ltd and Merck Sharp & Dohme International Services BV, represented by Romano Subiotto and Mario Siragusa; of Primecrown Ltd, Ketan Himatlal Mehta, Bharat Himatlal Mehta, and Necessity Supplies Ltd, represented by Martin Howe and Nicholas Shea; of Beecham Group plc, represented by David Kitchin; of the United Kingdom Government, represented by Lindsey Nicoll and Gerald Barling QC; of the Danish Government, represented by Peter Biering, Head of Division in the Ministry of Foreign Affairs, acting as Agent; of the Greek Government, represented by Vasileios Kontolaimos; of the Spanish Government, represented by Gloria Calvo Díaz, Abogado del Estato, acting as Agent; of the French Government, represented by Philippe Martinet, Foreign Affairs Secretary in the Legal Affairs Directorate in the Ministry of Foreign Affairs, acting as Agent; of the Italian Government, represented by Oscar Fiumara; of the Swedish Government, represented by Erik Brattgaard and Staffan Sandstroem, Departementsraad in the Department of Foreign Trade of the Ministry of Foreign Affairs, acting as Agents; and of the Commission, represented by Richard Wainwright, at the hearing on 13 March 1996,
after hearing the Opinion of the Advocate General at the sitting on 6 June 1996,
gives the following

Judgment

Grounds

1 By two orders of 13 July 1995, received at the Court on 8 August 1995 in Case C-267/95 and on 9 August 1995 in Case C-268/95, the High Court of Justice of England and Wales, Chancery Division, Patents Court, referred to the Court for a preliminary ruling under Article 177 of the EC Treaty questions concerning the interpretation of Article 47 and Article 209 of the Act concerning the Conditions of Accession of the Kingdom of Spain and the Portuguese Republic and the Adjustments to the Treaties (OJ 1985 L 302, p. 23, hereinafter `the Act of Accession') and of Articles 30 and 36 of the EC Treaty.

2 The questions have been raised in proceedings brought, in Case C-267/95, by Merck & Co. Inc., Merck Sharp & Dohme Ltd and Merck Sharp & Dohme International Services BV (hereinafter `Merck') against Primecrown Ltd, Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd (hereinafter `Primecrown') and, in Case C-268/95, by Beecham Group plc (hereinafter `Beecham') against Europharm of Worthing Ltd (hereinafter `Europharm').

3 Merck claims that Primecrown has infringed its United Kingdom patents for a hypertension drug marketed under the trade mark Innovace in the United Kingdom and under the trade mark Renitec elsewhere, for a drug prescribed in prostrate treatment, marketed under the trade mark Proscar, and for a glaucoma drug marketed under the trade mark Timoptol. It complains that Primecrown has carried out parallel imports of those products into the United Kingdom. Renitec and Proscar have been imported from Spain whilst Timoptol has been imported from Portugal.

4 Beecham has brought an action against Europharm for infringing its United Kingdom patents covering an antibiotic called Augmentin in the United Kingdom and Augmentine in Spain. Beecham complains that Europharm has imported this product from Spain into the United Kingdom with a view to applying to the competent authorities for an import licence which would allow it to import more of the product.

5 Merck and Beecham consider that they are entitled to oppose parallel imports of a drug for which they hold patents when, as in these cases, those imports come from a Member State where their products are marketed but were not patentable there.

6 Primecrown and Europharm refer, for their part, to the case-law of the Court on Articles 30 and 36 of the Treaty and in particular to the principle of the exhaustion of rights, as interpreted by the Court in its **judgment in Case 187/80 Merck v Stephar and Exler ([1981] ECR 2063**, hereinafter `Merck v Stephar' or `Merck'). They deduce from Merck v Stephar that, upon expiry of the transitional periods laid down in Articles 47 and 209 of the Act of Accession, they are entitled to import the products in question from Spain and Portugal where they have been marketed by, or with the consent of, the patent holders.

7 In **Merck v Stephar**, the Court referred to its case-law on Articles 30 and 36 of the Treaty according to which the proprietor of an industrial and commercial property right protected by the legislation of a Member State may not rely on that legislation to oppose the importation of a product which has been lawfully put on the market in another Member State by, or with the consent of, the proprietor of that right himself. The Court held that this case-law also applied where the product concerned was put on the market by, or with the consent of, the proprietor in a Member State where the product was not patentable.

8 Article 42, concerning the Kingdom of Spain, and Article 202, concerning the Portuguese Republic, of the Act of Accession, impliedly referring to Articles 30 and 34 of the Treaty, abolished, as from 1 January 1986,

quantitative restrictions on imports and exports and all measures having equivalent effect existing between the Community and those two new Member States.
9 Articles 47 and 209 of the Act of Accession (in relation to Spain and Portugal respectively) provide in substance that, by derogation from Articles 42 and 202 of that Act, the rule in **Merck v Stephar** is not to apply to pharmaceutical products during a certain transitional period.
10 The first paragraph of Articles 47 and 209 of the Act of Accession provides that the holder, or his beneficiary, of a patent for a chemical or pharmaceutical product or a product relating to plant health, filed in a Member State at a time when a product patent could not be obtained in Spain or in Portugal for that product may rely on the rights granted by that patent in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection even if that product was put on the market in Spain or in Portugal for the first time by him or with his consent.
11 According to the second paragraph of those two articles, that right may be invoked until the end of the third year after Spain and Portugal have made those products patentable.
12 Protocols Nos 8 and 19 to the Act of Accession require the Kingdom of Spain and the Portuguese Republic to make their legislation on patents compatible with the level of industrial property protection in the Community. For that purpose, they provide that those two States must accede to the Munich Convention of 5 October 1973 on the European Patent and make pharmaceutical products patentable within a certain period. In accordance with those provisions, pharmaceutical products were made patentable on 7 October 1992 in Spain and on 1 January 1992 in Portugal.
13 In the order for reference the national court explains that the present disputes have arisen because the holders of the patents in question do not have, and never could have got, patent protection in Spain or Portugal for the drugs concerned. Prices in those Member States are lower than elsewhere in the European Union, and medicines sold by the patent holders to wholesalers there, instead of going to Spanish or Portuguese consumers, are immediately exported.
14 The national court considers that the cases before it raise two distinct questions concerning the interpretation of Community law: (i) the question of the duration of the transitional arrangement provided for by the Act of Accession and (ii) the question whether the principle of the exhaustion of patent rights, as laid down by the Court in **Merck v Stephar**, must be reconsidered in view of the particular circumstances referred to in the order for reference.
15 In those circumstances, the High Court decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:
`1. Will the provisions and effect of Article 47 of the Spanish Treaty of Accession to the European Communities continue to apply to pharmaceutical products
1.1 imported from Spain; or 1.2 first marketed in Spain
until
(a) 7 October 1995; or (b) 31 December 1995; or (c) 7 October 1996; or (d) 31 December 1996; or
(e) the end of the third year after the particular pharmaceutical, protected by a product patent in one or more Member State(s) of the European Union and which was previously unpatentable in Spain, has become patentable in Spain
and which of such dates is applicable with regard to such acts?
2. Will the provisions and effect of Article 209 of the Portuguese Accession to the European Communities continue to apply to pharmaceutical products
2.1 imported from Portugal; or 2.2 first marketed in Portugal;
until
(a) 1 January 1995; or (b) 31 December 1995; or (c) 1 June 1998; or (d) 31 December 1998; or
(e) the end of the third year after the particular pharmaceutical, protected by a product patent in one or more Member State(s) of the European Union and which was previously unpatentable in Portugal, has become patentable in Portugal
and which of such dates is applicable with regard to such acts?
3. After the expiration of Article 47 (and/or Article 209, as appropriate), in a case where:
3.1 an undertaking is the proprietor ("the Proprietor") of a patent ("the Patent") in one or more Member States of the European Communities ("the Member State") for a pharmaceutical product ("the Pharmaceutical");
3.2 the Pharmaceutical was first put on the market in a country by the Proprietor after that country's accession to the EC but at a time when the Pharmaceutical could not be protected by a product patent in that country;
3.3 a third party imports the Pharmaceutical from that country into the Member State;
3.4 and the patent legislation in the Member State granted the proprietor of the Patent the right to oppose by legal action the importation of the Pharmaceutical from that country
do the rules set forth in the EC Treaty concerning the free movement of goods prevent the Proprietor from availing himself of the right referred to in paragraph 3.4 above, in particular if:
(a) the Proprietor had and continues to have a legal and/or ethical obligation to market and to continuing marketing the Pharmaceutical in that country; and/or
(b) that country's and/or EC legislation effectively requires that, once the Pharmaceutical is put on the market in that country, the Proprietor supply and continue to supply sufficient quantities to satisfy the needs of domestic patients; and/or
(c) that country's legislation grants to its authorities, and its authorities exercise, the right to fix the sale price of the Pharmaceutical in that country and legislation prohibits the sale of the Pharmaceutical at any other price; and/or
(d) the price of the Pharmaceutical in that country has been fixed by its authorities at a level at which substan-

tial exports of the Pharmaceutical from such country to the Member State are anticipated with the result that the economic value of the Patent would be significantly eroded and research and development for future pharmaceuticals planned by the Proprietor significantly undermined, contrary to the rationale underlying the recent introduction by the EC Council of the Supplementary Protection Certificate?'

16 By order of the President of the Court of 6 September 1995 Cases C-267/95 and C-268/95 were joined for the purposes of the written procedure, the oral procedure and the judgment.

The first two questions

17 By its first two questions, which should be examined together, the national court asks this Court to specify the dates on which the transitional periods provided for by Articles 47 and 209 of the Act of Accession expired.

18 According to both those provisions, the holder of a patent for a pharmaceutical product may, until the end of the third year after that type of product has become patentable in the Kingdom of Spain and the Portuguese Republic, invoke the rights granted by that patent in order to prevent the import and marketing of pharmaceutical products put on the market in Spain and Portugal by himself or with his consent. Such products became patentable in Spain on 7 October 1992 and in Portugal on 1 January 1992.

19 As regards the different dates of expiry of the transitional arrangements envisaged in the first two questions, for the reasons given by the Advocate General in points 181 to 194 of his Opinion, only two dates may reasonably be considered in the case of each State as marking the end of the third year after pharmaceutical products became marketable, namely 6 October 1995 and 31 December 1995 in the case of the Kingdom of Spain and 31 December 1994 and 31 December 1995 in the case of the Portuguese Republic.

20 The choice between those two dates for each of the two Member States depends on whether the transitional period expired exactly three years after pharmaceutical products became patentable, that is to say 6 October 1995 in the case of Spain and 31 December 1994 in the case of Portugal, or whether it expired at the end of the third calendar year after the date on which the products became patentable, that is to say 31 December 1995 in the case of both States.

21 That question cannot on any view be resolved solely on the basis of the wording of Articles 47 and 209 of the Act of Accession (`jusqu'à la fin de la troisième année après'; `indtil udgangen af det tredje aar efter', `bis zum Ende des dritten Jahres nachdem', `ìÝ÷ñé ôï ôÝëïò ôïõ ôñssôïõ Ýôïõò áðue', `hasta el final del tercer año después', `until the end of the third year after', `alla fine del terzo anno successivo', `tot het einde van het derde jaar', `até três anos após'). While the wording of most of the language versions favours the first solution, that of the other versions favours the second.

22 It is therefore appropriate to take account of other criteria of interpretation, in particular the general scheme and the purpose of the regulatory system of which the provisions in question form part.

23 In so doing, it is important to bear in mind that Articles 47 and 209 of the Act of Accession introduced a derogation from the principle of free movement of goods and that it is settled case-law that such derogations are to be interpreted strictly (see, to this effect, **Case C-191/90 Generics and Harris Pharmaceuticals [1992] ECR I-5335, paragraph 41**).

24 The provisions in question must therefore be interpreted in a way that the transitional periods expire on the date which ensures the earliest application, in the field concerned, of the principle of free movement of goods in Spain and Portugal.

25 Consequently, the answer to the first two questions must be that the transitional periods provided for in Article 47 and 209 of the Act of Accession expired on 6 October 1995 in the case of the Kingdom of Spain and on 31 December 1994 in the case of the Portuguese Republic.

The third question

26 By its third question the national court asks whether Articles 30 and 36 of the Treaty preclude application of national legislation which grants the holder of a patent for a pharmaceutical product the right to oppose importation by a third party of that product from another Member State in circumstances where the holder first put the product on the market in that State after its accession to the European Community but before the product could be protected by a product patent in that State. In this regard, the national court mentions certain specific circumstances and asks what relevance they have.

27 In substance, the High Court is seeking to ascertain whether it is necessary to reconsider the rule in **Merck v Stephar** or whether, having regard to the specific circumstances mentioned, its scope should be limited.

28 Merck and Beecham consider that there are weighty reasons for departing from the rule in **Merck v Stephar**. They point out first of all that an important change in the situation has occurred since Merck. At the time when the Court gave that judgment, it was the exception rather than the rule for pharmaceutical products to be patentable in Europe. Nowadays, such products are patentable in all the countries of the European Economic Area, with the exception of Iceland. Similarly, the Community institutions have emphasized the importance of patents in the pharmaceutical sector, in particular by the adoption of 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). Merck and Beecham then point to the increasingly serious financial consequences of maintaining the rule in **Merck** which, in their view, appreciably reduce the value of patents granted in the Community. Finally, they argue that the specific subject-matter of a patent can be exhausted only if the product in question is marketed with patent protection and that Merck is incompatible with the later case-law of the Court.

29 It is first necessary to recall the Court's reasoning in **Merck**.
30 In that judgment, the Court referred to its judgment **in Case 15/74 Centrafarm v Sterling Drug [1974] ECR 1147** in which it held, in paragraphs 8 and 9, that as an exception, on grounds of the protection of industrial and commercial property, to one of the fundamental principles of the common market, Article 36 of the Treaty admitted such derogation only in so far as it was justified for the purpose of safeguarding rights constituting the specific subject-matter of that property, which, as regards patents, is, in particular, in order to reward the creative effort of the inventor, to guarantee that the patentee has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements.
31 In paragraphs 9 and 10 of **Merck**, the Court then stated that it followed from the definition of the specific purpose of a patent that the substance of a patent right lies essentially in according the inventor an exclusive right to put the product on the market for the first time, thereby allowing him a monopoly in exploiting his product and enabling him to obtain the reward for his creative effort without, however, guaranteeing such reward in all circumstances.
32 The Court held, finally, in paragraphs 11 and 13 of **Merck** that it was for the holder of the patent to decide, in the light of all the circumstances, under what conditions he would market his product, including the possibility of marketing it in a Member State where the law did not provide patent protection for the product in question. If he decides to do so, he must then accept the consequences of his choice as regards free movement of the product within the common market, this being a fundamental principle forming part of the legal and economic circumstances which the holder of the patent must take into account in determining how to exercise his exclusive right. Under those conditions, to permit an inventor to invoke a patent held by him in one Member State in order to prevent the importation of the product freely marketed by him in another Member State where that product was not patentable would cause a partitioning of national markets contrary to the aims of the Treaty.
33 For the reasons set out below, the arguments for reconsideration of the rule in **Merck** are not such as to call in question the reasoning on which the Court based that rule.
34 It is true, as Merck and Beecham point out, that it is now the norm for pharmaceutical products to be patentable. However, such a development does not mean that the reasoning underlying the rule in **Merck** is superseded.
35 The same is true in relation to the arguments based, first, on the efforts made by the Community institutions to give enhanced protection to holders of patents for pharmaceutical products and, second, on the consequences of maintaining that rule for research and development by the pharmaceutical industry.
36 There can be no doubt now, any more than at the time when the judgment in **Merck** was given, that if a patentee could prohibit the importation of protected products marketed in another Member State by him or with his consent, he would be able to partition national markets and thereby restrict trade between the Member States. By the same token, if a patentee decides, in the light of all the circumstances, to put a product on the market in a Member State where it is not patentable, he must accept the consequences of his choice as regards the possibility of parallel imports.
37 The arguments put forward in the present cases have not shown that the Court was wrong in its assessment of the balance between the principle of free movement of goods in the Community and the principle of protection of patentees' rights, albeit that, as a result of striking that balance, the right to oppose importation of a product may be exhausted by its being marketed in a Member State where it is not patentable.
38 It is important to remember in this respect that the transitional measures provided for by Articles 47 and 209 of the Act of Accession were adopted in the light of the ruling in **Merck**. Although the Member States considered it necessary to postpone the effects of that ruling for a long period, they provided that, upon expiry of the transitional arrangements, Articles 30 and 36 of the Treaty, as interpreted in Merck, should apply in full to trade between Spain and Portugal, on the one hand, and the existing Member States, on the other.
39 Furthermore, the situations addressed by the ruling in **Merck** are set to disappear since pharmaceutical products are now patentable in all the Member States. If, upon accession of new States to the Community, such situations were to recur, the Member States could adopt the measures considered necessary, as was the case when the Kingdom of Spain and the Portuguese Republic acceded to the Community.
40 Finally, Merck's and Beecham's argument that judgments given by the Court after **Merck**, in particular those in **Case 19/84 Pharmon v Hoechst ([1985] ECR 2281**) and in **Case 158/86 Warner Brothers and Metronome Video v Christiansen ([1988] ECR 2605**), support their point of view must be rejected.
41 Contrary to their contention, the judgment in **Pharmon** shows that the Court confirmed the principles laid down in Merck. In Pharmon, the Court emphasized the importance of the patentee's consent to the product in question being put into circulation. At paragraph 25 it held that, where the authorities of a Member State grant a third party a compulsory licence allowing him to carry out manufacturing and marketing operations which the patentee would normally have the right to prevent, the patentee cannot be deemed to have consented to those operations and he may therefore oppose importation of products made by the holder of the compulsory licence.
42 Unlike the cases now under consideration, **Warner Brothers** concerned legislation of the importing State which allowed the author of a musical or cinematographic work not only to control the initial sale but also to oppose the hiring out of videos of that work for as

long as he refused specific consent for such hiring out. In that judgment, the Court held that, since there was a specific market for hiring out distinct from the market for sales, such a specific right would lose its substance if the proprietor of the work were unable to authorize hiring out, even in the case of video cassettes already put into circulation with his consent in another Member State whose legislation allowed the author to control the initial sale without giving him the right to prohibit hiring out.

43 Since none of the arguments for re-examining the rule in **Merck** which the Court has thus far considered have been accepted, the Court must next determine whether, having regard to the specific circumstances mentioned by the national court, the scope of that rule must be restricted.

44 The first question to be considered is whether the rule in **Merck** also applies where the patentee has a legal or ethical obligation to market or to continue to market his product in the exporting State. Here the national court is concerned to know what importance is to be attached to a requirement of that State's legislation or of Community legislation that, once the product has been put on the market in that State, the patentee must supply and continue to supply sufficient quantities to satisfy the needs of domestic patients.

45 The second question is whether the rule in **Merck** applies where the legislation of the exporting State not only grants to its authorities the right, which they exercise, to fix the sale price of the product but also prohibits the sale of the product at any other price. Here the national court is concerned to know whether it is relevant that those authorities have fixed the price of the products at a level such that substantial exports of the product to the Member State of importation are foreseeable.

46 Merck and Beecham maintain in particular that, in the circumstances mentioned in the order for reference, their right to decide freely on the conditions in which they market their products is removed or considerably reduced. In their view, it follows from **Pharmon** that the rule in **Merck** does not apply in the present cases.

47 As to that, although the imposition of price controls is indeed a factor which may, in certain conditions, distort competition between Member States, that circumstance cannot justify a derogation from the principle of free movement of goods. It is well settled that distortions caused by different price legislation in a Member State must be remedied by measures taken by the Community authorities and not by the adoption by another Member State of measures incompatible with the rules on free movement of goods (see **Case 16/74 Winthrop [1974] ECR 1183, paragraph 17**; **Joined Cases 55/80 and 57/80 Musik-Vertrieb Membran and K-tel International v GEMA [1981] ECR 147, paragraph 24**; and **Joined Cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb and Others [1996] ECR I-3457, paragraph 46**).

48 The next question which must be examined is how far the rule in **Merck** applies where patentees are legally obliged to market their products in the exporting State.

49 In answering that question it is to be remembered, first, that in **Merck** the Court emphasized the importance of the fact that the patentee had taken his decision to market his product freely and in full knowledge of all relevant circumstances and, second, that it follows from **Pharmon** that a patentee who is not in a position to decide freely how he will market his products in the exporting State may oppose importation and marketing of those products in the State where the patent is in force.

50 It follows that, where a patentee is legally bound under either national law or Community law to market his products in a Member State, he cannot be deemed, within the meaning of the ruling in Merck, to have given his consent to the marketing of the products concerned. He is therefore entitled to oppose importation and marketing of those products in the State where they are protected.

51 It is for the patentee to prove, before the national court from which an order prohibiting imports is sought, that there is a legal obligation to market the product concerned in the exporting State. He must in particular show, for example by reference to decisions of the competent national authorities or courts or of the competent Community authorities, that there is a genuine, existing obligation.

52 According to the information given to the Court in these proceedings and as the Advocate General observes in points 152 and 153 of his Opinion, such obligations can hardly be said to exist in the case of the imports in question.

53 Finally, as regards the argument that ethical obligations may compel patentees to provide supplies of drugs to Member States where they are needed, even if they are not patentable there, such considerations are not, in the absence of any legal obligation, such as to make it possible properly to identify the situations in which the patentee is deprived of his power to decide freely how he will market his product. Such considerations are, at any rate in the present context, difficult to apprehend and distinguish from commercial considerations. Such ethical obligations cannot, therefore, be the basis for derogating from the rule on free movement of goods laid down in **Merck**.

54 In view of the foregoing, the answer to be given to the third question must be that Articles 30 and 36 of the Treaty preclude application of national legislation which grants the holder of a patent for a pharmaceutical product the right to oppose importation by a third party of that product from another Member State in circumstances where the holder first put the product on the market in that State after its accession to the European Community but before the product could be protected by a patent in that State, unless the holder of the patent can prove that he is under a genuine, existing legal obligation to market the product in that Member State.

Decision on costs

Costs

55 The costs incurred by the United Kingdom, Belgium, Danish, Greek, Spanish, French, Italian and Swedish Governments and by the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the actions pending before the national court, the decision on costs is a matter for that court.

Operative part
On those grounds,
THE COURT,
In answer to the questions submitted to it by the High Court of Justice of England and Wales, Chancery Division, Patents Court, by orders of 13 July 1995, hereby rules:
1. The transitional periods provided for in Articles 47 and 209 of the Act concerning the Conditions of Accession of the Kingdom of Spain and the Portuguese Republic and the Adjustments of the Treaties expired on 6 October 1995 in the case of the Kingdom of Spain and on 31 December 1994 in the case of the Portuguese Republic.
2. Articles 30 and 36 of the EC Treaty preclude application of national legislation which grants the holder of a patent for a pharmaceutical product the right to oppose importation by a third party of that product from another Member State in circumstances where the holder first put the product on the market in that State after its accession to the European Community but before the product could be protected by a patent in that State, unless the holder of the patent can prove that he is under a genuine, existing legal obligation to market the product in that Member State.

Opinion of the Advocate-General
I - Introduction
1 These joined cases raise, in the form of three questions, two important but distinct issues concerning the free movement of pharmaceutical products between Spain and Portugal, on the one hand, and the remaining Member States, on the other. (1) The first two questions concern the date of expiry of certain transitional provisions contained in the Act of Accession of the Kingdom of Spain and the Portuguese Republic, which permit the restriction of parallel imports of pharmaceuticals from those countries to other parts of the Community. The other question is more fundamental. It concerns the legal regime applicable to parallel imports following the expiry of the relevant transitional periods. Essentially the Court is asked to renounce or, alternatively, revise its 1981 judgment in Merck v Stephar and Exler, (2) that the rules contained in the Treaty concerning the free movement of goods prevent the proprietor of a patent for a medicinal product who has voluntarily marketed the product in one Member State which does not recognize the patentability of the product from invoking his national patent rights in other Member States to prohibit parallel imports of that product from the first Member State.

II - Legal framework
2 According to Articles 42 (Spain) and 202 (Portugal), respectively, of the Act of Accession of the Kingdom of Spain (hereinafter `Spain') and the Portuguese Republic (hereinafter `Portugal') to the European Communities (hereinafter `the Act of Accession'), (3) quantitative restrictions on imports and exports and any measures having equivalent effect were to be abolished on 1 January 1986 between the Community and Spain and Portugal. (4) However, pursuant to Article 47 regarding Spain and Article 209 regarding Portugal, the entry into force of Article 30 of the EC Treaty was postponed for the patented products with which the present cases are concerned in the following terms:
`1. Notwithstanding Article 42 [Article 202], the holder, or his beneficiary, of a patent for a chemical or pharmaceutical product or a product relating to plant health, filed in a Member State at a time when a product patent could not be obtained in Spain [Portugal] for that product may rely upon the rights granted by that patent in order to prevent the import and marketing of that product in the present Member State or States where the product enjoys patent protection even if that product was put on the market in Spain [Portugal] for the first time by him or with his consent.
2. This right may be invoked for a product referred to in paragraph (1) until the end of the third year after Spain [Portugal] has made these products patentable.'
3 In Merck v Stephar the Court held that `the rules contained in the EEC Treaty concerning the free movement of goods, including the provisions of Article 36, must be interpreted as preventing the proprietor of a patent for a medicinal preparation who sells the preparation in one Member State where patent protection exists, and then markets it himself in another Member State where there is no such protection, from availing himself of the right conferred by the legislation of the first Member State to prevent the marketing in that State of the said preparation imported from the other Member State.' (5)
4 Article 379 of the Act of Accession provides that the Commission may authorize new or existing Member States to take `protective measures' in the event of serious and persistent economic difficulties. This provision was invoked by France, Belgium, Austria, Denmark, Ireland, the United Kingdom and Germany regarding the importation from Spain of pharmaceutical products protected by patents in their respective territories, but not so protected in Spain, as from 7 October 1995. (6) By decisions of 20 December 1995 (7) the Commission rejected these applications. (8)
5 The Act of Accession contained parallel provisions providing transitional provisions subject to the introduction of effective patent laws by those two Member States. Protocol No 8 concerned Spanish patents, while Protocol No 19 concerned Portuguese patents.
6 Paragraph 1 of Protocols No 8 and No 19 each provide that Spain and Portugal separately shall:
`... adjust its patent law so as to make it compatible with the principles of the free movement of goods and with the level of protection of industrial property attained in the Community ...

[and that]
To that end, close cooperation shall be instituted between the Commission services and the Spanish [Portuguese] authorities; this cooperation shall also cover the problems of transition of current Spanish [Portuguese] law towards new law.'
Each of those Protocols further required the removal of special features of Spanish and Portuguese law which have no specific bearing in the present cases.
7 Paragraph 3 of Protocol No 8 provides that:
`The Kingdom of Spain shall accede to the Munich Convention of 5 October 1973 on the European patent within the required time-limits so as to allow it to invoke the provisions of Article 167 of the said Convention solely for chemical and pharmaceutical products.
In this context and taking account of the fulfilment of the undertaking entered into by the Kingdom of Spain under paragraph 1, the Member States of the Community in their capacity as contracting States to the Munich Convention undertake to use their best endeavours to ensure, should a request be submitted by the Kingdom of Spain in accordance with that Convention, an extension - beyond 7 October 1987 and for the maximum period laid down in the Munich Convention - of the validity of the reserve laid down in the said Article 167 [...] it being understood that the Kingdom of Spain will, in any event, accede to that Convention not later than 7 October 1992.'
Under Article 167(2)(a) of the European Patent Convention (hereinafter `the EPC') each Contracting State may reserve the right to provide that European patents covering pharmaceuticals shall be ineffective or revocable. Furthermore, Article 167(3) provides that:
`Any reservation made by a Contracting State shall have effect for a period of not more than ten years from the entry into force of this Convention. However, where a Contracting State has made any of the reservations referred to in paragraph 2 (a) and (b), the Administrative Council may, in respect of such State, extend the period by not more than five years for all or part of any reservation made ... .'
8 Paragraph 3 of Protocol No 19 provided:
`The Portuguese Republic shall accede on 1 January 1992 to the Munich Convention of 5 October 1973 on the European patent and to the Luxembourg Convention of 15 December 1975 on the Community patent.'
9 The Protocols also required the two new Member States to introduce into their national legislation a provision on shifting the burden of proof corresponding to Article 75 of the Luxembourg Convention of 15 December 1975 on the Community patent. This provision was to apply, in the case of Spain, not later than 7 October 1992, and, in that of Portugal, not later than 1 January 1992, for patents filed, respectively, before those dates. (9)
10 Article 4 of the Law of 20 March 1986, which entered into force on 26 June 1986, provides for the patentability of pharmaceutical products in Spain. However, its entry into force in respect of such products was delayed in reliance on the Act of Accession by a transitional provision until 7 October 1992. In Portugal, Decree-Law No 42/92 brought the EPC into force as from 1 January 1992. Article 1(2) of the Portuguese Law provides for the inapplicability of any provisions of the Portuguese Industrial Property Code which infringe the terms of the EPC. Thus, it became possible to obtain patents for pharmaceutical products in Portugal by specifying Portugal in EPC applications on or after that date.
III - Facts and procedure
11 Two cases involving three separate causes of action have been brought before Mr Justice Jacob sitting in the Patents Court of the Chancery Division of the High Court of Justice in England and Wales (hereinafter `the national court'). In the first action (10) the plaintiffs, Merck & Co. Inc. and Others (11) (hereinafter `Merck'), claim that the defendants Primecrown Ltd and Others (hereinafter `Primecrown') have infringed their patent for a hypertension drug (known by the trade mark `Innovace' in the United Kingdom and that of `Renitec' elsewhere) and their patent for a prostate drug known by the trade mark `Proscar'. In the second action (12) Merck claims that Primecrown has infringed its patent for a glaucoma drug known by the trade mark Timoptol. The complaints concern parallel importing and sale of the products in the United Kingdom. Renitec and Proscar were imported from Spain and Timoptol from Portugal.
12 Merck filed for its British product patent covering Proscar (EP0155096) on 20 February 1985. This patent is due to expire on 20 February 2005 but, pursuant to Council Regulation (EEC) No 1768/92 of 18 June 1992 (13) concerning the creation of a supplementary protection certificate for medicinal products (hereinafter the `SPC Regulation'), effective patent protection will last until 26 May 2007. The registration papers relating to Proscar were submitted in Spain in July 1991. Marketing authorization was granted in September 1993, whereupon the product was launched in Spain. Merck filed for its British product patent covering Renitec (0012401) on 10 December 1979. It will expire on 10 December 1999. It filed for Timoptol (1524405) on 23 September 1976; that patent will expire on 23 September 1996.
13 In the second case Beecham Group plc (hereinafter `Beecham') has brought an action against Europharm of Worthing Ltd (hereinafter `Europharm') for infringing two patents covering an antibiotic product marketed under the trade mark `Augmentin' in the United Kingdom and `Augmentine' in Spain. One of these patents expired on 10 April 1995. The other was found to be invalid by the High Court in July 1995. An order that it be revoked is stayed pending the hearing of an appeal towards the end of 1996. A third, European patent will not expire until 2003, though the main proceedings appear to concern only the United Kingdom patents. According to the national court Europharm intends to import the product from Spain. (14)
14 The national court explains that the problems in the main proceedings arise firstly because the patentees do not have, and never could have obtained, patent protec-

tion in Spain or Portugal for the products concerned. In addition, it says that prices in those countries are much lower than elsewhere in the European Union so that medicines sold by the patentees to wholesalers there are, instead of going to Spanish or Portuguese patients, immediately exported to other Member States.
15 The national court distinguishes two classes of questions of interpretation of Community law arising in the main proceedings: (i) the true meaning of the transitional provisions of the Act of Accession raised in the first two questions; (ii) whether the judgment of the Court in Merck v Stephar should be reconsidered or modified having regard to changed circumstances or further consideration. They are worded as follows:
`1. That the provisions and effect of Article 47 of the Spanish Treaty of Accession to the European Communities will continue to apply to pharmaceutical products
1.1. imported from Spain; or 1.2. first marketed in Spain
until
(a) 7 October 1995; or (b) 31 December 1995; or (c) 7 October 1996; or (d) 31 December 1996; or
(e) the end of the third year after the particular pharmaceutical, protected by a product patent in one or more Member State(s) of the European Union and which was previously unpatentable in Spain, has become patentable in Spain
stating which of such dates is applicable with regard to such acts.
2. That the provisions and effect of Article 209 of the Portuguese Treaty of Accession to the European Communities will continue to apply to pharmaceutical products
2.1. imported from Portugal; or 2.2. first marketed in Portugal;
until
(a) 1 January 1995; or (b) 31 December 1995; or (c) 1 June 1998; or (d) 31 December 1998; or
(e) the end of the third year after the particular pharmaceutical, protected by a product patent in one or more Member State(s) of the European Union and which was previously unpatentable in Portugal, has become patentable in Portugal
stating which of such dates is applicable with regard to such acts.
3. After the expiration of Article 47 (and/or Article 209, as appropriate), in a case where:
3.1. an undertaking is the proprietor (the "Proprietor") of a patent (the "Patent") in one or more Member States of the European Communities (the "Member State") for a pharmaceutical product (the "Pharmaceutical");
3.2. the pharmaceutical was first put on the market in a country by the proprietor after that country's accession to the EC but at a time when the pharmaceutical could not be protected by a product patent in that country;
3.3. a third party imports the pharmaceutical from that country into the Member State;
3.4. and the patent legislation in the Member State granted the proprietor of the patent the right to oppose by legal action the importation of the pharmaceutical from that country
do the rules set forth in the EC Treaty concerning the free movement of goods prevent the proprietor from availing himself of the right referred to in paragraph 3.4. above, in particular if:
(a) the proprietor has and continues to have a legal and/or ethical obligation to market and to continue marketing the pharmaceutical in that country; and/or
(b) that country's and/or EC legislation effectively requires that, once the pharmaceutical is put on the market in that country, the proprietor supplies and continues to supply sufficient quantities to satisfy the needs of domestic patients; and/or
(c) that country's legislation grants to its authorities, and its authorities exercise, the right to fix the sales price of the pharmaceutical in that country and legislation prohibits the sale of the pharmaceutical at any other price; and/or
(d) the price of the pharmaceutical in that country has been fixed by its authorities at a level at which substantial exports of the pharmaceutical from such country to the Member State are anticipated with the result that the economic value of the patent would be significantly eroded and research and development for future pharmaceuticals planned by the proprietor significantly undermined, contrary to the rationale underlying the recent introduction by the EC Council of the Supplementary Protection Certificate?'
16 Regarding the first two questions concerning the expiry of the relevant transitional provisions, the national court summarizes the arguments considered in detail later in this Opinion, and expresses a clear preference for the earliest date, i.e. 7 October 1995 in the case of Spain and 1 January 1995 in that of Portugal. In effect, it therefore accepted Primecrown's argument. It points out that Spain, on acceding to the EPC, was permitted by the EPC's Administrative Council under Article 167(2) of the EPC to postpone the obligation to recognize the patentability of pharmaceutical products for the maximum permissible period, namely until 6 October 1992; thus from 7 October 1992 such products were patentable in Spain. By virtue of Article 42 of the Act of Accession, the prohibition contained in Article 30 of the Treaty was, under Article 47 of the Act of Accession, to apply from `... the end of the third year after Spain has made these products patentable'.
17 The national court states that Merck argued that the three-year period should be read as referring to three years after the date when the particular pharmaceutical product at issue became patentable, because Article 47(1) of the Act of Accession speaks of `a time when a product patent could not be obtained in Spain for that product', while Article 47(2) refers to `the end of the third year after Spain has made these products patentable'. (15) The national court agrees with Primecrown that this argument is absurd; once an individual product was on the market before Spain made it patentable it would, by reason of its lack of novelty, never become patentable and, thus, the three-year period would never begin to run. Indeed, the national court states that there would be no need for a three-year period if the product was patentable. (16)

18 The national court comes to the clear conclusion that the transitional period for Spain expired on 7 October 1995. Indeed, the judge states that `were it not for the warnings often given that sometimes the Court may, when faced with a fresh question, do something unexpected, [he] would have found the matter acte clair'.
19 In so far as Portugal is concerned the national court states that the starting date is stated to be 1 January 1992 when, pursuant to paragraph 3 of Protocol No 19 to the Act of Accession, it acceded to the EPC. (17) It points out that Merck has not disputed that patents could be obtained for Portugal for pharmaceutical products under the EPC via the European Patents Office from 1 January 1992. (18) It thus articulates a strong preference for 1 January 1995 as the expiry date of the relevant transitional provision, based on the lapse of three calendar years from 1 January 1992. (19)
20 On the third question, the national court notes that, of the various arguments advanced by Merck in favour of a reconsideration of the judgment in Merck v Stephar, two in particular, which were not raised in that case, may negative the central conclusion that a free decision to market in Spain and Portugal had been made:
(i) the argument that pharmaceutical companies have an ethical obligation to supply their products in Spain and Portugal, particularly where they have already released the product there and doctors are prescribing it;
(ii) the argument that there may be a legal obligation either under national law or under Community law requiring supply to the Spanish and Portuguese markets.
21 The national court also describes Merck's arguments, regarding the need to protect research and development in Europe and to promote a healthy European pharmaceutical industry, as now stronger than they were when first advanced in Merck v Stephar. The national court suggests that the Court may need to consider limiting the retroactive effects of any qualification of Merck v Stephar, `... for it would obviously be wrong for the Court to depart from a previous decision in such a way as to turn parties into wrongdoers for past acts which were lawful under that decision - to make past lawful parallel imports into infringements'.
IV - Observations submitted to the Court
22 Written observations were submitted by Merck (plaintiffs in Case C-267/95), Beecham (plaintiffs in Case C-268/95), Primecrown (defendant in Case C-267/95), by the Governments of the United Kingdom, Belgium, Greece, Spain and Italy and by the Commission of the European Communities. Oral submissions were presented by Merck, Beecham, Primecrown, the Government of the United Kingdom, the Spanish, Greek, Italian, Danish, French and Swedish Governments and by the Commission.
A. The first and second questions
(i) Merck and Beecham
23 Merck submits that Article 47 of the Act of Accession applies to pharmaceutical products imported from Spain until 31 December 1996. It bases this contention on the wording of Article 47 (`at the end of the third year after' and not `three years after'). Merck claims that this interpretation is supported by the fact that all transitional measures contained in the Act of Accession expire at the end of a calendar year. It refers particularly to Article 379 of the Act of Accession which permits the adoption of emergency measures until 31 December 1995.
24 Merck contends alternatively that Article 47 will expire at the end of 1996 because, pursuant to Article 4C(1) of the Paris Convention for the Protection of Industrial Property of 20 March 1883 (as revised, hereinafter the `Paris Convention'), a person who has duly filed an application for a patent in one Paris Convention country enjoys, for the purpose of filing in the other Contracting States, (20) a right of priority during a 12-month period from the date of the first filing. This provision allows an applicant 12 months in which to file patent applications for the same invention in the other Paris Convention countries and to claim priority over later applicants. The novelty of an invention is determined as at the date of the first filing; i.e. the invention is considered to be novel throughout the Paris Convention countries during that 12-month period. The patentability of a product in a Paris Convention country thus includes as an essential element the right to claim the priority flowing from an application made for the same invention in the preceding 12 months in any other Paris Convention country.
25 However, Merck maintains that, at the request of the Patent Office, the Spanish Council of State held on 18 February 1993 that priority would be recognized in Spain only in respect of applications filed in other EPC countries after 7 October 1992. (21) Merck claims that the notion of patentability as employed in Article 47 of the Act of Accession should be interpreted in accordance with the Paris Convention and, thus, as including the possibility of obtaining patents in Spain after 7 October 1992, through priority based on applications filed in the preceding 12 months in other Paris Convention countries. Merck concludes that Spain's failure to recognize such claims effectively means that it permitted full patentability of pharmaceuticals only as from 7 October 1993.
26 Regarding Portugal, Merck submits that Article 209 of the Act of Accession will continue to apply to pharmaceutical products until 31 December 1998, namely at the end of the third calendar year after Portugal effectively made pharmaceutical products patentable. Effective patentability of pharmaceutical products was not available in Portugal before 1 June 1995, when the framework relating to European product patents established in the Portuguese Decree-Law No 42/92 of 31 March 1992 was completed by the enactment of a new Industrial Property Code permitting the grant of Portuguese patents for pharmaceutical products. (22)
27 Beecham submits that Article 47 of the Act of Accession will continue to apply to pharmaceutical products such as Augmentine until three years after Spain introduces legislation to make Augmentine patentable. To construe Article 47 as providing protection only until the end of the third year after Spain made a

general class of products patentable, would merely result in the provision of `an arbitrary 3- to 4-year holiday' from the effect of imports of cheap pharmaceutical products flooding into other Member States from Spain, followed by a period with no protection at all.

28 Alternatively, if the transitional period is interpreted as running from the date when Spain made pharmaceutical products as a generic class patentable (i.e. 7 October 1992), Beecham considers that Article 47 should at least be interpreted in accordance with a rule based on the calendar year. However, its favoured expiry date (31 December 1996) is reached by combining this approach with the priority date argument based on the Paris Convention, as advanced by Merck.

(ii) Primecrown

29 Primecrown observes that the EPC came into force on 7 October 1977 independently of calendar date considerations, when, in accordance with Article 169 thereof, a sufficient number of instruments of ratification were lodged. In accordance with Article 167(5) of the EPC, the benefit of the withdrawal of a reservation under Article 167(2) applies only to patent applications filed after the expiry of the reservation. Primecrown submits that it was clear particularly from Article 3 of Protocol No 8 that Spain would accede to the EPC with effect from 7 October 1992 and would then grant patents in respect of new applications filed on or after that date. Article 47 of the Act of Accession is plainly linked with Protocol No 8, which makes reference to the EPC. By bringing the EPC into force in Spain on 7 October 1992, Spain followed the path contemplated by Protocol No 8 and, thus, the derogation of three years referred to in Article 47 expired on 7 October 1995.

30 Primecrown then refers to Protocol No 19 to the Act of Accession providing for Portuguese accession to the EPC on 1 January 1992. As there was no provision for a reservation in respect of Portugal under Article 167 of the EPC, chemical and pharmaceutical substances became patentable in Portugal on that date. The derogation provided by Article 209 of the Act of Accession is linked to Protocol No 19 which refers to the EPC. Again, a narrow interpretation of the derogation requires that it be interpreted as expiring three years after the date of entry into force of the EPC, namely 1 January 1995.

31 Primecrown argues that any person wishing to obtain a patent in Portugal for a pharmaceutical product has been able to do so by filing an application at the European Patent Office designating Portugal (whether alone or in addition to other countries) on or after 1 January 1992, despite the fact that Portugal did not permit applications for pharmaceutical products to be filed through its national patent office until 1 June 1995, when the Industrial Property Code, contained in Decree-Law No 16/95 of 24 January 1995, came into force. Neither Article 209 of the Act of Accession nor Protocol No 19 required Portugal to allow pharmaceutical product patents to be obtained by any particular procedure; there was therefore no obligation on Portugal to establish a national patent office in order to comply with its obligation to adjust its patent law `so as to make it compatible with ... the level of protection of industrial property attained in the Community'.

32 Primecrown submits that the words `these products' used respectively in Articles 47(2) (Spain) and 209(2) (Portugal) of the Act of Accession can only be interpreted as referring to the generic class of products covered by Article 47. If the intention was to refer to a specific product covered by a specific patent, then the singular would have been used so as to agree with the references to, inter alia, `a product' in Article 47(1). More fundamentally, Primecrown maintains that the reason that patents could not be obtained from 7 October 1992 for some pharmaceutical products in Spain was no longer the exclusion of pharmaceutical products as a class from the scope of national patent law, but the individual act of the inventor in making the invention public at a date before he could first have applied for a product patent in Spain. Nothing in Protocol No 8 to the Act of Accession requires Spain to give product protection to inventions which have come into the public domain before 7 October 1992. On the contrary, Protocol No 8 makes explicit reference to Article 167 of the EPC which contains its own transitional provisions (at paragraph 5), under which patents applied for after the date when Spain's reservation expires may be granted, but those applied for before that date may not.

33 Primecrown claims that attributing a calendar-year calculation to the interpretation of the three-year period would mean that the Member States intended at the time of negotiating the Act of Accession that the length of the transitional period envisaged in Article 47(2) could vary by as much as 33%, depending arbitrarily on the time of the year when pharmaceuticals were made patentable. The purpose of the derogation is to permit market conditions to adjust prior to the abolition of the restriction on parallel imports. Primecrown submits that it cannot be contemplated that the drafters of the derogation believed that market conditions might take longer to adjust if Spain introduced patentability for pharmaceutical products near to the beginning rather than to the end of a calendar year. The reason for the general pattern in Community Treaties of periods terminating with the end of calendar years is historical; the EEC Treaty entered into force on 1 January 1958 and subsequent accessions have always occurred on 1 January of a year. The obligatory date for patentability of pharmaceutical products in Spain is linked, not with the Community Treaties, but with a period of years counted from the coming into effect of the EPC, which is not a Community Treaty. The date, 7 October 1992, is explicitly named in the Act of Accession.

34 Primecrown also maintains that the use of a calendar-year method would be contrary to `the normal and universal "anniversary" rule' for the calculation of time applied generally by Member States. (23) In the United Kingdom, Primecrown contends that the normal rule is the corresponding date rule, (24) while Article 5.1 of the Spanish Civil Code indicates that Spanish law also recognizes the concept of computing time in `broken' years, rather than starting the period from the beginning of the next calendar year. Furthermore, Primecrown

contends that, when Community legislation intends to achieve expiry of a term at the end of a calendar year, clear and unambiguous language is used. (25)

35 Primecrown states that Article 47(2) of the Act of Accession merely requires Spain to make pharmaceutical products patentable and imposes no obligation to operate a system of Paris Convention priority. Furthermore, even under the Paris Convention, priority depends upon the first, home country, application being recognized as an application for an invention according to the law of the country in which Convention priority is claimed. As such applications filed outside Spain before 7 October 1992 would not have been valid applications under Spanish law, no ensuing priority claim can arise.

(iii) Other observations

36 The Spanish, United Kingdom, Italian and Danish Governments submit that the expiry date of the transitional period should be 31 December 1995 for Spain and Portugal. Though variously expressed, their argument is, in essence, that the expression `the end of the third year' in Articles 47 and 209 of the Act of Accession refers to 31 December in the third calendar year to elapse after the requisite patent protection has been made available and that the reference to `the end' is linguistically inapt to signify the anniversary of an event which may take place during the course of a calendar year. The United Kingdom argues that an examination of the calendar dates stipulated in all other transitional provisions in the Act of Accession shows that these transitional periods must also have been intended to expire at the end of a calendar year.

37 The Greek Government considers that the transitional period expires once three years have elapsed since pharmaceutical products were made patentable. The Swedish, French and Belgian Governments expressed no opinion on this issue.

38 The Commission stated at the hearing that the broken-years interpretation was more in accordance with the text of the derogations; if calendar years had been intended, the texts would have expressly contained such an indication. Furthermore, since, in its view, the precise dates upon which patentability would be introduced by Spain and Portugal were unknown at the time of the negotiation of the Act of Accession, it was more reasonable to adopt the broken-years approach. This was the working hypothesis of most people involved in the sector before October 1995, and certainly the view expressed publicly by Commission officials and underlying the applications brought under Article 379 of the Act of Accession by various Member States. Finally, the Commission maintained that the Court should also have regard to the very clear view of the national court in favour of this approach.

B. The third question

(i) Merck

(a) First line of argument

39 Merck's primary argument is that the rule adopted by the Court in Merck v Stephar should be reconsidered so that a patentee will be deemed not to have exhausted his patent right in respect of a product only when he has had the opportunity of first marketing it in the Community with the protection of the patent and with the concomitant guarantee of absence of competition from unauthorized copies. It advances six principal arguments in support of this submission.

40 Firstly, at the time of Merck v Stephar, the patentability of pharmaceuticals in Europe was the exception rather than the rule, whereas it is now recognized by most industrialized nations. Pharmaceuticals are now patentable in all EEA countries except Iceland. (26)

41 The Community has in recent years emphasized the importance of patents to the pharmaceutical sector. Merck draws attention to the SPC Regulation (27) and, in particular, to recitals 1 to 4 in its preamble as well as paragraphs 1 and 5 of the preceding explanatory memorandum of the Commission. (28)

42 Moreover, the negative repercussions of the continued application of the Merck v Stephar rule will be magnified following the entry into force of association agreements with the countries of central and Eastern Europe, as a result of the permanent non-patentability - due to lack of novelty - of pharmaceuticals first put on the market in those countries before pharmaceuticals became patentable there during the early 1990s. Merck submits that, when these countries join the EC, the Merck v Stephar rule will apply to all pharmaceuticals originating or put on the market in these countries (where prices are on average up to 33% lower than in the EC).

43 Secondly, Merck v Stephar significantly reduces the value of patents granted in the EC. Merck claims that the presence of unauthorized copies on the Spanish and Portuguese markets has enabled the authorities to use national price regulations to fix prices below the average level in the EC. Such copies can be launched before, at the same time as, or, in any event, within 12 months of, the launch of the original. At the hearing Merck submitted that the link between non-patentability and price levels was clearly demonstrated by the effect of the appearance of generic products once patents in Member States where patent protection is recognized have expired. A very rapid fall in price occurs both in contemplation of and in the aftermath of the end of the period of patent protection. Furthermore, Merck (supported fully by Beecham) submitted at the hearing that the presence or absence of patent protection affects the bargaining position of pharmaceutical companies when negotiating with national authorities; if a generic alternative has been or is about to be launched, the price negotiating position of those authorities is strengthened vis-à-vis the patentee. Merck also claimed that the price control systems operated in Spain and Portugal in the present case are in fact stricter than the regime operated in Italy at the time of the Merck v Stephar decision. (29)

44 Merck maintains that parallel imports from Spain and Portugal generally work to the benefit of parallel traders rather than patients or national health authorities in the importing Member States, while exposing the proprietors of pharmaceutical patents to large losses by

reducing the value and, thus, effectively shortening the patent life of affected products. (30) It submits that, in the absence of common Community rules concerning the marketing of patentable products, obstacles to free movement within the Community designed to encourage research for pharmaceutical products should be accepted as necessary to satisfy a mandatory requirement as defined in `Cassis de Dijon'. (31)

45 In its third and fourth arguments, Merck submits that there can be no exhaustion of patent rights where such rights do not exist. In Merck v Stephar the Court held that the specific subject-matter of a patent right does not guarantee that the patentholder will always obtain a reward for his creative effort, while Advocate General Reischl stated that it merely presented the patentee with an opportunity to obtain a recompense for his creative effort. Merck, on the other hand, submits that a reasonable reward for the patentee's creative effort is crucial to the pharmaceutical industry, given that the average cost of researching and developing a new medicinal product is now estimated at ECU 200 million. The survival of pharmaceutical companies depends on the profitability of a small number of successful products and on the regular renewal of portfolios of patents on new medicinal products. On average, out of every 10 000 substances synthesized by the pharmaceutical industry, only one or two will become marketable medicines. The huge risks involved make individual companies very vulnerable, not least because 90% of the cost of research is financed by the industry itself. The return on research investment depends on numerous market factors, including the commercial potential of the patented product and the early presence of substitute products. Substitute products include `fast follower' products which are therapeutically similar to the initial product but sufficiently differentiated to avoid patent infringement.

46 In these circumstances, Merck submits that a patent should be deemed to be exhausted only where the patentee consents to the use of that patent's essential and constant characteristic, namely the right to put the patented product on the market for the first time with the assurance that no unauthorized copies will be put on the market for the duration of the patent. Thus, the financial value of the product is protected from the competition of unauthorized cheaper copies. (32) The mere receipt of a financial reward should not be regarded as exhausting the patent where the commercial potential of the product was limited by the absence of patentability. Merck relies upon Pharmon v Hoechst (33) where, in the context of a compulsory licence, the acceptance of royalties by the patentee was held not to have exhausted the patent, because they were not received in return for the voluntary exercise of the guaranteed property right. Merck cites the view of Advocate General Warner in his Opinion in Musik-Vertrieb Membran v GEMA (34) that `[T]here can be no exhaustion of rights where no rights exist'.

47 Fifthly, in Warner Brothers v Christiansen (copyright) (35) and IHT Internationale Heiztechnik v Ideal-Standard (trade marks), (36) Merck submits that the Court accepted that, in the absence of parallel levels of protection in both the exporting and importing Member States, Community law should not export the legislative policy of the former to the latter. Merck submits that this reasoning should apply a fortiori in respect of patents.

48 Finally, Merck submits that, contrary to the apparent assumption of Advocate General Reischl in Merck v Stephar, temporary similarities between the prices of patentable and unpatentable pharmaceuticals do not make these products comparable. The Merck v Stephar rule is, thus, not necessary to avoid discrimination between parallel trade in patentable and unpatentable products; where the rights of a patentee are recognized, it benefits from the assurance that no unauthorized copies will be marketed for the duration of the patent, which is not the case where that protection is denied.

(b) Second line of argument

49 In the alternative, Merck proposes that the consent required for the application of the Merck v Stephar rule is not satisfied in the circumstances of this case. The four suppositions appended to the third question referred by the national court are closely related to this point.

50 Firstly, pharmaceutical companies - unlike producers of other consumer products and services - are not free to decide whether or not to launch new products on a market or to interrupt existing supplies, since ethical considerations oblige them to provide pharmaceuticals where they are needed, even where patentability is not recognized. (37)

51 Merck submits that it would now be impossible on ethical grounds for a variety of health-care reasons for it to withdraw the products in question from the Spanish and Portuguese markets; nor is its obligation reduced by the presence of copies. Withdrawal of its products would, it maintains, lead to the eventual discontinuation of supplies of these copies: as the originator of a product, it is the only company that has complete information on the results of clinical trials. By reason of its expertise and resources it is perceived as having the ethical obligation to ensure continuous pharmacovigilance (i.e. the observation of unforeseen effects on patients), particularly through the maintenance of a permanent staff of scientists to advise doctors prescribing its products. By contrast, copiers are generally companies that invest only in the necessary importation or manufacturing and distribution facilities and, consequently, doctors faced with unexpected clinical problems with a copy of a Merck product will look to Merck for advice.

52 Secondly, for commercial reasons, Merck contends that it is not free to discontinue supplies. Withdrawal would require patients currently being treated with products prescribed by their doctors to switch to other products possibly perceived to be less well suited to them. Such a withdrawal would irremediably tarnish Merck's reputation as a company at the service of public health and undermine its goodwill with the Spanish and Portuguese medical community.

53 Merck also contends that it is prevented from interrupting existing supplies by obligations imposed by both national law and EC competition law. An interruption of existing supplies to the Spanish or Portuguese markets would, in its view, probably constitute a violation of the Spanish Medicines Law No 25/1990 or the Portuguese Decree-Law No 135/95 respectively. Moreover, Article 85 of the Treaty prevents it from interrupting existing supplies to Spanish and Portuguese purchasers. Merck claims that the Commission, in a view which has been confirmed by the Court, has qualified as agreements or concerted practices within the meaning of Article 85(1) apparently unilateral acts, such as a manufacturer's instructions to its distributors not to export to other EC Member States in the context of an existing contractual relationship.

(ii) Beecham

54 Beecham submits that the purpose of patent protection is the provision of incentives for innovation; the inventor must be afforded the opportunity to earn a reward for its inventive effort through exclusive market access rights. It relies upon the Court's judgment in Centrafarm v Sterling Drug (38) as the basis of the doctrine of exhaustion in the context of parallel patents. In holding in Merck v Stephar that the patentee's right could be exhausted by consenting to marketing in a country where he enjoyed no patent protection, Beecham submits that the Court incorrectly extended the exhaustion doctrine. Beecham criticizes Merck v Stephar because its reasoning is flawed and cannot be reconciled with either subsequent case-law of the Court or Community legislative developments.

55 According to Beecham, Merck v Stephar cannot be reconciled with the decision of the Court in Warner Brothers. It also refers to Pharmon v Hoechst and particularly to the fact that the Court rejected the view of Advocate General Mancini that a patentee, by voluntarily exposing himself to the possibility of being deprived of his exclusive right through compulsory licensing, must accept the consequences of his choice.

56 Beecham submits that the judgment in Merck v Stephar is wrong in principle because it undermines the ability of the patentee to obtain a reward for his creative effort. In particular, the Court did not address the effects of imports from countries where no patent protection exists on the ability of the patentee to maintain prices at a level sufficient to guarantee such a reward in countries where such patentability is recognized. (39) Moreover, it argues that Advocate General Reischl mistakenly advised the Court that there was no causal connection between patentability and price levels: Beecham submits that, if he had carried out a general price comparison between patented and unpatented products within each Member State, rather than between different Member States, he would have found that the pricing of unpatented products, which are subject to competition from generic copies, differs from the pricing of patented products, which are not subject to such competition.

57 Beecham submits in reliance on Warner Brothers that, in the absence of harmonizing Community measures, it falls to the Member States to make the necessary legislative choices regarding the patenting of products. It also submits that Merck v Stephar is irreconcilable with the new objectives of the EC Treaty concerning both research and development and health protection (40) and particularly with the current difficult circumstances of the pharmaceutical industry. (41)

58 Beecham, like Merck, argues, in the alternative, that the circumstances of the present case can be distinguished from those of Merck v Stephar; it is not free to `consent' or withdraw `consent' to the marketing of Augmentine in Spain, for legal and ethical reasons. An ethical obligation is not an entirely subjective notion; it can arise from objectively verifiable consumer demand. Furthermore, a pharmaceutical supplier should not be dissuaded from meeting demand in a particular Member State for fear that such supplies might result in parallel imports jeopardizing its profitability on other markets. If it had to establish the existence of an ethical obligation before national courts, it would not be confined to drawing inferences based on the therapeutic qualities of the product, but could also offer direct evidence, such as that of physicians or pharmacists from the Member State of exportation.

59 Beecham contends that a withdrawal from the Spanish market, by refusal to supply existing customers and by instructing its customers elsewhere not to supply to Spain, might be prohibited not only by Article 85(1) but also by Article 86 of the Treaty. Although any possible infringement of Article 86 would depend on those affected being able to show that it enjoyed a dominant position in a relevant market in Spain, or some other part of the Community, Beecham contends that the possible success of such an action would leave it open to being ordered by a Spanish court either to pay damages or to continue supplies.

60 At the hearing Beecham insisted that neither the requirement of legal certainty nor the entrenchment by the Act of Accession of the Merck v Stephar decision should prevent the Court reconsidering its previous decision, and that subsequent developments in the Court's case-law had cast doubt on the authority of that decision. The mere fact that the Act of Accession was negotiated in the light of Merck v Stephar cannot curtail the freedom of the Court to reassess its merits, particularly as the effects of Merck v Stephar would, if upheld, continue to apply to patented products marketed in Spain prior to the introduction of patentability for about ten years. On the other hand, reversing Merck v Stephar would not affect parallel trade in newer products first marketed in Spain after its introduction of patent protection. Beecham conceded that the Court might consider limiting the retroactivity of its judgment.

(iii) Primecrown

61 Primecrown submits that the principle laid down in Merck v Stephar, whereby exhaustion is based on consent to marketing, is still correct. At the time of this judgment, the Court was aware that it would apply to imports from Spain and Portugal as potential new members of the Community. (42) The principle was

assumed to be correct during the negotiations concerning the conditions of accession of Spain and Portugal and, accordingly, a series of provisions designed both to strengthen the Spanish and Portuguese patent systems and to permit the adjustment of pharmaceutical industries in existing Member States prior to the full application of the free movement rules to Spain and Portugal was expressly adopted. Since the Act of Accession is an instrument of equivalent status to the founding Treaties, Primecrown contends that it was the clear intention of the negotiators that only the specific and limited derogations from the principle of free movement set out in the Act of Accession and its Protocols should, henceforth, restrict free trade between the new and existing Member States. In its judgment in Generics v Smith Kline & French Laboratories (43) the limited nature of the derogations contained in Articles 47 and 209 and the applicability after their expiry of the principle contained in Merck v Stephar to imports from Spain and Portugal was expressly reaffirmed by the Court.

62 The Merck v Stephar rule provides legal certainty to traders, the public and holders of industrial property rights because, according to Primecrown, national courts can normally readily assess whether the necessary consent exists. To accept Merck's argument, which is based on the need for the exhaustion of a parallel patent, would require national courts to determine whether the patent rights in the country of first marketing were equivalent to the patent rights in the country of importation. This could lead to fragmentation of the Common Market caused by major pharmaceutical companies, backed by their considerable financial resources, pursuing litigation against smaller parallel importers.

63 On the existence of consent, Primecrown denies that Merck has demonstrated that either Spain or Portugal placed a legal obligation on pharmaceutical companies to introduce medicinal products on to their markets; Merck thus chose freely to place the drugs in issue on the market when it was aware both of the decision of the Court in Merck v Stephar and the terms of Article 47 of the Act of Accession. (44) An obligation to continue supplies can arise, Primecrown submits, only if Merck is in a dominant market position, which cannot be the case regarding the products concerned. (45) Furthermore, at the hearing, Primecrown disputed the plaintiff pharmaceutical companies' allegation that they were obliged to continue supplying products for which marketing authorizations have been obtained in Spain. (46) Primecrown submits that the combined effect of Merck v Stephar and Pharmon v Hoechst is that Articles 30 to 36 of the Treaty must be interpreted so that the rule of free movement applies to goods placed on the market in one Member State, unless they were placed on the market wholly without the patentee's consent, of which there is no evidence in the present case.

64 Primecrown also submits that a claimed ethical obligation to supply cannot form the basis of an exception to Community rules regarding free movement of goods. Ethical obligations are self-defined and, thus, inherently subjective. Moreover, referring to a report, relied upon by Merck before the national court, Primecrown contends that the existence of such an ethical obligation has not been established. (47) Furthermore, the position in Spain in respect of ethical obligations has not been shown to be different from that of Italy described in Merck v Stephar. The claimed ethical obligations were inconsistent with the complaint that the absence of patent protection deprives the companies of the monopoly bargaining position in price negotiations, which implies a willingness to withdraw or curtail supplies.

65 According to Primecrown, the argument that price control measures in a Member State can justify the use of an intellectual property right to prevent the import of a product placed on the market by the proprietor in that Member State or with his consent must be rejected. (48) The imposition of a barrier to trade has never been acceptable as a response to perceived market distortion. (49) A similar approach has been applied to the exercise of intellectual property rights. (50) Spanish prices are fixed independently of the availability in Spain of product patent protection and are based on comparisons with other Member States, in which patent protection exists for pharmaceutical products. The Spanish price control system serves the same social purpose as those operated in other Member States and, furthermore, as it is applied equally to imported and domestic products, does not infringe Article 30 of the Treaty. The high consumption of pharmaceutical products per head of population compensates for the slightly reduced price levels in Spain. Thus, the total return to the pharmaceutical industry from this high-volume market is favourable even if price levels have in the past been lower than in other markets. (51)

66 Primecrown submits that Merck has exaggerated the alleged adverse effects of parallel imports from Spain. It points out that there are very considerable barriers against parallel importation, some of which are inherent and others the result of deliberate strategies adopted by pharmaceutical companies to suppress the parallel trade. (52) A very significant price difference must exist between national markets before parallel importation will be worthwhile for traders or pharmacists. (53) Primecrown claims that parallel importation is a temporary phenomenon affecting a limited number of products for a limited period. Since the Act of Accession, the prospect of free movement of goods and the introduction of patentability has resulted in a general upward trend in Spanish drug prices with a reduction in differentials. Merck, Primecrown says, ignores the large benefits accruing to it and the pharmaceutical industry generally from Spanish and Portuguese accession.

67 Finally, Primecrown claims that losses caused by parallel imports will not damage future research and development in the pharmaceutical industry. Firstly, it would be irrational to reduce prospective research on future patentable drugs by reason of losses on earlier unpatentable ones. Secondly, research is a worldwide activity; a product, once developed, can then be mar-

keted worldwide in a climate which is increasingly favourable to pharmaceutical companies as a result of the progressive extension of patent protection flowing, inter alia, from Annex 19 to the Agreement on Trade-Related Aspects of Intellectual Property (hereinafter `TRIPS') concluded as part of the Uruguay Round of GATT negotiations. (54)

(iv) The intervening governments

68 I shall not recount in detail the submissions of the eight Member States who have made written or oral observations. All of the points they make appear in one form or another in the pleadings of the main parties. They all take as their starting point the need to balance the objective of free movement of goods in the Community with appropriate protection for the rights of patentees. However, they take differing views about the issue of reversing or modifying the rule laid down in Merck v Stephar. Only the Belgian Government joins the plaintiffs in explicit support of the rejection of that decision, but it links its arguments with the existence of price control in Spain. The Spanish and, to a lesser extent, the Greek Governments support the retention of Merck v Stephar. The Governments of Denmark, France, Italy, Sweden and the United Kingdom propose a qualification of the type of consent to marketing which should be taken as leading to the exhaustion of patent rights. These Member States, joined by Belgium, consider that the existence of price controls in Spain and Portugal either alone or combined with legal or ethical obligations to supply or continue to supply these markets should be considered as potentially undermining the conclusion that the plaintiffs had freely decided to market their respective products in those markets. I should emphasize the breadth of different positions adopted by these Member States. The United Kingdom, for example, considers in principle that apparently voluntary acts may be shown, in reality, to have been undertaken under compulsion but is unimpressed by any of the factors advanced by Merck in the instant case as sufficient to establish lack of consent.

(v) The Commission

69 The Commission submits that although the Merck v Stephar rule can be criticized, (55) it should not be abandoned because: firstly, of the need to respect the principle of legal certainty; secondly, of the potentially important consequences of such a decision for trade in pharmaceutical products between Spain and Portugal and the rest of the Community for the next ten years, and; thirdly, because the rule served implicitly as the basis for accession negotiations with those countries.

70 The Commission, in its written observations, advanced three arguments in favour of excluding from the scope of the Merck v Stephar rule cases where there is a legal or ethical obligation to market. (56) At the hearing it endorsed the observations of the Government of the United Kingdom regarding the difficulties inherent in attempting to develop a clear legal notion of an ethical obligation, and said that Merck v Stephar should be qualified only in circumstances where a legal obligation to market exists. (57) Such a legal obligation could derive either from Community or national law. Accordingly, the Commission contends that a refusal to supply a market where a product is not patentable could amount to an abuse of a dominant position contrary to Article 86 of the Treaty. (58) In respect of Spanish law, the Commission observes that, under Article 33 of Real Decreto 767/1993 of 21 May 1993 and Article 71(c) of Ley 25/1990 of 20 December 1990, the holder of a marketing authorization is obliged to market medicinal products for which he has received an authorization. (59)

71 The Commission submits, finally, that the right of the authorities to fix the sale prices of pharmaceutical products in the country of export should not be given any decisive importance with regard to the exhaustion of the rights of a patentee. While the fixing of prices at lower levels in an exporting than in an importing country gives impetus to the parallel importer, the same is equally true where patent protection exists in the exporting country.

72 The Commission accepted at the hearing that there was a link between patentability and pharmaceutical prices but said that there were many other factors which also affected prices. For example, the prices of some generic products in Denmark were higher than patented pharmaceuticals in France. In its opinion, the effects of national price control mechanisms represent a more significant factor in the pricing of pharmaceuticals in the Community than differences between national patent laws. However, it conceded that it was unlikely that there would be any harmonization of such controls at Community level in the foreseeable future. (60)

V - Schema for remaining sections of this Opinion

73 Question (3) poses the fundamental question of reassessing the balance to be struck between the Community objective of the free movement of goods, on the one hand, and the protection of national patent rights, on the other, or, in other words, whether Merck v Stephar should be followed. It is clear that the answer given to this question will greatly affect the significance of the first two questions referred which concern the expiry of the relevant transitional provisions in the Act of Accession. If Merck v Stephar is no longer to be applied, these questions become largely irrelevant. I propose therefore initially to deal in Section VI with this third question, the general considerations governing the abandonment by the Court of the reasoning underlying an earlier judgment and the alternatives to departing from Merck v Stephar. I will then address in Section VII the need, should the Court follow my principal recommendation regarding the rejection of the reasoning underlying Merck v Stephar, temporally to limit the effect of the judgment. Penultimately, I will deal in Section VIII with Questions (1) and (2) before, finally, stating my general conclusions in Section IX.

VI - Consideration of Question (3)

74 The primary contention of the pharmaceutical companies is that they should be permitted to invoke their rights under the patent law of the United Kingdom to oppose parallel imports from Spain and Portugal of the pharmaceutical products at issue for which they hold

patents in the United Kingdom. (61) They rely above all on the absence of patent protection for pharmaceutical products in Spain and Portugal which deprived them of the opportunity, when first marketing the products in those Member States, of the exclusivity which would have flowed from such protection.

A. Patents and pharmaceutical products

(i) Background to the pharmaceutical industry

75 Many companies in the pharmaceutical industry operate on a world-wide basis. They are concentrated principally in the United States, the European Community and Japan.

76 While the fact-finding function is the preserve of the national judge, there are large areas of agreement on the facts, particularly those concerning the essential role and soaring cost of research and development as they affect the industry. This has been recognized by Community institutions, and has influenced legislation.

77 On 2 March 1994, the Commission communicated to the Council and to the European Parliament a report `on the Outlines of an Industrial Policy for the Pharmaceutical Sector in the European Community' (hereinafter `the 1994 Report'). (62) Although not concerned per se with the issue of patenting, the 1994 Report repeats some of the points made in the explanatory memorandum attached to the Commission's proposal of 11 April 1990 for what subsequently became the SPC Regulation. In the 1994 Report the Commission highlighted certain features of the cost of research and its influence world-wide on the pharmaceutical industry which have already been cited from the arguments of Merck. It states that the rapid increase in cost of research was `generally attributed to progress in molecular biology and especially in knowledge of the pathogenesis of diseases, to technical improvements in tools for therapy or prevention and to increasingly stringent technical requirements designed to ensure the quality, safety and efficacy of medicinal products'. (63)

78 The 1994 Report supports the plaintiffs' claim that the industry in practice finances research and development from its own resources and only occasionally resorts to borrowing. Consequently, the cost incurred in research must be recovered in the form of the price of the extremely small number of successful products. In effect, only large multi-national firms have the resources and the ability to spread these costs. This combination of very high research costs and very low frequency of successful product development provides the crucial argument in favour of patent protection for pharmaceutical products.

79 Until quite recent times, the patentability of pharmaceutical products was the exception rather than the rule in many European States. According to Primecrown, the courts in the United Kingdom recognized such patents in the early years of this century. (64) First explicit recognition was given in statute law in the United Kingdom by Section 4(7) of the Patents Act 1949 and in Ireland by Section 2 of the Patents Act 1964. Pharmaceutical products were thus, for example, made patentable in Germany on 4 September 1967; (65) in Denmark on 1 December 1983; (66) in Norway on 1 January 1992; (67) in Finland on 1 January 1995. (68) Greece, like Spain, initially operated a reservation pursuant to the EPC which expired on 7 October 1992; Portugal acceded to the EPC as from 1 January 1992.

80 The case of Italy is of more than passing interest, since it provided the background to the decision in Merck v Stephar. Both pharmaceutical products and processes for their manufacture were excluded from patentability by Article 14(1) of the Italian patent law. (69) That article was subsequently declared unconstitutional and therefore inapplicable by a judgment of the Italian Constitutional Court of 20 March 1978. However, the drug at issue in that case, `Moduretic', encountered problems similar to those involved in the present case; it could not be patented in Italy even after Italian law had made such pharmaceutical product patenting possible, because of lack of novelty. (70)

81 The EPC constituted an important step on the road to the creation of a general, unified system of patent laws and more particularly for the patenting of chemical and pharmaceutical products. It provided, as seen earlier, for a maximum permissible period of 15 years of reservation from the obligation to provide patenting of such products so as to terminate on 7 October 1992. Merck's written observations provide a wealth of detail, into which I will not enter, on the obligation to introduce patentability imposed on a number of Central and Eastern European States from the beginning of the 1990s by agreement with the European Community. Primecrown referred to TRIPS concluded as part of the Uruguay Round of GATT negotiations. (71)

82 This all amounts to a convincing body of evidence of a world-wide trend in favour of recognizing the patentability of chemical and pharmaceutical products as such, and not merely of the processes for making them. In particular, once the periods of reservation permitted by the EPC have been exhausted, there will be a common 20-year period for patents for pharmaceutical products in all signatory countries to that Convention and, therefore, in effect, in all EC Member States. Consistently with that trend, the other Member States, by the Act of Accession, required Spain and Portugal, subject to transitional provisions, `to provide the level of protection of industrial property attained in the Community' subject to a limited power to postpone that effect in the case of chemical and pharmaceutical products. Whether or not this obligation implies a reciprocal obligation for other Member States, it seems to me that patent protection, without losing its national and territorial character, has become something more than a mere permissive derogation pursuant to Article 36 of the EC Treaty and has attained Community recognition.

(ii) The role of marketing authorization

83 The 20-year basic protection given by a European patent through the EPC has been, however, eroded through the effect of Member States' marketing authorization procedures. The Commission has acknowledged that `by the time a medicinal product has been developed and a marketing authorization obtained, only eight to ten years' protection remained'. (72) Upon the discovery of a new pharmaceutical sub-

stance, the inventor, usually in effect a pharmaceutical company, will file for patent protection, in order to protect the invention and to establish novelty. However, the necessarily very stringent stipulations of the authorities of Member States requiring that the quality, safety and efficacy of the product be established by means of evidence of clinical trials and other experimental information postpones the grant of authorization to market. (73)

84 Council Directive 65/65/EEC of 26 January 1965 (74) sought to harmonize certain disparities between these national provisions. In Council Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC (on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products), (75) the Council noted the need to ensure `that innovative firms are not placed at a disadvantage' and provided that, without prejudice to existing patent protection, a minimum period must elapse between the grant of the first marketing authorization for a new medicinal product, which requires comprehensive trials to prove quality, safety and efficacy, and the filing of a second, abridged application for the authorization of a generic copy of the product. It was left to Member States to decide whether to extend this period beyond the date of expiry of the original patent. (76)

85 The Commission was ultimately persuaded on 11 April 1990 to submit to the Council its proposal for the SPC Regulation. (77) In the explanatory memorandum to the proposal the Commission spoke of the need, as part of the Community health policy, to guarantee therapeutic, scientific, economic and social progress and stated that the aim of its proposal was `to improve the protection of innovation in the pharmaceutical sector'. (78) It considered that the patent protection system was `... essential to this innovating sector, in that investment in research is financed by means of returns obtained during a period of exclusive exploitation'. (79)

86 The fruit of this proposal was the SPC regulation. (80) The first four recitals in the preamble to that Regulation state:

`Whereas pharmaceutical research plays a decisive role in the continuing improvement in public health;

Whereas medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research;

Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research;

Whereas this situation leads to a lack of protection which penalizes pharmaceutical research.'

Article 13 provides, in effect, that the lapse between the filing of the original patent application and the grant of the first marketing authorization is to be added to the period of protection given by the patent, but subject to a maximum of five years.

87 Thus the Community as an integral part of a new industrial policy is committed to promoting the protection of industrial property rights, the most important of which in relation to the pharmaceutical sector is patent protection.

B. Patents and the free movement of goods

88 The relationship between the Treaty provisions concerning the free movement of goods and its competition rules, on the one hand, and national rules on the protection of intellectual property rights, on the other, has always created difficulties which require the development of fine distinctions by the Court. (81)

(i) The territoriality of national intellectual property rights

89 Article 222 of the Treaty provides that the Member States' `system of property ownership' is unaffected by the Treaty. In so far as the status of industrial and commercial property (hereinafter `industrial property') is concerned, the Treaty does not lay down any exhaustive code of rules; `[i]t merely provides a skeleton. The task of putting flesh on the bones falls to the Community legislature and to the Court of Justice'. (82) The rules on the free movement of goods, however, `articulate a conflict between two competing interests', (83) namely the fundamental objective of free trade in the establishment of the common market and the need to safeguard the national interest in respect of industrial property rights. Whereas the common market is concerned with the fusion of national markets into one single market, the Member States' industrial property laws are inherently territorial. In order to identify national laws which contravene the principle of freedom of movement of goods expressed, in particular, in Article 30, the Court developed the doctrine of the exhaustion of the specific subject-matter, object or substance of such rights. (84)

90 Copinger and Skone James on Copyright, for example, referring to the Opinion of Advocate General Roemer in Deutsche Grammophon, explain the territoriality principle as follows: (85)

`The fact that an industrial property right is the creature of the national laws of the State granting the right necessarily places limits on the territory within which such right is effective. This has been referred to as the "territoriality principle" of industrial property rights, ... but it is really no more than a necessary reflection of the territorial limit to the sovereignty of the State concerned. In the present context no English court can entertain an action under the Copyright Act 1956 by a plaintiff who is the author of a work entitled to copyright under that Act in respect of acts complained of as being committed in France, even if being committed by a defendant who is within the jurisdiction of the English Court ... .' (86)

While the precise policies underlying national patent laws may vary, there is a reasonable level of agreement that patents are intended to `... make it worthwhile for inventors and their capitalist backers to make their efforts and risk their money [...]. The simplest, cheapest

and most effective way for society to hold out these incentives is to grant temporary monopolies in the form of exclusive patent rights in inventions'. (87)
91 At the time of the entry into force of the Treaty between the original Member States, it appears that virtually all of the national patent laws limited the patentee's monopoly to the first sale of the patented product (88) whether as a result of the statutory definition of patent infringements or as a result of an express exhaustion doctrine. (89) The accession of the common law Member States to the Community altered somewhat the underlying national positions; United Kingdom and Irish patent laws are different because purchasers of patent-protected products are allowed to use such products under the fiction that an implied licence is granted on their sale by the patentee. This implied licence may, however, be restricted by contract. (90) More significantly, all of the original Member States' laws recognized generally that the effect of the territorial nature of patents was that the marketing abroad of the patented product, even with the patentee's consent, did not negate the patentee's right to oppose imports of such products as infringements of its national patent; (91) the patentee's monopoly thus continued until it had marketed or consented to the marketing of the protected product on the national territory. The attendant conflict between `the national monopoly of the holder of the patent, derived from national patent law, and the aims pursued by the EEC, in particular in creating a free market within which goods can be sold from one country to another without any obstacle' was brought to the attention of the Court particularly through the observations of the Dutch Government in the seminal industrial property rights case of Parke, Davis. (92) In the event of the Court's now departing from Merck v Stephar, it will naturally be for the national court to decide whether a similar approach ought to be adopted in relation to the products at issue in the instant cases, namely those manufactured under licence (we are told by local subsidiaries of the patentees) in circumstances where no patent protection was available in either Spain or Portugal.
(ii) The genesis of the exhaustion doctrine in Community law
92 In Parke, Davis the pharmaceutical company invoked its Dutch patent for chloramphenicol in the Dutch courts to prevent imports by Centrafarm and Others of products manufactured in Italy, allegedly in breach of its patent, at a time when no patent could be obtained there for pharmaceutical products or their processes. (93) The Court noted that `variations between the different legislative systems are capable of creating obstacles ... to the free movement of patented products ... within the Common Market', and ruled that `prohibitions and restrictions on imports may be justified under Article 36 on grounds of the protection of industrial property, but subject to the expressly stated reservation that these "shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States"'. (94)
93 The `watershed' in respect of the conflict between the Community objective of the free movement of goods and the generally territorial nature of national industrial property rights `was marked by the Deutsche Grammophon case'. (95) The Court was asked essentially `whether the exclusive right of distributing the protected articles which is conferred by a national law on the manufacturer of sound recordings may, without infringing Community provisions, prevent the marketing on national territory of products lawfully distributed by such manufacturer or with his consent on the territory of another Member State'. (96) The Court drew a distinction between the `existence of rights' and `the exercise of such rights'; the free movement rules would only permit industrial property rights to be exercised which were `justified for the purpose of safeguarding rights which constitute the specific subject-matter of such property'. (97) The distinction between the `existence' and the `exercise' of rights can, at times, be quite unreal; it has not been referred to in recent case-law, such as HAG II, and may now, at least in so far as the interpretation of Articles 30 to 36 of the Treaty is concerned, be discarded. (98) However, the identification of the rights which constitute the specific subject-matter of the national intellectual property is central to the Community notion of `exhaustion', though not under that name, developed by the Court in Deutsche Grammophon - admittedly in respect of a form of copyright, but one which bore all the usual features inherent in a patent. (99) In the crucial paragraph of the judgment, the Court stated: (100)
`If a right related to copyright is relied upon to prevent the marketing in a Member State of products distributed by the holder of the right or with his consent on the territory of another Member State on the sole ground that such distribution did not take place on the national territory, such a prohibition, which would legitimize the isolation of national markets, would be repugnant to the essential purpose of the Treaty, which is to unite national markets into a single market.'
Thus even before the Court expressly used the term `exhaustion', it attached importance to whether the marketing of the relevant products had taken place with the consent of the owner of the industrial property right. (101)
(iii) The specific subject-matter of a patent
94 The Court defined the specific subject-matter of a patent for the first time in Centrafarm v Sterling Drug. A New York company (Sterling Drug Inc.) owned parallel (process) pharmaceutical patents in both the United Kingdom and the Netherlands. In the United Kingdom the patent was owned and the product was manufactured by a British subsidiary (Sterling-Winthrop Group Ltd), whereas in the Netherlands it was distributed through a subsidiary of the British company. Centrafarm imported into the Netherlands consignments of the patented product, which had been lawfully put on the market by Sterling Drug's subsidiaries in the United Kingdom and Germany; Centrafarm v Sterling Drug was thus clearly a case where parallel

patents existed in the United Kingdom and the Netherlands.
95 On the basis of Dutch law, Sterling Drug's Dutch subsidiary was entitled to block the marketing of these products as the patentee's Dutch patent was not exhausted by the sale in the exporting countries, but the national court asked whether the Treaty's free movement of goods rules would prevent this. The Court in reliance on Deutsche Grammophon held that Article 36 of the Treaty `only admits of derogations from the free movement of goods where such derogations are justified for the purpose of safeguarding rights which constitute the specific subject-matter of the property'. (102) No doubt influenced by Advocate General Trabucchi, (103) the Court defined the specific subject-matter of the patent as `the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements'. (104)
96 The Court proceeded to rule that the application of a principle of national law whereby `a patentee's right is not exhausted when the product protected by the patent is marketed in another Member State, with the result that the patentee can prevent importation of the product into his own Member State when it has been marketed in another State' would constitute an obstacle to the free movement of goods. It recognized that such a right might be invoked subject to the dual conditions of absence both of patentability and of consent to marketing in the exporting Member State. (105) Invoking such a right would not, on the other hand, be justified `where the product ha[d] been put on to the market in a legal manner, by the patentee himself or with his consent, in the Member State from which it ha[d] been imported, in particular in the case of a proprietor of parallel patents'. (106) Acceptance of such a right would enable the patentee to partition off national markets, thus restricting trade where `no such restriction was necessary to guarantee the essence of the exclusive rights flowing from the parallel patents'. (107)
97 It follows in my view that once the patentee has enjoyed guaranteed exclusivity at the point of first marketing, which is not a guarantee of any monopoly profits, the specific subject-matter of its patent is exhausted. Unlike national patent laws which (to varying degrees) permit a patentee to oppose imports of the patented product marketed outside the national territory, the Community-law version of the exhaustion doctrine now developed permits the patentee merely to choose the place where he wishes first to market the relevant products in the Community; once that choice is made the marketed units must, in accordance with the Community exhaustion principle, thereafter be allowed to circulate freely throughout the Common Market.
98 Does the guarantee of exclusivity recognized in Centrafarm v Sterling Drug consist, as Beecham claims, of the right of first marketing the product with the benefit of patent protection? In view of the pivotal place of this decision in the developing case-law of the Court, it is important to address this question. The explicit basis of the question referred was that the patented product had been marketed in the exporting Member State both with the benefit of patent protection and the consent of the patentee. This was the question answered. On the other hand, the language used applies to a wider set of circumstances. At paragraph 11 of its judgment the Court acknowledged one situation in which an obstacle would be permissible, where both the conditions of patentability and consent were absent and referred cumulatively to an import `coming from a Member State where it is not patentable and has been manufactured by third parties without the consent of the patentee' (emphasis added), which of course was the actual situation in Parke, Davis. It did not deal with a situation where only one of those conditions is satisfied. Further ambiguity arises from the phrase `in particular in the case of a proprietor of parallel patents', as implying that this is only one situation in which the prevention of parallel imports is not justifiable. Strictly speaking, Centrafarm v Sterling Drug decided that issue only for such a case. However, the Court attached great importance to consent to first marketing and in that respect the decision is consistent with Deutsche Grammophon. The converse problem of interpretation arises in that case, where there was (at least at the material time) no parallel equivalent protection in France to that conferred on the producers of sound recordings by the pertinent German copyright law. However, no such distinction was adverted to either by the Advocate General or by the Court and it does not appear to have formed part of the reasoning of the decision.
99 The strongest argument in favour of the pharmaceutical companies' interpretation of Centrafarm v Sterling Drug is that, since the specific subject-matter consists of the exclusive right of first marketing the patented product, a rule permitting parallel imports of such products marketed by the patentee in a Member State where no patent protection exists and where, consequently, the patentee was subject to potential competition at the first marketing stage, would empty that exclusive right of much of its significance, i.e. the patentee must at least have had the opportunity of obtaining monopoly profits in the exporting Member State before its national rights in the importing Member State can be said to have been exhausted. (108) This, of course, was the principal submission of Merck and the intervening Member States which was rejected by the Court in Merck v Stephar.
(iv) Merck v Stephar
100 The factual circumstances of Merck v Stephar correspond in all but one important respect with those of Parke, Davis. Merck owned parallel patents in most Member States for Moduretic, a pharmaceutical product used in the treatment of hypertension. It marketed the patented product in Italy at a time when patent protection was expressly excluded for pharmaceutical products and their manufacturing processes. Stephar purchased batches of the product sold in Italy by Merck and imported them into the Netherlands where, due to

the prevailing high Dutch prices, it was able to undercut the prices charged by Merck. Merck argued that its rights under Dutch patent law could not be exhausted by the marketing in Italy in the absence of patent protection.
101 Beecham argues that, by holding in Merck v Stephar that a patentee can exhaust the specific subject-matter of its right through marketing in a Member State where no patent protection exists, the Court incorrectly extended the scope of the doctrine laid down in Centrafarm v Sterling Drug. In Merck v Stephar, the Commission and Stephar argued that the absence of a parallel patent was irrelevant because the crucial factor was the consent of Merck to the marketing in Italy. Merck, supported by the Governments of France and the United Kingdom, while agreeing with the definition of the specific subject-matter of a patent laid down in Centrafarm v Sterling Drug, maintained that a patentee must have the opportunity to earn a monopoly profit at least once.
102 I believe that it is appropriate to set out the reasoning employed by the Court and Advocate General Reischl in some detail.
103 In his Opinion, having stated that the circumstances of Deutsche Grammophon (absence of equivalent French right not precluding exhaustion of German copyright) were akin to those raised by Merck v Stephar, (109) Advocate General Reischl stated that paragraph 11 of the Court's judgment in Centrafarm v Sterling Drug `plainly refers to the case of a territory where there is no patent protection'. (110) He enumerated three principal reasons for rejecting the view that exhaustion can only occur if the patented product has been put on the market of a Member State where patent protection existed:
(i) the rights recognized as forming part of the specific subject-matter of a patent cannot be regarded as an end in themselves; but they are designed to provide the patentee with `the possibility of obtaining a recompense for his creative effort of invention ... [which although being] one of the objectives of a patent right [...] is not ... inherent in that right ... the realization of which depends on numerous market factors such as the presence of substitute products, commercial exploitability and similar conditions'; (111)
(ii) the inability to obtain patent protection is irrelevant because Merck `was in a position to decide freely in which Member State it wished to place on the market the product patented in the Netherlands', this choice was guided by its own interests and, in Italy, it `held, moreover, a de facto monopoly for the product in question'; (112)
(iii) the operation of the exhaustion doctrine cannot be affected by the fact that parallel traders, rather than consumers, are likely to be the principal beneficiaries because one of the essential aspects of the common market was that products should be manufactured or placed on the market where this can be done as cheaply as possible.
104 The Court's judgment is equally categoric. It states that the specific purpose of a patent `lies essentially in according the inventor an exclusive right of first placing the product on the market'. It is this right which `enables the inventor, by allowing him a monopoly in exploiting his product, to obtain the reward for his creative effort without, however, guaranteeing that he will obtain such a reward in all circumstances'. (113) The patentee must make the decision `in the light of all the circumstances ... including the possibility of marketing it in a Member State where the law does not provide patent protection'. If he decides to market in such a country `he must then accept the consequences of his choice as regards the free movement of the product within the Common Market, which is a fundamental principle forming part of the legal and economic circumstances which must be taken into account by the proprietor of the patent in determining the manner in which his exclusive right will be exercised'. (114) The Court continued: `[T]o permit an inventor, or one claiming under him, to invoke [a patent right in those circumstances] would bring about a partitioning of the national markets which would be contrary to the aims of the Treaty'. (115)
105 The lengthy arguments now advanced for the express abandonment of Merck v Stephar may essentially be summarized in two principal but interdependent contentions: (i) that the specific subject-matter of a national patent cannot in logic be exhausted in Community law unless the protected product is first marketed with the benefit of patent protection; (ii) that the Merck v Stephar judgment is incompatible with the subsequent case-law of the Court.
C. Reconsideration of Merck v Stephar
106 Advocate General Jacobs, in his Opinion in HAG II, considered that there was no rational basis for the doctrine of common origin of trade marks propounded in Van Zuylen v HAG. (116) The decision in Merck v Stephar represents, at least in so far as patents are concerned, the high point of the adoption of consent to marketing as the basis for the exhaustion of industrial property rights. Once a patentee has consented to the first marketing of a consignment of its products in any Member State, then, whether or not patent protection exists in that State, parallel patent rights in respect of that consignment are exhausted throughout the Community. I am satisfied, however, that Merck v Stephar should no longer be applied. The Court's rationale in Merck v Stephar was flawed and based, at most, on what was an implicit statement in Centrafarm v Sterling Drug - where the issue had not been raised by the facts of the referred case - concerning the appropriate balance between the free movement of goods and the protection of national patent rights in circumstances where there were no parallel patents. In my view Merck v Stephar went too far in ensuring that industrial property rights are not used to compartmentalize national markets to the detriment of the common market and thus undermined what should have been recognized as the fundamental core of a patent, namely the right of a patentee to market each particular unit of its patented product for the first time in a Member State with the

benefit of the absence of competition from unauthorized copies for the duration of the patent.
(i) The flawed basis of the judgment
107 It is clear from Article 36 of the Treaty that national industrial property rights are not inherently incompatible with the freedom of movement of goods within the Common Market. In the absence of harmonized Community rules, they remain unaffected by Community law. Community law is, however, legitimately concerned with the activities of owners of parallel patents which have the effect of partitioning national markets. (117) National industrial property laws have traditionally discriminated between domestic and foreign marketing by the proprietor of the right. Thus, whereas marketing on the national territory would generally preclude the proprietor of a patent from further controlling the domestic marketing of the protected product, this would not usually follow in the case of units marketed abroad. This difference permitted the proprietors of parallel patents to compartmentalize national markets in the hope of extracting monopoly profits from each controlled marketplace. It is self-evident that such discriminatory treatment can no longer be tolerated in a Community whose fundamental aims include the establishment of a single market without internal frontiers. (118) However, Merck v Stephar goes further by applying the same treatment to imports not so controlled. The sole rationale for this is the supposedly voluntary act of marketing.
108 I am not convinced that an import restriction granted in favour of a patentee constitutes an arbitrary restriction on intra-Community trade simply because the products concerned were marketed voluntarily in another Member State without the benefit of patent protection. (119) The effect of Merck v Stephar is to export not merely the product but also the commercial consequences of the legislative choice made by the exporting State to the importing State because the patentee has made a commercial choice to sell the product even in a less protected environment. The effect of the rule would be that, in order to avoid damage to the value of its national patent rights in those Member States which protect them, the patentee is encouraged to partition the Common Market in a different way, i.e. through refusing to supply units of its products to the markets of those Member States where his rights are not recognized: the product will therefore not be available for parallel traders and the patentee may in any event rely on his patent rights in other Member States to oppose any parallel imports of unauthorized copies manufactured in unprotected markets. (120) In other words, it would favour commercially irrational decisions to withhold products from the markets of such States, where sales of the product would hold out some prospect of profit. (121)
109 One undesirable result that would flow from the exercise by the plaintiffs of the `choice' recognized by paragraph 11 of the Court's judgment in Merck v Stephar would be that Spanish and Portuguese patients would be restricted to using unauthorized locally-produced copies of medicinal products patented in other Member States. I do not think this approach tends to contribute either to achieving an internal market in pharmaceutical products or to `ensuring a high level of human health protection'. (122)

110 In my view the reliance on the notion of free consent to marketing in Merck v Stephar unacceptably glosses over the logical fallacy that a patentee can be said to have exhausted his rights by choosing to market units of the protected product in Member States where no patent protection exists. Accepting, as I do, the Court's definition of the specific subject-matter of a patent, (123) I do not consider that commercially rational marketing of a protected product in a Member State where no protection exists is accompanied by the crucial element guaranteed by that specific subject-matter. In Merck v Stephar the Court described the `substance of a patent right' as lying `essentially in according the inventor an exclusive right of first placing the product on the market' which `enables the inventor, by allowing him a monopoly in exploiting his product, to obtain the reward for his creative effort without, however, guaranteeing that he will obtain such a reward in all circumstances'. (124)
111 While I believe that the Court has correctly been concerned about the potential partitioning of national markets flowing from the exploitation by the owners of industrial property of their inherently territorial (and thus protective) rights, I consider that such concern is misplaced in cases where no parallel rights exist. The diverging policies of Member States regarding the patentability of pharmaceutical products was the real cause of the non-uniformity in the common market. (125) In such circumstances, to impose a form of `venire contra factum proprium' (as suggested by Advocate General Reischl in his Opinion in Merck v Stephar) (126) on patentees attempting to exercise their national patent rights, on the sole basis that they have already sought to profit from another national market despite being denied patent protection there, effectively imposes on patentees the discipline of the Common Market where it does not in fact exist. Advocate General Reischl stated that patentees do not always make a monopoly profit and identified various extraneous factors which can seriously undermine profitability, such as the presence of substitute products. (127) The Court's view that the patentee in such circumstances must accept the consequences of its marketing decision `is not a reason but a conclusion'. (128)
112 If the plaintiffs were to withdraw, for example, their products from the Spanish and Portuguese markets and, at least as far as the Community is concerned, seek exclusively to recover their research investment in those products from other national markets where their patents are recognized, they claim that they would suffer significant adverse commercial damage, particularly in Spain and Portugal, to their goodwill and reputation. I was impressed by these arguments, particularly as such damage would flow from the withdrawal of or refusal to supply medicinal products in respect of an

entire market. Potential commercial damage is not, of course, a reason for refusing to give effect to free trade between Member States. However, this type of damage is clearly linked with the potential loss of incentive to investors. I would reject arguments to the effect that loss of the right to recover research costs on one or two markets should be ignored unless it can be shown that this will probably lead to reduced research investment in future. A balanced and fair approach should be adopted. This requires that the Spanish and Portuguese markets, even if they cannot be made to contribute to the recovery of research expenditure, should, at least, not be used to undermine that procedure on other markets. Unfortunately, the current logical implications of Merck v Stephar not only encourage pharmaceutical companies to partition Spain and Portugal from the rest of the Community by withdrawing from those markets, but thus also constitute a potential copyists' charter for those two markets which will last at least until research-orientated pharmaceutical companies are able to bring through to the marketing stage on those markets novel and therefore patentable products.

113 The commercial choice left to pharmaceutical companies by paragraph 11 of the Merck v Stephar judgment becomes even more stark when considered in the context of pharmaceutical markets. For reasons articulated in paragraphs 155 to 161 below, I do not recommend that the Court reconsider in what circumstances the free will of pharmaceutical companies is vitiated by an ethical obligation to market a product. However, these considerations are not wholly devoid of merit or relevance to reconsideration of the fundamental basis of the Merck v Stephar judgment. It may be possible to speak of major pharmaceutical companies having the option of withdrawing their foreign-patented products from the Spanish and Portuguese markets. It should not, on the other hand, be supposed that such an extreme proposal would necessarily represent a feasible course of action. In my view compelling commercial considerations with significant ethical content would unite to render such a proposal unacceptable in practice.

114 The reasons for not following Merck v Stephar are not, in my opinion, affected by its implicit acknowledgment by the Member States in the Act of Accession. The Act of Accession did not entrench Merck v Stephar in Community law. On the contrary, both its long-term and its short-term effect is to negate and exclude the rule in Merck v Stephar from operating permanently. In the long term, Spain and Portugal are required to amend their patent laws so as to be `compatible with the level of protection of industrial property attained in the Community'. (129) This is reinforced, as we have seen, in the specific case of patenting for chemical and pharmaceutical products by the obligation, admittedly delayed until 1992, to accede to the EPC. Thus, since 1992, all such products have been patentable in those Member States. Parallel patenting will become the rule rather than the exception. Those products patented in other Member States prior to 1992, by reason of lack of novelty and consequent non-patentability in Spain and Portugal, remain a potential source of parallel imports, if marketed there by the patentees, and, consequently, potential beneficiaries of Merck v Stephar. Even here, however, the operation of the rule is countermanded for three years by the transitional derogation. In no respect, therefore, is Merck v Stephar restated or reinforced by the Act of Accession. At most, it can be said that the transitional period is an implicit recognition that the rule has been adopted by the Court, but that its effects should be postponed.

115 In summary, I am satisfied that the judgment in Merck v Stephar represented an unacceptable restriction on the proper exercise of national patent rights. It is based exclusively on the criterion of consent to marketing. I believe that it is unacceptably detrimental to the legitimate interests of patentees and to the increasingly recognized Community function which patents perform. I am most struck by its logical fallacy. Patents are creatures of national, not Community law. The doctrine of exhaustion exists in some, not all Member States. A right conferred by a national patent cannot be exercised and, consequently, cannot be exhausted by an act of marketing in a Member State which recognizes neither that nor any other patent right in the relevant product. The national court observed, with justification, that the `doctrine of exhaustion was hardly appropriate to the Merck case'. The Community doctrine of exhaustion, enunciated in Centrafarm v Sterling Drug, should be reserved for those cases where there are genuine parallel patent rights. There, the logic is that the patentee has availed of his monopoly right once in the Member State of export. That is when the exhaustion occurs. Article 30 of the Treaty then intervenes to prevent the patent right in the importing Member State from being used to partition markets to the benefit of the dual patentee. Merck v Stephar does not fit within this scheme of logic.

(ii) Recommendation to the Court

116 I am thus satisfied, even before examining the subsequent cases cited by the plaintiffs in support of reconsidering the judgment of the Court in Merck v Stephar, that it should no longer represent the law. In my view, Article 36 of the Treaty ought to be interpreted as permitting the proprietor of a patent for a medicinal preparation in one Member State who also markets units of the product in a second Member State, where there is no patent protection, to avail of rights under the law of the first Member State to prevent imports into that first State of products which were initially marketed in the second Member State.

(iii) Case-law support for departing from Merck v Stephar

117 I also believe that the plaintiffs are correct in submitting that the case-law of the Court subsequent to the Merck v Stephar judgment supports the view that the scope of the judgment should be reviewed. The plaintiffs have relied especially on Pharmon v Hoechst, Warner Brothers v Christiansen and Ideal-Standard.

(a) Musik-Vertrieb Membran and Pharmon v Hoechst

118 It is difficult fully to assess the relevance of Pharmon v Hoechst without also examining the judgment in

Musik-Vertrieb Membran, which was decided only a few months before Merck v Stephar. Section 8 of the United Kingdom Copyright Act 1956 applied if a musical work had already been produced in the United Kingdom on a sound recording for the purpose of retail sale by or on behalf of the owner of the copyright. In the absence of agreement, a prospective manufacturer of records of the musical work would, in order to obtain a statutory licence, merely have to inform the composer of his intention to reproduce the work and agree to pay a licence fee of 6.25%, which became de facto the ceiling for royalties for record manufacturers in the United Kingdom. GEMA, exercising in Germany the rights of the copyright owner, opposed imports there of sound recordings first marketed in the United Kingdom and effectively sought to obtain the difference between the prevailing German and British royalty rates. The Court ruled however that: (130)

`... in a common market distinguished by free movement of goods and freedom to provide services an author, acting directly or through his publisher, is free to choose the place, in any of the Member States, in which to put his work into circulation. He may make that choice according to his best interests, which involve not only the level of remuneration provided in the Member State in question but also other factors such as, for example, the opportunities for distributing his work and the marketing facilities which are further enhanced by virtue of the free movement of goods within the Community. In those circumstances, a copyright management society may not be permitted to claim, on the importation of sound recordings into another Member State, payment of additional fees based on the difference in the rates of remuneration existing in the various Member States.

It follows from the foregoing considerations that the disparities which continue to exist in the absence of any harmonization of national rules on the commercial exploitation of copyrights may not be used to impede the free movement of goods in the Common Market.'

Advocate General Warner had, however, taken the contrary view that the effect of national law was effectively to cut down the relevant industrial property right and that, in such circumstances, `the legislation of the importing Member State may be invoked to the extent necessary to counteract that restriction'. (131)

119 It is difficult to reconcile the judgment in Musik-Vertrieb Membran or, by logical extension, Merck v Stephar, with the subsequent judgment in Pharmon v Hoechst. (132) Hoechst owned a process patent in Germany, the Netherlands and the United Kingdom for a pharmaceutical product, called `Frusemide'. DDSA Pharmaceuticals Ltd obtained a compulsory but non-exclusive and non-exhaustive licence pursuant to Section 41 of the Patents Act 1949. At the end of 1976 and on the eve of the expiry of the United Kingdom patent, DDSA decided to ignore an express export prohibition contained in the licence and sold directly a large consignment of Frusemide tablets to Pharmon in the Netherlands. Hoechst brought an action against Pharmon in the Netherlands based on its exclusive right to exploit Frusemide on that market.

120 The national court, as interpreted by this Court, asked `... in substance whether Articles 30 and 36 of the EEC Treaty preclude the application of legal provisions of a Member State which give a patent proprietor the right to prevent the marketing in that State of a product which has been manufactured in another Member State by a holder of a compulsory licence granted in respect of a parallel patent held by the same proprietor'. The Court did not distinguish the case of the direct import of a patented product from that of a parallel import.

121 As summarized by Advocate General Mancini, Pharmon effectively argued that in Merck v Stephar the Court had accepted `the principle of constructive consent' by a patentee to the disadvantages which the application of the law under which the patent has been obtained may reserve for the patentee. (133) The Court, however, ruled that:

`It is necessary to point out that where, as in this instance, the competent authorities of a Member State grant a third party a compulsory licence which allows him to carry out manufacturing and marketing operations which the patentee would normally have the right to prevent, the patentee cannot be deemed to have consented to the operation of the third party. Such a measure deprives the patent proprietor of his right to determine freely the conditions under which he markets his products.

As the Court held most recently in its judgment of 14 July 1981 (Merck v Stephar [...]), the substance of a patent right lies essentially in according an inventor an exclusive right of first placing the product on the market so as to allow him to obtain the reward for his creative effort. It is therefore necessary to allow the patent proprietor to prevent the importation and marketing of products manufactured under a compulsory licence in order to protect the substance of his exclusive rights under his patent.' (134)

122 The national court also asked whether it would make any difference if, first of all, an export prohibition was attached to the compulsory licence and, secondly, a system of guaranteed royalties had been incorporated in the licence and those royalties had been accepted or received by the patentee. The Court simply ruled that:

`It is sufficient to state that the limits referred to above imposed by Community law on the application of the law of the importing Member State in no way depend on the conditions attached by the competent authorities of the exporting Member State to the grant of the compulsory licence.' (135)

In other words it would seem that `these points made no difference whatsoever'. (136)

123 Pharmon v Hoechst, in my view, represents a careful application of the rationale underlying the consent to first marketing doctrine as the means of reconciling national patent rights with the free movement of goods. While compulsory licences cannot be equated fully with voluntary licences, they nevertheless offer the pat-

entee valuable protection. The patentee may voluntarily apply for a patent but deliberately not exploit the patent in that State in the expectation of a compulsory licence. Following the grant of such a licence the patentee will have the opportunity of obtaining recompense from that market (through royalties at a rate fixed by public authorities) while retaining the right to oppose all direct or parallel imports of the patented product from that State into other Member States. In brief, the patentee's profit levels will, depending on the level of the royalty imposed and possibly on the number of contractual licences granted, be reduced only in the first (exporting) Member State while its national rights in other Member States will remain unaffected.

124 The Court in Pharmon v Hoechst was clearly influenced by the territorial nature of compulsory licences and probably also by the discriminatory basis upon which many Member States granted such licences. It was clearly correct to reject the notion that exploitation by a compulsory licensee in one Member State could exhaust the patentee's rights in another, particularly as the compulsory license may only have been granted because the patentee was either unwilling to exploit the patent by manufacturing the product in that State or because it was actually importing the patented product into that State. In that sense the Court was reiterating the need for the dual conditions of patentability and consent to marketing before a free choice to market is inferred. The latter condition was absent in that case; in the present cases it is the former which is lacking. There was no Community justification for preferring the national policy decision reflected in the Patents Act 1949 to that underlying the rights accorded to Hoechst by virtue of its Dutch patent.

125 Some of the language, at least, used in Pharmon v Hoechst is difficult to reconcile with Merck v Stephar. I am satisfied that if `the substance of a patent right lies essentially in according the inventor an exclusive right of first placing the product on the market so as to allow him to obtain the reward for his creative effort', (137) the patentee must actually enjoy such an exclusive right if the doctrine of exhaustion is to be applied.

126 While Pharmon v Hoechst and Musik-Vertrieb Membran may be reconciled on a purely formal level - by reference to the voluntary nature of the licence in Musik-Vertrieb Membran and the compulsory nature of the licence in Pharmon v Hoechst - they are incompatible in substance: if the copyright owner had refused `voluntarily' to license the record manufacturer in Musik-Vertrieb Membran, the latter could simply have invoked the statutory licence. I do not think a patentee's avoidance of the inevitable through agreeing contractual terms with the prospective record manufacturer can easily be differentiated from his subjection to a compulsory licence in Pharmon v Hoechst. Demaret has succinctly expressed the underlying inconsistency: (138)

`In some way, the economic interest of copyright owners of musical works in the United Kingdom and in other Member States may be better served if the works in question are mainly exploited by compulsory licensees in the United Kingdom rather than by the copyright owners themselves. In the former situation, they are entitled to oppose imports of musical recordings originating in the United Kingdom, in the latter situation, they are not. No valid reason can explain such a discrepancy.'

127 I believe that a formalist approach to consent does not convincingly explain the different results achieved in Pharmon v Hoechst and Musik-Vertrieb Membran. (139) I am satisfied that it is only an approach based on whether or not the exclusive first marketing principle applies which can avoid the `erratic results' inherent in a formalist application of the consent test approach and which permits the focus to be placed on the `economic substance of the exclusive rights'. (140)

(b) Warner Brothers v Christiansen

128 The plaintiffs have perhaps placed the greatest reliance on the judgment in Warner Brothers v Christiansen. Danish law confers on the holder of copyright in video-cassette recordings the additional right to oppose the rental of the video-cassette even when it has been sold with the copyright holder's consent. The law of the United Kingdom, at the material time, did not grant any equivalent right. The voluntary sale by or on behalf of the holder of the copyright exhausted his rights in United Kingdom but not in Danish law. Mr Christiansen purchased in London, for the express purpose of hiring it out at his video shop in Copenhagen, a video-cassette of a film the copyright of which was owned by Warner Brothers and which at the material time was not available in Denmark. Warner Brothers and its Danish assignee (Metronome Video ApS) obtained an injunction at first instance restraining the envisaged hiring-out but, on appeal, a reference was made to the Court asking essentially whether the legislative provisions permitting such a prohibition were compatible with Community law.

129 Mr Christiansen relied on Musik-Vertrieb Membran. He cited paragraph 25 of that judgment to emphasize the free choice exercised by the holder of an intellectual property right in placing a product on the market. (141) Warner Brothers, he said, had chosen to market the video-cassette in the United Kingdom. If it had `been marketed in Denmark or Germany the authors' remuneration would have been appreciably lower than it was in the United Kingdom' since the `high (British) sale-price of the cassette included a component to cover the intellectual property rights represented by the possibility of hiring it out'. (142)

130 In its observations the Commission pointed out the serious potential loss of revenue for copyright owners in view of the increased popularity of renting as opposed to purchasing video-cassettes. In its view, the fact that not all Member States recognize such a right should not prevent copyright owners from relying on the laws of those which do.

131 Advocate General Mancini based his Opinion on Musik-Vertrieb Membran. He summarized the issue raised as being whether the purchaser of a cassette sold voluntarily in one Member State `may hire it out to third parties in another Member State against the copy-

right owner's will; in short, ... whether the principle of the exhaustion of copyright is applicable in this instance'. (143) He argued that the principle expressed in paragraph 15 of the Court's judgment was `decisive' and that:

`Once the maker of a film has sold the cassette to a third party, thereby transferring permanently his proprietary right over the recording and permitting it to circulate freely, he may not thereafter avail himself of the provisions of another [Member] State so as to assert his exclusive right over the work recorded on the cassette and thereby in practice prevent it from entering that State.' (144)

132 The Court, however, taking account of the evolution in market conditions, endorsed the Commission's submission that a specific market for the hiring-out of video-cassette recordings had emerged, stating that laws designed `to guarantee to makers of films a remuneration which reflects the number of occasions on which the video-cassettes are actually hired out and which secures for them a satisfactory share of the rental market. [...] are ... justified on grounds of the protection of industrial and commercial property pursuant to Article 36 of the Treaty'. (145) It followed that: `[I]t cannot therefore be accepted that the marketing by a film-maker of a video-cassette containing one of his works, in a Member State which does not provide specific protection for the right to hire it out, should have repercussions on the right conferred on that same film-maker by the legislation of another Member State to restrain, in that State, the hiring-out of that video-cassette'. (146)

133 The Spanish and the United Kingdom Governments seek to reconcile the present cases with Merck v Stephar on very similar lines. Whereas Merck in that case consented to the placing of its patented product on the Italian market in full knowledge of the potential consequences for its rights in other Member States, the exhaustion of Warner Brother's copyright in respect of the video-cassette sold in the United Kingdom did not operate to exhaust its secondary Danish rental rights. I do not think these arguments serve convincingly to distinguish Warner Brothers v Christiansen from Merck v Stephar: the specific subject-matter of a patent right may not be divisible in the same way as copyright into several individual acts restricted by copyright. But each of the several rights is an item of industrial or intellectual property whose existence flows from the law of a Member State. The Court made it clear in Warner Brothers v Christiansen that the exhaustion of one right in one Member State does not exhaust a different right in the same product in another Member State. Indeed, in so far as the special copyright of rental of video-cassettes in Danish law creates a distinction relevant to Merck v Stephar, it leads to a conclusion different from that recommended by Spain and the United Kingdom. If even the sale in the United Kingdom with the benefit of copyright protection did not exhaust the secondary rental right recognized in Denmark, it follows a fortiori in my view that the sale in one Member State without any patent protection should not be taken to exhaust that right in another Member State where such protection exists. The essence of the rights (if, admittedly, not the extent) conferred in two parts on a copyright owner (the exclusive rights to reproduce and to perform) and in one part in respect of a single act of marketing by a patentee are indistinguishable. Nowhere is this more plainly emphasized than in the Court's judgment in Warner Brothers v Christiansen. (147)

134 In my opinion the decision in Warner Brothers v Christiansen amounts to a fundamental departure in the Court's approach to the relationship between copyright and the free movement of goods. Warner Brothers undoubtedly profited from the voluntary sale of the video-cassette to Mr Christiansen in the United Kingdom, (148) but the Court nevertheless ruled that it could still invoke its Danish copyright to restrict the further exploitation by Mr Christiansen of that cassette. Applying this approach to Merck v Stephar, I cannot but conclude that the exploitation by Merck in Italy of its patented products, where no patent right whatsoever was recognized by Italian law, should not have been viewed as exhausting its exclusive patent right in the Netherlands. To paraphrase slightly the language used by the Court at paragraph 18 (quoted at paragraph 132 above) of its judgment in Warner Brothers v Christiansen, `... it cannot therefore be accepted that the marketing [by a patentee of a patented product], in a Member State which does not [recognize the patent right], should have repercussions on the right conferred on that same [patentee] by the legislation of another Member State to restrain, in that State, [the parallel importation of that product]'. In plain terms, the patentee should not have to bear the consequences of marketing in a Member State where its patent right is not recognized.

135 Professor Joliet explained very cogently why the rationale of the judgment in Warner Brothers v Christiansen is to be preferred to that of Merck v Stephar. The exhaustion doctrine is based on the availability of parallel prerogatives in both the country of exportation and that of importation; a decision applying the doctrine in the absence of such parallelism would be tantamount to lowering the protection available in the country of importation to the level of the less protective legislation of the country of exportation, thus operating a choice of legislative policy which must be left to the Member States. (149) In my opinion, there is no convincing reason associated with the freedom of movement of goods why the previous Spanish and Portuguese policies of refusing to recognize the patentability of pharmaceutical products should be imposed upon other Member States, who abandoned that particular policy many years before the Act of Accession required Spain and Portugal to follow suit.

136 The Court followed a similar `choice of legislative policy' reasoning in its recent decision in Ideal-Standard. The complicated factual background to this case may be summarized as follows: until 1984 the American Standard Group held through its French and German subsidiaries the trade mark `Ideal Standard' in Germany and France for sanitary fittings and heating

equipment. In July 1984 the French subsidiary sold the French `Ideal Standard' trade mark for heating equipment to another French company which later assigned it to a further French company known as CICh. Neither of the French assignees had any links with the American Standard Group. IHT, a German company, began marketing heating equipment made in France by CICh and bearing the trade mark `Ideal Standard' but was subject to infringement proceedings brought by the German subsidiary of the American Standard Group (Ideal Standard GmbH) in respect of the use of the trade mark in Germany, although that German company had stopped manufacturing and marketing heating equipment in 1976.

137 The relevance of the judgment for the present cases is limited by the specific trade mark aspects of the exhaustion of rights issue raised, namely whether there was a risk of confusion on the part of German consumers in the circumstances of the case and whether the proprietor of the German trade mark had any means of controlling the quality of the imported products. (150) However, based on the situation in French law, which, unlike German law, permits an assignment of a trade mark to be confined to certain products, IHT submitted that the French subsidiary had adjusted itself to a situation where products (heating equipment and sanitary fitting) from different sources could be marketed under the same trade mark on the same national territory and that the conduct of the German subsidiary in opposing the marketing in Germany of heating equipment from another source under the relevant trade mark was abusive. This argument was emphatically rejected by the Court in terms which are relevant to the instant cases: (151)

`The effect of IHT's argument, if it were accepted, would be to extend to the importing State whose law opposes such co-existence the solution prevailing in the exporting State despite the territorial nature of the rights in question.'

I would apply that reasoning mutatis mutandis to this case.

D. Departure from principles established in previous case-law

138 As I am recommending to the Court that it should no longer apply its judgment in Merck v Stephar, I believe that it is incumbent upon me to address the Court concerning the circumstances in which it should feel at liberty in departing from a previous, unambiguous interpretation of the Treaty.

139 As a matter of principle, the Court is of course not bound by its own previous judgments, in the way that the supreme courts of the two common law jurisdictions of the Community follow the doctrine of precedent or stare decisis. The Irish Supreme Court, though committed to the principle of `following precedent as the normal, indeed almost universal, procedure', will depart from its own previous judgments for compelling reasons: `... where the Supreme Court is of the opinion that there is a compelling reason why it should not follow an earlier decision of its own ... where it appears to be clearly wrong, is it bound to perpetuate the error? [...] However desirable certainty, stability and predictability of law may be, they cannot in my view justify a court of ultimate resort in giving a judgment which they are convinced, for compelling reasons, is erroneous'. (152) Likewise, the House of Lords declared in a practice statement in 1966 that `too rigid adherence to precedent may lead to injustice in a particular case and also unduly restrict the proper development of the law. [Their Lordships] propose therefore to modify their present practice and, while treating former decisions of this House as normally binding, to depart from such a decision when it appears right to do so'. (153)

140 The position of the Court as regards following rulings it has given in the framework of proceedings under Article 177 of the Treaty was described thus by Advocate General Lagrange in his Opinion in Da Costa:

`... the system of reference for a preliminary ruling ... is thus a collaboration between the Court of Justice and the national courts which ought to result, by way of case-law, in that unity of interpretation which is so desirable: through decisions and not through regulations. In other words, the Court of Justice should, in this as in all other matters, remain free when giving its future judgments. However important the judgment which it is led to give on some point may be, whatever may be the abstract character which the interpretation of some provision of the Treaty may present - or appear to present - the golden rule of res judicata should be preserved: it is from the moral authority of its decisions, and not from the legal authority of res judicata, that a jurisdiction like ours should derive its force. Clearly no one will expect that, having given a leading judgment ... the Court will depart from it in another action without strong reasons, but it should retain the legal right to do so'. (154)

141 The Court did not itself provide any statement of principle on the question of res judicata and precedent in its judgment in this case. It did, however, explicitly reject the view put forward by the Commission that, as the questions were identical to those which had been referred in Van Gend en Loos, (155) the request for a preliminary ruling should be dismissed for lack of substance. While holding that it should give judgment in the instant case, the Court simply repeated the interpretation of Article 12 of the Treaty it has given in the earlier case, and concluded that there was `no ground for giving a new interpretation' thereof. (156)

142 It is none the less obvious that the Court should, as a matter of practice, follow its previous case-law except where there are strong reasons for not so doing. In the first place, many important aspects of Community law, including the relationship between the principles of the free movement of goods and the exercise of industrial property rights, which is of direct concern in the present proceedings, are not comprehensively dealt with in the Treaty; the applicable principles and rules of Community law are thus to a large extent `judge-made law', and, as interpretations of Treaty provisions, are not amenable to modification or qualification through legislative means. Secondly, it is inherent in the system of

preliminary rulings that the Court's main function in this regard is to ensure the uniform application of Community law. It follows that national courts should be able to rely on rulings on the interpretation of provisions of Community law given on requests emanating from other national courts, and indeed the Court has itself held that a declaration in one preliminary ruling that a particular provision is void is a sufficient reason to dispense a national court from any obligation to refer a question concerning the same provision to the Court. (157) The same expectation that the Court will seek consistency in its judgments underlies its ruling in C.I.L.F.I.T., that no obligation to refer a question of Community law will arise `where previous decisions of the Court have already dealt with the point of law in question, irrespective of the nature of proceedings which led to those decisions, even though the questions at issue are not strictly identical'. (158) This is further reflected in Article 104(3) of the Court's Rules of Procedure, which provides that `[where] a question referred to the Court for a preliminary ruling is manifestly identical to a question on which the Court has already ruled, the Court may ... give its decision by reasoned order in which reference is made to its previous judgment.'

143 This is not to say that the Court should refuse to reconsider a previous decision in the face of strong evidence that this was wholly or partially incorrectly decided. The situation arose in a relatively stark form in the `Chernobyl' case, when the Court was asked to reconsider its unqualified conclusion in the `Comitology' judgment, delivered just 20 months previously, that `the applicable provisions [of the Treaty] as they stand at present, do not enable the Court to recognize the capacity of the European Parliament to bring an action for annulment'. (159) In the latter judgment, the Court was led to admit that `the circumstances and arguments adduced in the present case show that the various legal remedies provided for both in the Euratom Treaty and in the EEC Treaty, however effective and diverse they may be, may prove to be ineffective or uncertain', (160) notwithstanding the fact that the very same legal remedies had been examined in the previous judgment, and that the solution the Court adopted in `Chernobyl' was in effect identical to that which had been proposed by Advocate General Darmon in his Opinion in the earlier case.

144 A similar situation arose in Keck and Mithouard, (161) where the Court was requested to rule on whether the principle laid down in the `Cassis de Dijon' (162) case applied to rules governing national selling arrangements, as well as to rules on product composition and presentation. While reaffirming the generality of the `Cassis' principle, the Court held that `contrary to what has previously been decided, the application to products from other Member States of national provisions restricting or prohibiting certain selling arrangements' (163) was not even within the scope of measures having equivalent effect to quantitative restrictions prohibited by Article 30 of the Treaty, as defined in Dassonville, (164) so long as the national provisions apply to all relevant traders and affect domestic and imported products equally.

145 The judgment of the Court which is perhaps most at point in the present case is HAG II. There the Court was invited to reconsider the doctrine of the common origin of trade marks which it had established in HAG I, where the Court had ruled incompatible with the free movement of goods the reliance on a trade mark to prohibit the importation of a product legally bearing a trade mark in another Member State where the two trade marks have the same origin. In a powerful Opinion, Advocate General Jacobs concluded that the doctrine of common origin had no Treaty basis or other rational basis, and that its maintenance was incompatible with subsequent developments in the Court's case-law on the relationship between the free movement of goods and the protection of intellectual property rights. (165) At the outset of its judgment the Court expressly noted that it was `necessary to reconsider the interpretation given in [HAG I] in the light of the case-law which has developed with regard to the relationship between industrial and commercial property and the general rules of the Treaty, particularly in the sphere of the free movement of goods'. (166) The Court went on to emphasize the importance of trade mark rights in ensuring conditions of undistorted competition, to define the specific subject-matter of trade marks, and to identify the absence of consent on the part of the trade mark proprietor as `the determinant factor' in factual situations such as that which had given rise to the instant case. The Court concluded that `the essential function of the trade mark would be jeopardized if the proprietor of the trade mark could not exercise the right conferred upon him by national legislation to oppose the importation of similar goods bearing a designation liable to be confused with his own trade mark ... [this] analysis cannot be altered by the fact that the mark protected by national legislation and the similar mark borne by the imported goods ... originally belonged to the same proprietor who was divested of one of them following expropriation by one of the two States prior to the establishment of the Community'. (167)

146 While the judgments outlined above are too few to admit of extensive generalizations, it appears that the Court will reexamine and, if need be, decline to follow earlier judgments which may have been based on an erroneous application of a fundamental principle of Community law, which interpret a Treaty provision as applicable to situations which are properly outside its scope, or which result in an imbalance in the relationship between differing principles, such as the free movement of goods and the protection of intellectual and commercial property.

147 For the reasons already articulated, I believe that the Court incorrectly emphasized the requirements of free trade at the expense of national patent rights in Merck v Stephar. While I am led to believe that the balance struck in that judgment should no longer be applied, I also think that the Court should carefully consider the need to limit the retroactive effect of a new

judgment which rejects the reasoning underlying Merck v Stephar. (168)

E. Alternative to departing from Merck v Stephar

148 The third question referred by the national court raises the issue of whether Merck v Stephar should be followed, firstly, as a general proposition, but, as a subsidiary matter, asks whether the presence of four particular factors (whether individually or cumulatively) would permit the patentee in one Member State to oppose the importation of patented products which have been marketed in Spain and Portugal after the accession of those countries, but at a time when the products could not have been protected by a patent. The relevance of these factors is their capacity to demonstrate that products were not, if they are at present, freely marketed in the exporting Member State. For the reasons already given, I believe that the Court should no longer apply Merck v Stephar. In the event of the Court not accepting that recommendation, I would, in the alternative, advise the Court to consider that none of the factors identified by the national court or any of the alternative arguments advanced by the plaintiffs furnishes a sufficient justification for qualifying its judgment in Merck v Stephar.

(i) Legal obligation to market

149 The national court identifies as one of the strongest potential arguments in this context the existence of a legal obligation to supply the Spanish and Portuguese markets with the relevant products. There is general agreement in the observations submitted to the Court that if a pharmaceutical company is obliged, whether pursuant to national or Community law, to supply a particular national market with a certain product it cannot be said to have consented to the first sale of its product in that Member State. To invoke the language employed by the Court in Merck v Stephar, a patentee who is obliged to market cannot be said to have decided `in the light of all the circumstances, under what conditions he will market his product'. (169)

150 The decision in Pharmon v Hoechst means that the grant of a compulsory licence negates the consent of the patentee, even if the latter is aware of the national policy of granting such licences when he applies for his patent. In my opinion, no substantive distinction can be made between the grant of a compulsory licence and the imposition, whether by law or administrative action, of an effective obligation on the patentee or his assignee to supply a market. In reality, as appears from the observations submitted in these cases, a Member State which wishes to compel a pharmaceutical company to supply a particular product on its national territory is likely to do so by granting or threatening to grant compulsory licences.

151 The plaintiffs have argued that both Spanish and Portuguese law effectively enable the relevant national authorities to compel pharmaceutical companies who have obtained marketing authorizations for particular medicinal products actually to market those products. These submissions are contradicted by Primecrown and by the Spanish Government (in its oral observations). It falls within the competence of the national court to determine their accuracy in accordance with national rules for the proof of the content of national law.

152 Primecrown distinguishes between a voluntary decision to market products for the first time and a subsequent obligation to continue supplies. This distinction is not however relevant to the exhaustion of rights doctrine under Community law. As Beecham correctly argued at the oral hearing, the Community rules on free movement apply to the placing of a particular product on the market; consent to marketing of such a product does not exclude the possibility that later batches of that product were marketed under compulsion. In my opinion, if the national court finds that the authorities in the exporting Member State forced the pharmaceutical companies to continue supplies, then, in so far as Community law is concerned, such marketing would not be the result of a free decision. Subsequent reliance by such companies on rights conferred by the patent law of the importing Member State (here the law of the United Kingdom) to restrain parallel imports of those particular units of their products may be justified by reference to Article 36 of the Treaty. On the other hand, the mere existence of such legal provisions which have not been invoked would not have that effect, any more than the mere existence of the compulsory powers referred to in Pharmon v Hoechst would have been enough to negate a voluntary act of marketing, if Hoechst had so acted in that case. It is not suggested that any compulsory powers have been invoked against either of the plaintiffs in Spain or Portugal.

153 Reference has also been made by the plaintiffs to the possibility that, once a patented pharmaceutical product is initially marketed on a particular national market, the patentee or his assignee may be obliged by reason of the provisions of Articles 85 or 86 of the Treaty to continue supplies. The circumstances in which those provisions could be invoked to undermine consent have not, in my view, been developed sufficiently in argument to support the far-reaching proposition which the plaintiffs advance. In the first instance, it is not suggested that, to date, any steps or even hints of action have been taken against either of the plaintiffs either at national or Community level. The points made are, at best, speculative. If Article 85 is to be applied, one or other of the plaintiffs must have been party to agreements or concerted practices which `have as their object or effect the prevention, restriction or distortion of competition within the common market'. Obviously, neither of the plaintiffs suggests that it is in that position. I would, in any event, be unfavourably disposed to allowing an undertaking claiming to be party to such activity to establish that its marketing was thus involuntary because it was only designed to avoid a breach of Article 85. Very similar considerations would have to apply to arguments based on Article 86, except that the plaintiffs or either of them would have to establish that it was in a dominant position in a substantive part of the common market, which, having regard to the high level of substitutability of pharmaceutical products, would not be an easy task. The

expressions of apprehension that others might make allegations of anti-competitive behaviour fall a long way short of a basis for serious consideration of this argument.

154 Before turning to consider possible ethical obligations, I wish to highlight an important practical aspect of all of these possible grounds of legal compulsion. They imply that a national court in one (importing) Member State will assess the substantive terms of the law of another (exporting) Member State or assess whether the effect of the application of Community competition law in that exporting State was such as effectively to compel a patentee to sell or continue to sell certain pharmaceutical products. While no doubt procedural rules of the various Member States permit appropriate evidence to be adduced regarding the legal and/or factual situation in another Member State, the fact that the national courts would be required to carry out this task in the context of applying a derogation from the Treaty's free movement of goods rules could only be regarded at least as presenting a source for possible conflict. If such a conflict concerning the rules of national as opposed to Community law arose, it is difficult to see how even a reference to the Court could resolve such a conflict. In my view, qualifying the Merck v Stephar notion of consent in the context of legal compulsion, as opposed to departing from that judgment, could thus potentially present more problems than it might resolve.

(ii) Ethical obligation to market

155 The plaintiffs have also submitted that the rule in Merck v Stephar should be qualified so as to recognize an exception where the free will of the patentee, at least of a pharmaceutical product, in deciding to market his product is affected by compelling ethical obligations. Essentially the plaintiffs, with the support of the Danish, Swedish and Italian Governments and, initially, the Commission, submit that pharmaceutical products are developed to meet specific health-care requirements and that because of their great importance for human health, pharmaceutical companies are under an obligation to market such products in as many countries as possible.

156 I accept that there is some force to these arguments. I do not question the plaintiffs' assertion that they are committed to the pursuit of a general ethical policy of ensuring the widest possible availability of their products and the related pharmacovigilance. The plaintiffs have submitted that the existence of an ethical obligation in relation to a particular product is not entirely subjective but can, in fact, be gauged objectively by reference to public health-care needs or demand for that product. Thus, although a pharmaceutical company may simultaneously be responding to commercial considerations in deciding to enter or continue marketing on a particular market, it may still be able to show that it is not acting freely.

157 I do not, however, accept that the pursuit of an ethical policy by pharmaceutical companies can, consistently with the requirement of promoting legal certainty, inter alia, for parallel traders, be divorced from the concomitant commercial considerations which govern their marketing decisions. Ethical pressure to supply a product might, for example, be exerted by the medical profession in a particular Member State so that failure to supply would damage the reputation and thus commercial interests of the pharmaceutical company. The ethical obligation proposed is self-defined and expressed in slightly different terms by the two plaintiffs. There is no objective set of rules. At best some examples have been cited of companies which adopt a principled approach. I do not see why a company should be morally obliged to supply the public health services of a Member State where, for example, prices are fixed at such a low level as to entail a loss. Nor is it easy to see that there would be an ethical obligation in every case to supply, particularly if the relevant health-care needs were being met adequately by generic copies.

158 Furthermore, if the Court were to rule that the possible existence of such an obligation was relevant to the application of the rule in Merck v Stephar, the plaintiffs accepted that they would be obliged to adduce independent evidence before the national court about the ethical factors affecting the particular products which allegedly vitiated their free will regarding the sale of those products in Spain and Portugal. As the Government of the United Kingdom correctly stated at the hearing, `[S]ubstantial inroads could be made into the important Community principle of free movement and considerable uncertainties would exist for parallel importers and manufacturers alike if the concept of consent was held to encompass such obligations'. I am satisfied that ethical considerations can at most constitute a persuasive reason for choosing to market a particular medicinal product but cannot, for example, be equated with a compulsory marketing obligation imposed on a patentee by an appropriate national authority having the power to do so. To accept that the consent to first marketing, which is central to the rule in Merck v Stephar, would have to be established in the light of such considerations would, in my view, open up the Community exhaustion principle, as applied to patents, to a significant degree of uncertainty. I would be particularly concerned that, if an ethical qualification were accepted, as indeed Primecrown contends, the considerable financial resources of such patentees would be deployed to frustrate the activities of parallel traders.

159 There is a further and more compelling reason why the argument should be rejected. While ethical considerations may not have been advanced in Merck v Stephar as a justification for preventing the parallel imports, the relevance of a similar argument had already been rejected by the Court (and Advocate General) in Centrafarm v Sterling Drug. One of the national court's questions in that case requested the Court `to state whether the patentee is authorized to exercise the rights conferred on him by the patent, notwithstanding national rules on the free movement of goods, for the purpose of controlling the distribution of a pharmaceutical product with a view to protecting the public

against the risks arising from defects therein'. (170) The Court's response is telling:

`The protection of the public against the risks arising from defective pharmaceutical products is a matter of legitimate concern, and Article 36 of the Treaty authorizes the Member States to derogate from the rules concerning the free movement of goods on grounds of the protection of health and life of humans and animals. However, the measures necessary to achieve this must be adopted in the field of health control, and must not constitute a misuse of the rules concerning industrial and commercial property.

Moreover, the specific considerations underlying the protection of industrial and commercial property are distinct from the considerations underlying the protection of the public and any responsibilities which that may imply.' (171)

160 The Court was clearly correct to separate public health issues from the issue of protecting industrial and commercial property. As Advocate General Trabucchi succinctly put it, `[T]he protection of public health is a different matter from the protection of the property right of a private party'. (172) In my opinion the pharmacological factors advanced by the plaintiffs in these cases as constituting an ethical obligation to market merely represent a restatement of the concerns expressed in Centrafarm v Sterling Drug. The plaintiffs' claimed ethical obligation to distribute their products in Spain and Portugal implies their adoption of a self-defined role as guardians of public health in those countries.

161 Finally, if the Court were now to view such considerations as relevant, I think that it would be difficult to develop criteria which would convincingly confine their relevance to parallel trade in patented products first sold in Member States where no patent protection was recognized. If a pharmaceutical company can claim that it was ethically obliged to market one of its patented products in such a country, why could it not claim that similar considerations also compelled it to market units of the same product in other Member States where such protection was recognized? It is clear from the observations which have been submitted to the Court regarding the nexus between governmental price controls and the price levels of patented products, that pharmaceutical companies might, even if they benefit from patent protection, be dissatisfied with the level of prices fixed in a particular Member State. The Court is informed by Merck that it is never influenced by prices in deciding to make one of its products available on a particular market. In such circumstances, if the Court were to accept the relevance of ethical considerations, pharmaceutical companies may seek to argue that they were compelled ethically to market their products despite what they might regard as commercially untenable controlled prices. I do not believe that the presence or absence of patent protection could provide a satisfactory basis to distinguish the relevance of ethical consideration in both situations.

(iii) Governmental price controls

162 The national court raised the possibility that the imposition of national price controls, either alone or in combination with a legal or ethical obligation to market or continue marketing, might justify a qualification of the rule in Merck v Stephar. It should first be noted that the submissions presented to the Court indicate that the nature of public price control mechanisms differs from Member State to Member State; in some, such as Spain and Portugal, it is the national authorities who apparently fix the prices whereas in others they are either voluntarily agreed between the industry and the relevant public authorities or there are no formal controls in operation.

163 It must also be stressed that the national court clearly stated that the legitimacy of the price-fixing measures adopted by the Spanish and Portuguese authorities was not an issue before it. This, of course, is perfectly consistent with the case-law of the Court. In Centrafarm v Sterling Drug, the Court was asked whether the existence of price differences resulting from governmental price measures adopted in the exporting Member State with a view to controlling the price of the protected product would justify the patentee in the importing State in seeking to prevent the imports. The Court replied that, while the Community would be competent to harmonize the measures applied by Member States in so far as they were likely to distort competition between Member States, the existence of such factors `cannot justify the maintenance or introduction by another Member State of measures which are incompatible with the rules governing the free movement of goods, in particular in the field of industrial and commercial property'. (173) Indeed, it has not been suggested in the observations submitted to the Court that either Member State operates its system of price controls in a manner which discriminates against imported medicinal products. As correctly submitted by a number of Member States and the Commission, it is clearly permissible, in the absence of harmonized Community price-fixing arrangements for Member States, as part of their public health and social security policies of ensuring the availability of adequate supplies of medicinal products at a reasonable cost, to seek to limit the prices of pharmaceutical products. The fact that the application of such price controls may, along with various other factors, affect the potential profits of pharmaceutical patentees is not relevant for the interpretation of the balance between the free movement of pharmaceutical products and the protection of national patent rights.

164 The issue that is raised by the national court's third question is, however, whether the combination of such governmental price controls and the lack of patent protection in a Member State is a factor which would justify qualifying the rule in Merck v Stephar; should a patentee who has sold a patented product in such a Member State be entitled to rely upon his national patent rights on the importation of those products into another Member State by a parallel trader? In order to clarify the views of the parties and the interveners on this issue, the Court asked them to address in their oral

observations the question of whether a direct causal link exists between the fact that a product cannot be protected by a patent, on the one hand, and the level of prices of pharmaceutical products in a given Member State, on the other, and, if so, the reasons why such non-recognition of pharmaceutical patents influences the pricing adopted by the national authorities of the State. The plaintiffs, who were supported to varying degrees by some of the intervening governments and the Commission, argued that the non-recognition of pharmaceutical patents weakens the patentee's price negotiating position. By the time the patentee obtains his marketing authorization it is likely that those authorities will already have received applications for marketing authorizations from copyists. This fundamentally alters the balance of negotiating power; the authorities are in a position to fix the official price by reference to the costs plus a reasonable profit margin of such copyists, which is clearly not the case where the patentee enjoys patent protection. The authorities know that if the patentee refuses to accept the price offered, it is highly likely that their markets will be supplied by copyists who are in a position to accept a lower price given their lower overheads and minimal research costs. Beecham submitted that the arguments advanced by Spain in its challenge to the validity of the SPC Regulation demonstrate that the Spanish Government is well aware of the link between patent protection and prices. (174) Primecrown denied that there was necessarily a causal link between governmental price controls and patent protection. This view was supported in particular by the Commission and the Government of the United Kingdom, who each referred to the variety of factors which influence the prices of medicinal products. (175)

165 In substance the plaintiffs are arguing that they ought not to be regarded as having consented to the first marketing of patented products in Spain and Portugal, because the lack of patent protection in those States significantly reduced their ability to influence the prices fixed on those markets. This argument ignores the various other factors which influence pharmaceutical prices on a particular market. I do not think that it would be possible without, at least, the benefit of what the Government of the United Kingdom described at the hearing as an `in-depth economic analysis' to formulate, for application by national courts, a set of criteria which would permit the determination of whether the lack of patent protection itself was the principal determining factor in the price set by a government on a particular market, without calling into question the method of price control used by that government.

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166 I believe that the distorting effect of the lack of patent protection combined with national price controls should be regarded as further supporting the view which I have already taken in respect of the application of the Community exhaustion doctrine where products are first marketed in a Member State which does not recognize patent protection. I am therefore satisfied that the most appropriate way to address the reduced bargaining position enjoyed by proprietors of pharmaceutical patents in those Member States where their patents are not recognized is to abandon the rule in Merck v Stephar. This approach avoids the need to formulate criteria which would effectively require national courts to engage in extensive economic analyses of the relationship between price controls and non-patentability in order to determine a point at which the effect of the lack of patent protection would be such as to negate the voluntary nature of a decision to market.

VII - Temporal effects of the Court's judgment

167 The Court is competent to limit the retroactive effects of an interpretation of Community law `in the actual judgment ruling upon the interpretation sought'. (176) It should not be constrained in exercising that power because of the difficulties of predicting the extent to which economic operators may have entered into legal relationships on the basis of Merck v Stephar. On the one hand the possible injustice to parallel traders affects only the period following the expiry of the temporal derogation contained in Articles 47 and 209 of the Act of Accession. On the other hand, the Court should bear in mind the possibility of similar parallel trade between the other Member States and Finland or Greece, for example, where the patentability of pharmaceutical products has only recently been recognized. The Court has no information about the nature or extent of commitments to such trade either for these countries or Spain or Portugal, but the possibility of injustice to even one trader who has relied on the existing understanding of the Merck v Stephar rule is enough. The normal principle that the Court's interpretation of a rule of Community law applies ex tunc ought not, in my view, to be applied in the present cases.

168 Such a temporal limitation would not require the Court to go further than its established case-law. The Court has recognized that the interests of legal certainty can justify a restriction on the temporal effects of a judgment. (177) Advocate General Tesauro has described as follows the two principles the Court applies when deciding whether to impose a temporal limitation:

`First, it weighs the possible consequences of its judgments in the absence of any temporal limitation, while pointing out that this "cannot go so far as to diminish the objectivity of the law and compromise its future application on the ground of possible repercussions which might result, as regards the past, from a judicial decision". Secondly, the Court considers whether there were any objective uncertainties as to the scope of the provisions of Community law which are the subject of the interpretative judgment and to what extent the actual conduct of the Community institutions might have nurtured these uncertainties.' (178)

169 There can be few clearer cases than the present where the interests of justice justify limiting ex nunc the effects of an interpretation of the Treaty. (179) It would be wrong for the Court now to interpret the Treaty provisions `as [they] must or ought to have been

understood and applied from the time of its coming into force' (180) when, as the national court has said, this would effectively transform such parallel traders into wrongdoers for past acts which were considered lawful when they were carried out. (181) Both defendants in the main proceedings took steps to be in a position to avail of the application of Merck v Stephar on the expiry of the temporary suspension of that judgment contained in the Act of Accession, but were restrained by the legal proceedings of the plaintiffs. There was no ambiguity in Merck v Stephar and the defendants - and possibly a significant number of other parallel traders - quite reasonably assumed that the market in the parallel trade of pharmaceutical products between Spain and Portugal and the rest of the Community was about to open up. (182) Uncertainty would only arise if the Court were to depart from Merck v Stephar without limiting the temporal effects of its new judgment.

170 The interpretation given by the Court should apply prospectively from the date of the judgment. The extent of such a restriction on retroactive effect would depend on the answers given by the Court to the first two questions. Merck v Stephar would continue to apply to parallel trade between Spain and Portugal and the rest of the Community for the period between the expiry of the transitional period and the judgment. Any inconvenience for pharmaceutical companies such as the plaintiffs caused by such a temporary application of Merck v Stephar, would, in my view, be compensated by the benefits conferred by the decision to depart from it for the future. (183) I am therefore satisfied that, if the Court decides no longer to apply Merck v Stephar, it should limit the temporal scope of its judgment to the date of its judgment in the present cases.

VIII - Consideration of Questions (1) and (2)

171 The first two questions referred concern, respectively, the length of the period of transitional protection (which I will call `the transitional period') against parallel imports from Spain, provided by Article 47, or from Portugal, by Article 209 of the Act of Accession. The answers to be given to these questions will become very significant if Merck v Stephar is maintained. Moreover, if the Court were to reverse the effect of Merck v Stephar but simultaneously to limit the temporal effects of such a judgment, the issue of the precise expiry dates will also be of major importance.

172 The Act of Accession allows the holder of a patent for a pharmaceutical product in a Member State to prevent imports of that product from Spain or Portugal for the transitional period, which runs from the date when that country has `made these products patentable'. Each of the alternative dates offered by the national court assumes a date for that event. The transitional period terminates at `the end of the third year after' that date. Each of the national court's alternatives also depends on the duration of that time. All of the alternatives thus depend on assumed starting and finishing dates for the transitional period. The alternatives are listed in the following table:

Letter of ref.
of National Court
Spain
(Question 1)
Portugal
(Question 2)
Basis for choosing this date
(a)
7 October 95
1 January 95
EPC accession + anniversary date
(b)
31 December 95
31 December 95
EPC accession + end calendar year of anniversary date
(c)
7 October 96
1 June 98
- Spain: Denial of Paris Convention priority
- Portugal: no national patent before this date + anniversary date in each case
(d)
31 December 96
31 December 98
Both countries: as at (c) + end calendar year of anniversary date
(e)
3 years after particular product becomes patentable

Option (a) is the third anniversary of the date when Spain or Portugal respectively acceded to the EPC. I call this the anniversary date. Option (c) would postpone for Spain, for one year, the date of patentability because of the Spanish Council of State's refusal to recognize the priority for one year of applications in Paris Convention countries. Options (b) and (d) represent the end of the calendar year of the dates in Options (a) and (c). Option (e) assumes that the transitional period cannot end for the products at issue in the national proceedings until three years after such future date as Spain or Portugal, as the case may be, makes those specific products patentable. It has not been expressly stated, though it may logically be assumed, that Merck and Beecham claim to apply the calendar-year rule to Option (e), if adopted by the Court.

173 Spain and Portugal each undertook by paragraph 1 of Protocol Nos 8 and 19, respectively, upon accession to `adjust its patent law so as to make it compatible with the principles of the free movement of goods and with the level of protection of industrial property attained in the Community ...'. That paragraph also envisaged cooperation between the new Member States and the Commission `to cover the problems of transition of current (Spanish/Portuguese) law towards new law'.

174 The objective of free movement is identically expressed in Article 42 for Spain and Article 202 for Portugal by requiring that, as from the date of accession, 1 January 1986, `quantitative restrictions on imports and exports and any measures having equivalent effect shall be abolished ... between the Community as at present constituted and the Kingdom of Spain', and `the Portuguese Republic', respectively.

175 Paragraph 3 of Protocol No 8 postponed Spain's obligation to change its patent laws `solely for chemical and pharmaceutical products'. Firstly, that paragraph obliged Spain to accede to the Munich Convention, i.e., the EPC. Secondly, it envisaged that Spain would invoke the reservation in respect of `chemical and pharmaceutical products' contained in Article 167(2)(a) of the EPC but obliged it to accede within the time allowed for that purpose. Article 167(1) of the EPC permits such a reservation if invoked by a Contracting State `at the time of signature or when depositing its instrument of ratification'. Spain duly made the reservation. (184) Consequently, any European patent in respect of these products was `in accordance with the provisions applicable to national patents ... ineffective or revocable'. (185)

176 The reservation thus granted is limited, by Article 167(3) of the EPC, to last for `not more than 10 years from the entry into force of th[e] Convention', i.e. ten years from 7 October 1977. (186) The same provision allowed the Administrative Council of the European Patent Organization to `extend the period [of such a reservation] by not more than five years ...' on the basis of a reasoned request submitted more than one year before the end of the ten-year period. With this provision in view, the Member States of the Community, `in their capacity as Contracting States of the Munich Convention,' recorded in Paragraph 3 of Protocol No 8 their undertaking to use their best endeavours to obtain such an extension for the maximum permitted period, should it be sought. The extension was sought and obtained, (187) for the period to 7 October 1992.

177 In what was presumably considered to be the unlikely event of this extension not being granted, Paragraph 3 of the Protocol further provided that Spain might rely on Article 174 of the EPC, a provision recognizing the right of any Contracting State at any time to denounce the Convention. Even in that event Spain was, `in any event, [to] accede to that Convention not later than October 7 1992'. In the interim Spain, by its new Patent Law 11/1986 of 20 March 1986, provided that inventions of chemical and pharmaceutical products should not be patentable before 7 October 1992. (188)

178 By these provisions, the patentability of chemical and pharmaceutical products was postponed in Spain for the entire permissible 15-year period of reservation permitted by the EPC, i.e., to 7 October 1992 and, in effect, between six and seven years after the date of Spanish accession. The reservation applied to any European patent application filed during that period and continues for the term of the patent. (189) Thus, the end of the reservation period benefits only patent applications filed after its expiry.

179 By Paragraph 3 of Protocol No 19, Portugal was obliged to accede on 1 January 1992 to the EPC and to that extent, its transitional arrangements were simpler than those of Spain.

180 Spain was not, therefore, obliged either by the Act of Accession or the EPC to introduce into its law provisions for the patenting of chemical or pharmaceutical products so as to have any effect prior to 7 October 1992 or to give any recognition to an application filed, whether in Spain or elsewhere, prior to that date. In plain terms, Spain did not have to make these products patentable before that date. It is also clear that 7 October 1992 was not at the time of the Act merely a possible or unpredictable future date but one which was clearly envisaged by the Protocol in this and in several other respects. (190) It is equally clear that 1 January 1992 was the date upon which Portugal was bound to introduce provisions for the patenting of pharmaceutical products. This date was equally foreseeable at the time of the Act of Accession.

181 I turn then to assess the effect of this conclusion on the interpretation of Articles 47(2) and 209(2) of the Act of Accession sought by the national court. Both Merck and Beecham argued in the national court, and Beecham in its written observations to this Court, that the expression `these products' found in each transitional provision must be interpreted as referring to the particular products whose import a patent-holder seeks to prevent. This argument cannot, in my view, survive serious scrutiny even in the light of the text of the Article itself. Articles 47(1) and 209(1) confer, for a transitional period, the rights or benefits there described on `the holder ... of a patent for a chemical or pharmaceutical product ...' and are expressed, throughout, in the singular. This is not surprising. A legal provision conferring a legal right capable of being exercised by an individual is quite properly expressed in the singular. One only has to recall that `[a]ny natural or legal person may ... [pursuant to Article 173 of the EC Treaty] ... institute proceedings against a decision addressed to that person ... which ... is of direct and individual concern ...'. As regards the fixing of the time-limit for enjoyment of this transitional privilege, on the other hand, Articles 47(2) and 209(2) are appropriately expressed in the plural and speak of the time when Spain or Portugal, as the case may be, `has made these products patentable'. The products in question are `chemical and pharmaceutical products' generally and not the particular product whose import is in question. In order to sustain the proposition, advanced by Merck and Beecham, that the time-limit should not terminate until the particular product is patented, that provision would have had to be expressed in the singular so as to correspond with the first paragraph.

182 An interpretation of the transitional period applying it to a particular product patented in a Member State other than Spain or Portugal prior to the obligatory date of patentability would be inconsistent with the general scheme of the Protocols, which demonstrably require Spain and Portugal, respectively, to make chemical and pharmaceutical products patentable only from 7 October 1992 or 1 January 1992, and then only in respect of applications made thereafter. It has been common ground throughout that the products in question in these cases can never obtain patent protection in Spain or Portugal even after these Member States have complied with their Treaty obligations to introduce patentability. This is, indeed, the starting point for the

attack on the decision in Merck v Stephar, raised in the third question. That exercise would be unnecessary if Merck and Beecham enjoyed indefinite protection by virtue of the transitional provisions. The Member States could not have had it in contemplation that the date on which Spain or Portugal might take additional voluntary steps to allow the patenting of these products would become the date from which the transitional period for these products would run. Special Spanish or Portuguese patents for pharmaceuticals starting after 7 October 1992 or 1 January 1992 would run counter to internationally accepted concepts of novelty (191) and would produce different expiry dates for the same product patent in different countries, raising the ultimate absurd possibility of later obstacles to parallel imports into Spain and Portugal upon expiry elsewhere of patents for the same products. A corollary would be the further inconvenience of different dates being read into Articles 47(2) and 209(2) for pharmaceutical products generally and for those, like the plaintiffs' products, which in reality will never be patentable in Spain but which, theoretically, might become so.

183 Furthermore, it must constantly be recalled that the transitional provisions permit a derogation from the principle of freedom of movement of goods, made effective in Spain and Portugal, by Articles 42 and 202, from 1 January 1986. The provisions of Article 30 of the EC Treaty are thus extended to trade between Spain and Portugal, on the one hand, and the rest of the Community, on the other. Article 30 is, of course, qualified by Article 36 of the EC Treaty in the restrictive manner described in the consistent case-law of the Court. (192) The introductory words to Articles 47 and 209 - `notwithstanding Article 42 (202)' - introduce an additional derogation by permitting the holder of a patent in a Member State to prohibit the import of the patented product from Spain or Portugal for a prescribed period. (193) Such derogations in an Act of Accession will, as the Court stated in Commission v Greece, be interpreted `so as to facilitate the achievement of the objectives of the Treaty and the application of all its rules'. (194) The Court continued: `In particular, with regard to the abolition of quantitative restrictions and measures having equivalent effect, the provisions of the Act of Accession in this area cannot be interpreted without reference to the provisions of the Treaty relating thereto.' The purpose of Articles 47 and 209 in particular is `to derogate in a limited area from the Community rules governing the free movement of goods and not to create new rights exceeding the protection conferred on the patent by national law'. (195) They should not be interpreted more widely than their plain terms justify. The interpretation proposed by Merck and Beecham would have the effect of extending indefinitely (subject only to expiry of the patent held in another Member State) the effect of the transitional period for products which could not, in all probability, ever be patented in Spain or Portugal. If such a result had been intended, it would have been a simple matter to provide for it in the transitional provisions. Protection could have been extended for the life of any patent granted in another Member State prior to 7 October 1992 in the case of Spain and 1 January 1992 in the case of Portugal. For these reasons, I reject the argument of Merck and Beecham that the expression `these products' includes products other than those which Spain and Portugal were obliged to make patentable by that date. Accordingly, I rule out Option (e) listed under Questions (1) and (2).

184 Next, I will review the argument, linked to alternatives (c) and (d) under the first question, for priority based on the Paris Convention. (196) The point is raised only in respect of Spain, although both Spain and Portugal are signatories of the Paris Convention. By filing a patent application in a country to which the Paris Convention applies, the applicant enjoys for the purpose of filing in any other Contracting State (which I will refer to as a `second country') a right of priority in respect of that patent for a period of 12 months from the date of the first filing. (197) In order to derive full benefit from this priority, he must thereafter file applications in any second country in which he wishes to protect his invention before the priority expires. The novelty of the invention, an essential condition of patentability, is determined at the date of first filing. In so applying, he defeats any challenge in any second country to the novelty of his invention based on prior publication. Merck claims that Paris Convention priority has existed since the turn of the century and is recognized in all Member States where patenting of pharmaceutical products is allowed. Both Merck and Beecham implicitly treat this priority as an essential element in the patentability of a product. Beecham complains that in Spain, unlike in other Convention countries, it was not possible to claim priority in respect of any application filed in the 12 months prior to 7 October 1992. To establish this, reliance is placed on a decision of the Spanish Council of State of 18 February 1993 which recognizes priority only in respect of applications filed in other Paris Convention countries after 7 October 1992. In other words, Spanish law does not recognize an application in another country for priority purposes unless on the same date a valid application could have been made in Spain for a corresponding product patent. At the same time priority applications filed in other Paris Convention countries in the 12 months before that date deprive the invention of novelty for the purpose of later applications in Spain. Merck and Beecham conclude that Spain did not, therefore, provide for full patentability of pharmaceuticals until 7 October 1993, from which date, therefore, the transitional period should be calculated. Spain, to paraphrase the argument, has not made pharmaceutical products fully patentable if it does not, at the same time, provide recognition in Spanish law of the priority given by the Paris Convention to applications filed in other Paris Convention countries up to one year prior to that date.

185 Whether or not Paris Convention priority is an essential feature of patentability, this summary of the situation in Spanish law cannot be accepted without qualification. In the period between 7 October 1992

and 7 October 1993, such priority took effect gradually, e.g. priority would be accorded to a prior application filed in, say, France on 10 October 1992 for the purposes of a Spanish application on 1 October 1993. The argument must be assessed, therefore, in view of the fact that Paris Convention priority was available progressively in Spain but only became available for a full 12 months on 7 October 1993.

186 The argument requires consideration of three international agreements, to wit the Act of Accession, the EPC and, now, the Paris Convention. The Court has jurisdiction to interpret the first but not the other two. However, the Merck and Beecham claim that, without Paris Convention priority, Spain has not made pharmaceutical products patentable until 7 October 1993 seems to imply a reading of its terms into the Act of Accession.

187 There is a further preliminary problem. Merck and Beecham proceed essentially from the opinion of the Spanish Council of State, to conclude that Spain had not made pharmaceuticals fully patentable on 7 October 1992. I cannot see that this automatically follows. Firstly, it appears from evidence submitted by Primecrown that the opinion of the Council of State is not binding and that there are still conflicting views about this matter in Spain which can be resolved by the Spanish courts. It is obvious that I can express no opinion about this. Secondly, and more importantly, it is clear that Spain provided for the patenting of pharmaceutical products from 7 October 1992. Some or many applications for patents for such products may have encountered problems because of lack of priority for earlier applications in other countries and consequent loss of novelty. Clearly, none of the products involved in the present case are affected in that way. If any particular applicant were so affected, he could bring his claim for recognition of Paris Convention priority before the Spanish Courts and, ultimately, seek to have the matter referred to this Court for interpretation. What does not appear to me to follow is that the end of the transitional period should be generally postponed for a year because of the opinion of the Council of State.

188 I should also consider, however, whether the point is meritorious. Was Spain bound, by the Act of Accession, to accord priority to Paris Convention applications? Article 4 of the Paris Convention provides, so far as relevant, as follows:

`A - (1) Any person who has duly filed an application for a patent, ... in one of the countries of the Union, ... shall enjoy, for the purpose of filing in the other countries, a right of priority during the periods hereinafter fixed.

(2) Any filing that is equivalent to a regular national filing under the domestic legislation of any country of the Union or under bilateral or multilateral treaties concluded between countries of the Union shall be recognised as giving rise to the right of priority.

(3) By a regular national filing is meant any filing that is adequate to establish the date on which the application was filed in the country concerned, whatever may be the subsequent fate of the application.

B - Consequently, any subsequent filing in any of the other countries of the Union before the expiration of the periods referred to above shall not be invalidated by reason of any acts accomplished in the interval, in particular, another filing, the publication or exploitation of the invention, the putting on sale of copies of the design, or the use of the mark, and such acts cannot give rise to any third-party right or any right of personal possession.

C - (1) The periods of priority ... shall be twelve months for patents ... .

(2) The periods shall start from the date of filing of the first application.'

189 Based on the presumed incorporation by reference of Article 4 of the Paris Convention into the Act of Accession and because its terms cannot be ignored if the argument of Merck and Beecham is to be considered, I will consider whether Spain was bound to accord the right of priority to applications filed in other Paris Convention countries prior to 7 October 1992. The core of the provision emerges from the combined reading of Article 4(A)(1) and (B). The `right of priority' must be recognized during the period of 12 months, which starts `from the date of filing of the first application' (Article 4(c)(2)). Spain could not have operated this provision prior to 7 October 1992 in respect of any second country application for a product patent for pharmaceutical products; for example, if the Spanish second country application had been filed on 1 October 1992, it could not, in Spanish law, have recognized the right of priority for any first application made after 7 October 1991. In order to survive, the Merck and Beecham argument has again to be modified to say that the right of priority should be accorded in the event that the Spanish second country application had been filed both within the period of priority but after 7 October 1992. In reality, the argument does not accord with the clear implication of Article 4. That article does not envisage a transitional application of the right of priority. It is expressed in terms which imply that a similar application can be filed in any second country at any date after the first and, consequently, that similar patent products are contemporaneously recognized in both countries.

190 It seems to me, however, that it is more relevant to quote the priority provisions of the EPC, which substantially replicate those provisions. Article 87 provides, so far as relevant, as follows:

`(1) A person who has duly filed in or for any State party to the Paris Convention for the Protection of Industrial Property, an application for a patent ... shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of twelve months from the date of filing of the first application.

(2) Every filing that is equivalent to a regular national filing under the national law of the State where it was made or under bilateral or multilateral agreements, including this Convention, shall be recognised as giving rise to a right of priority.

(3) By a regular national filing is meant any filing that is sufficient to establish the date on which the application was filed, whatever may be the outcome of the application.'
This provision has to be read in the light of the effect of Article 167(5) of the EPC on Spain's reservation in respect of chemical and pharmaceutical products. The reservation applies to European patent applications filed during the period of the reservation and for the term of the patent. In other words, in the context where Paris Convention priority is dealt with by the EPC its application is effectively excluded for present purposes.
191 Nothing in Protocol No 8 - Patents concerning Spain - appears to me to make recognition of priority applications for a year before 7 October 1992 an essential feature of Spain's obligations. A clear and express indication would have been required. We are concerned, after all, with transitional provisions and it is not surprising to find additional indications of gradualness, such as the fact that priority recognition was day by day becoming effective in Spain between 7 October 1992 and 7 October 1993. Ultimately, however, I am most struck by the fact that Merck and Beecham are seeking to add one year to the transitional period allowed by Article 47(2). To succeed in doing that, they have to show that Spain did not make pharmaceutical products patentable on 7 October 1992, and, in plain language, they have not done so.
192 In short, Spain made pharmaceutical products patentable from 7 October 1992 and not from any later date. This conclusion eliminates two more of the five possible dates, namely those at Options (c) and (d) proposed by the first question.
193 A separate point, linked to Options (c) and (d), arises by reference to the Portuguese situation. (198) Merck claims that pharmaceutical products could not effectively be patented in Portugal before 1 June 1995. It says that it was only on that date that the Portuguese Decree-Law No 42/92 of 31 March 1992 provided fully for the enactment of a new Industrial Property Code permitting the grant of patents for those products. For this reason, Merck contends that the transitional period for Portugal, under Article 209 of the Act of Accession, will not terminate either until 1 June 1998 or until 31 December 1998, i.e. at the end of the third calendar year following the year in which Portugal made those products patentable.
194 I agree that, by reason of the provisions of the Decree-Law, it was not possible, by an application made in Portugal, to obtain such a patent prior to 1 June 1995. However, Portugal complied with its obligation to accede to the EPC on 1 January 1992. The EPC entered into force in Portugal on 1 January 1992 as a result of an instrument of ratification lodged by the Portuguese Government on 14 October 1991. (199) By virtue of Article 8(2) of the Portuguese Constitution, that Treaty had binding effect in Portuguese law so as to override the provisions of the prior Industrial Property Code. Merck accepts that it was possible by means of an application at the European Patent Office to obtain a patent effective in Portugal for pharmaceutical products from 1 January 1992. That, in my view, is decisive. I agree with the national judge that Portugal was not bound even to have a patent office of its own under the Act of Accession. The commencement date, therefore, for the patentability of pharmaceutical products in Portugal was 1 January 1992 which becomes the date of commencement of the transitional period specified in Article 209 of the Act of Accession, thereby eliminating Options (c) and (d) from Question (2).
195 The final choice between Options (a) and (b) turns on the meaning to be attributed to `the end of the third year after Spain [Portugal] has made these products patentable' (emphasis added), i.e. after 7 October 1992 or 1 January 1992 respectively, since those are the dates, on my analysis, when Spain and Portugal made these products patentable. The national judge thought the choice of the anniversary date to be almost beyond argument. Nevertheless, four of the five Member State Governments who have made observations on this question disagreed and supported Merck and Beecham in opting for 31 December 1995.
196 Textual points can be made in favour of both dates. If the anniversary date was intended, it might have been simpler to say: `may be invoked ... for three years after Spain [Portugal]...' or until 7 October 1995 [1 January 1995]. This could be criticized for failure expressly to exclude later reliance upon the provision. To exclude such a reading, some limiting words such as `and not thereafter' might have been inserted. The expression `until the end of the third year ...' lays proper emphasis on the termination of the period. The only real textual support for the calendar-year approach is the use of the word `after' rather than `from'; but `from' could not be substituted without other changes. It would be necessary to add: `the date when', `the time when', or some other phrase defining temporally the Spanish or Portuguese action of rendering pharmaceutical products patentable. In my view, looking at what is meant here, the most natural reading is that the transitional period was for three years after 7 October 1992 or 1 January 1992, ending thus on the anniversary date, 7 October 1995 or 1 January 1995. The calendar-year approach would have required some explicit wording, such as `the end of the third year after the year in which ...' (emphasis added). There is a final important point. I treat the dates of patentability looked at from the date of the Act of Accession, as predictable future dates. The calendar-year approach would produce a transitional period of about three years and three months for Spain, but four years (less one day) for Portugal. No basis has been suggested for such a large discrepancy.
197 In support of 31 December 1995 as the date for the end of the transitional period, both Merck and Beecham rely upon the many provisions found in the Act of Accession providing for the termination of transitional measures or periods at the end of a calendar year. Merck have gone so far as to produce a lengthy schedule to demonstrate that, as they state, `all transitional measures contained in Spain's Act of Accession expire at the end of a calendar year.' It is true that there are very few exceptions to this assertion, which certainly

applies, for example, to the phased abolition of customs duties on imports (Article 31), the introduction of the common customs tariff (Article 37) and the elimination of quantitative restrictions (Article 43). I do not think, however, that any such general rule of interpretation as is implied by this submission emerges. On the whole adjustments in the agricultural sector are made by reference to `marketing years' or in one case the `wine growing year'. (200) Protocol Nos 8 and 19 contain the detailed provisions on Spanish and Portuguese patents and provide for a series of derogations from the overriding obligation. The period of the derogation runs to 7 October 1992 or 1 January 1992 and thus not necessarily to the end of any calendar year. This argument does not, therefore, lead to any particular conclusion as to the meaning of `end of the third year' in Article 47(2) or 209(2). Portuguese accession to the EPC, on the other hand, was to take place on 1 January 1992, which does coincide with the start of a calendar year. It is obvious that the three years should run to 1 January 1995. To add a further year, as Merck and Beecham claim, merely because the date is the first day of the year rather than the last day of the preceding year leads to an absurdity. They effectively seek to prolong the transitional period by a full year.

198 Merck bases a very similar argument upon the terms of Article 379 of the Act of Accession. (201) The principal provision of that Article permits a Member State to apply for authorization to take protective measures in order to rectify difficulties arising before 31 December 1992 `which are serious and liable to persist in any sector of the economy or which could bring about serious deterioration in the economic situation of a given area'. It is further provided that `this provision shall apply until 31 December 1995 for products or sectors in respect of which this Act allows transitional derogations of equivalent duration'. Merck claims that this demonstrates that the Act of Accession does not contemplate transitional derogations expiring after 31 December 1992 but before 31 December 1995. In my view, this argument carries only very slight weight. There is no internal evidence of any cross-reference between the provisions. It does not persuade me to a view different from that already expressed.

199 Merck also relies on the terms of a draft Protocol of 30 March 1992 modifying the conditions of entry into force of the Luxembourg Agreement of 15 December 1989 relating to Community patents (202) and approved by `Coreper' on 24 March 1992 for submission at the Lisbon conference of 1992 on the European Patent. It refers to the fourth preamble to this agreement which states that the Luxembourg Agreement should apply as regards Spain `as from 1 January 1996, the date on which the free movement of goods will apply fully between Spain and the other EC Member States'. This is also of only the very slightest weight, if it has any. Firstly, the draft Protocol in question postdated the Act of Accession and cannot be an aid to its interpretation. Secondly, as is admitted by Merck, the draft Protocol was not, in the event, adopted.

200 Left with the choice between two dates, 7 October 1995 and 31 December 1995 for Spain and 1 January 1995 and 31 December 1995 for Portugal, for the end of the transitional period, I believe that the text itself offers the clearest answer to the question posed. In my view, for reasons given in paragraph (203) That Convention applies to the calculation of time-limits in civil, commercial and administrative matters including time-limits laid down by law or by a judicial or an administrative authority. (204) Article 4(2) says that `where a time limit is expressed in months or in years the dies ad quem shall be the day of the last month or of the last year whose date corresponds to that of the dies a quo or, when there is no corresponding date, the last day of the last month'. While this Convention was signed by seven States which are now members of the European Community, it has not been signed by the United Kingdom, Spain or Portugal. (205) Secondly, Primecrown refers to the well-established rule in English law that a period of a month or a year following a date expires on the anniversary of that date. (206) Thirdly, it refers to a provision of the Spanish Civil Code to the effect that `if terms are fixed in months or years, then they shall be computed from date to date'. (207) At most, these provisions are helpful indications, all pointing in the same direction, of some accepted national rules and one international rule supporting the interpretation I propose. The decisive consideration must be, however, that, in the event of any doubt or difficulty in interpreting the text, the Court should bear in mind that it is being asked to interpret a provision permitting a significant derogation from the principle of freedom of movement of goods which, apart from being a general principle of Community law, is specifically applied to Spain by Article 42 and to Portugal by Article 202 of the same Act. For these reasons, I recommend that the expiry of the transitional periods referred to by the national court in its first and second questions should be interpreted, respectively, as 7 October 1995 and 1 January 1995.

IX - Conclusion

For the reasons set out above, I recommend that the questions referred to the Court should be answered as follows:

(1) The period referred to in Article 47(2) of the Act concerning the conditions of accession of the Kingdom of Spain and the Portuguese Republic and the adjustments to the Treaties should be deemed to have come to an end on 7 October 1995.

(2) The period referred to in Article 209(2) of the Act concerning the conditions of accession of the Kingdom of Spain and the Portuguese Republic and the adjustments to the Treaties should be deemed to have come to an end on 1 January 1995.

(3) The rules contained in the EC Treaty concerning the free movement of goods, including the provisions of Article 36, should be interpreted as not preventing the proprietor of a patent for a pharmaceutical product who sells that product in one Member State where patent protection exists, and who also markets it in another Member State at a time when that proprietor is unable to obtain such protection for that product, from availing

himself of the right conferred by the law of the first Member State to prevent the marketing in that State of units of the said product imported from the other Member State. This interpretation should have effect only from the date of the Court's judgment in the present cases.

(1) - The words `pharmaceutical' or `medicinal' products are variously used in the Act of Accession (see footnote 3 and accompanying text below), Community legislation and judgments of the Court. For present purposes, I find no reason to distinguish between them and I use them interchangeably; see further the discussion at footnote 61 below.

(2) - Case 187/80 [1981] ECR 2063; hereinafter simply referred to as `Merck v Stephar'.

(3) - OJ 1985 L 302, p. 23.

(4) - These provisions appear in Part Four of the Act of Accession concerning `Transitional Measures' as the first articles in sections entitled `Elimination of quantitative restrictions and measures having equivalent effect'; Section II of Title II for Spain, Section II of Title III for Portugal. In the interests of brevity, where texts are otherwise identical I have placed the Portuguese references in brackets.

(5) - Loc. cit., paragraph 14 and the operative part of the judgment.

(6) - The date of expiry assumed by the applicant Member States for the transitional period contained in Article 47 of the Act of Accession.

(7) - In response to a written request, the Commission supplied the Court by letter of 12 February 1996 with copies of the decisions adopted, which have been published consecutively in the Official Journal; see OJ 1996 L 122, pp. 20 to 26. This decision has since been challenged before the Court of First Instance by a number of pharmaceutical companies; see Case T-60/96 Merck and Others v Commission.

(8) - The Commission believes that they are not experiencing difficulties which are `serious or liable to persist' and that an increase of imports from Spain will not in the long term be so significant as to create such serious economic difficulties.

(9) - Paragraph 2 of Protocol No 8 for Spain; Paragraph 2 of Protocol No 19 for Portugal.

(10) - CH 1995 M No 1712.

(11) - The three plaintiffs are: Merck & Co. Inc., a company duly incorporated under the laws of the State of New Jersey; Merck Sharp & Dohme Limited, a company incorporated under the laws of England; Merck Sharp & Dohme International Services BV, a company incorporated under the laws of the Netherlands (hereinafter sometimes collectively referred to as `the plaintiffs' or `the pharmaceutical companies').

(12) - CH 1995 M No 3239.

(13) - OJ 1992 L 182, p. 1.

(14) - It appears that, at the date of the commencement of the national proceedings, Europharm had imported one consignment of the Spanish product for the purposes of applying for the requisite import licence for a pharmaceutical product from the appropriate national authority.

(15) - Emphasis of the national court. This argument was not repeated by Merck in its written observations but was briefly raised by Beecham; see paragraph 27 below.

(16) - In response to a question put at the hearing, Merck accepted that, after the introduction of the patentability of pharmaceutical products in Spain and Portugal, it would be impossible to obtain patent protection for products already patented in other Member States for want of the essential element of novelty.

(17) - Under Article 8(2) of the Portuguese Constitution international treaties become binding within the Portuguese internal legal order on their ratification by Portugal. Thus, the EPC entered into force in Portugal on 1 January 1992 pursuant to an instrument lodged by the Portuguese Government on 14 October 1991, despite the later adoption on 31 March 1992 of Decree-Law No 42/92.

(18) - It acknowledges Merck's argument that patents could not actually be obtained in the Portuguese Patent Office until a later date.

(19) - The date of 1 June 1998 is based on the expiry of three years from the date when the Portuguese Patent Office could clearly grant patents for pharmaceutical products; 31 December 1998 involves adding the calendar-year argument to the 1 June 1998 argument; the final date is again determined by adding three years to some earlier date.

(20) - Merck observes that there are currently about 100 such States, including Spain and the United Kingdom.

(21) - Recopilación de Doctrina/Año 1993, p. 1435.

(22) - Decree-Law No 16/95 of 24 January 1995, which entered into force on 1 June 1995.

(23) - Primecrown points out, inter alia, that seven Member States (not including Spain and the United Kingdom) have concluded the European Convention on the Calculation of Time-Limits (`the Basle Convention') which provides in its Article 4(2): `Where a time-limit is expressed in months or in years the dies ad quem shall be the day of the last month or of the last year whose date corresponds to that of the dies a quo or, when there is no corresponding date, the last day of the last month'.

(24) - Reference is made in particular to the speech of Lord Diplock in Dodds v Walker [1981] 1 WLR 1027, p. 1029.

(25) - Primecrown cites a number of provisions of international, national and Community law in support of this argument.

(26) - However, Iceland is obliged by Article 3(5) of Protocol No 28 to the EEA Agreement to permit such patentability by 1 January 1997.

(27) - Loc. cit., footnote 13 above.

(28) - COM(90) 101 final - SYN 255, p. 3.

(29) - Italian price controls did not apply to pharmaceuticals sold freely on the private market. In Portugal, Articles 2 and 3 of Decree No 29/90 of 13 January 1990 provide that the prices of pharmaceuticals are fixed annually by the authorities by establishing a reference price, which is the average for that of

comparable pharmaceuticals in Spain, France and Italy. In Spain, prices are imposed by the Ministry of Health under Royal Decree 271/1990 of 23 February 1990 for a minimum period of one year.
(30) - Merck refers, inter alia, to the SPC Regulation and Articles 3(m), 130(1) and 130f(1) of the EC Treaty, introduced by the Treaty on European Union, as supporting the new consensus in favour of fostering increased research in the Community.
(31) - Case 120/78 Rewe v Bundesmonopolverwaltung fuer Branntwein [1979] ECR 649.
(32) - Merck, referring to N. Koch `Article 30 and the Exercise of Industrial Property Rights to Block Imports' (1986) Fordham Corp. L. Inst. 605, p. 619, insists that this is not tantamount to arguing that patent protection must guarantee profits above market prices but, rather, merely a right to exclude third parties from manufacture and sale, which is itself the reward.
(33) - Case 19/84 [1985] ECR 2281.
(34) - Joined Cases 55/80 and 57/80 [1981] ECR 147, p. 178, hereinafter simply referred to as `Musik-Vertrieb Membran'.
(35) - Case 158/86 [1988] 2605, hereinafter simply referred to as `Warner Brothers'.
(36) - Case C-9/93 [1994] ECR I-2789, hereinafter simply referred to as `Ideal-Standard'.
(37) - Merck contends that it has always been committed to this principle. In answer to a question put at the hearing, Merck maintained that it believed itself to be ethically obliged to make all of its pharmaceutical products available all around the world, regardless of the prevailing prices and, thus, profitability of such action.
(38) - Case 15/74 [1974] ECR 1147.
(39) - At the hearing, Beecham claimed that, as the cost of research is met from current cash flow, the availability of cheaper parallel imports of pharmaceutical products in Member States where patent protection exists undermines profits on those markets and, thus, also ongoing research.
(40) - Beecham refers to Articles 3(m) and (o) and to Articles 130 and 129 of the Treaty.
(41) - Beecham refers to the Resolution of the European Parliament of 29 June 1995; OJ 1995 L 183, p. 26.
(42) - Primecrown notes that this fact was relied upon at the time by the Government of the United Kingdom and referred to in the report for the hearing; see [1981] ECR 2063, p. 2074, right column, middle paragraph.
(43) - Case C-191/90 [1992] ECR I-5335 (hereinafter `Generics').
(44) - The only compulsion, in Primecrown's opinion, flows from the possible grant of a compulsory licence, which is not the same as a positive legal obligation to supply a market.
(45) - Primecrown points out that with Renitec, there are apparently at least 19 generic equivalents of the product available on the Spanish market: regarding Proscar, Primecrown alleges that there are no generic equivalents present on the Spanish market, and thus finds it difficult to see how Merck is suffering from the absence in Spain of patent protection.
(46) - Reference was made to the Commission Decision of 10 January 1996 relating to a proceeding under Article 85 of the EC Treaty, Adalat (Case IV/34.279/F3), as supporting the view that Spanish law imposes no continuing supply obligation on patentees. The decision concerned alleged anti-competitive attempts by Bayer and its French and Spanish subsidiaries to limit wholesale supplies of the product `Adalat' in France and Spain to the actual requirements of those markets. The validity of this decision, which, inter alia, requires Bayer to terminate the alleged infringement of Article 85 of the EC Treaty, has been challenged before the Court of First Instance; see Case T-41/96 Bayer v Commission, while in Case T-41/96 R the applicant sought its interim suspension and, on 3 June 1996, the President of the Court of First Instance ordered the suspension of Article 2 of the decision.
(47) - The National Economic Research Associates (`NERA') Report, submitted by Merck as Annex 5 to its written observations to the Court. According to Primecrown, this report states that `of the 50 most prescribed products in Europe in 1991, only 40 were available in every EU Member State'. Primecrown thus claims that the ethical obligation asserted by Merck is not universally respected by the pharmaceutical industry as a whole.
(48) - At the hearing Primecrown expressly maintained that as virtually all Member States operate some form of price control, pharmaceutical companies should not be allowed to invoke the existence of such regimes to justify the use of national intellectual property rights to restrict parallel trade.
(49) - Case 7/61 Commission v Italy [1961] ECR 317.
(50) - It cites Centrafarm v Sterling Drug, paragraphs 22 to 25 of the judgment and, generally, Musik Vertrieb Membran and Case 78/70 Deutsche Grammophon v Metro [1971] ECR 487, hereinafter simply referred to as `Deutsche Grammophon'.
(51) - Spain was described by Primecrown at the hearing as being the eighth largest national pharmaceutical market in the world.
(52) - The most important barriers are said to be: (i) difficulties in obtaining a steady flow of goods for parallel importation, and periodic interruptions in supply, causing pharmacists to hesitate before using parallel imports; (ii) obstacles created by brand-name differences; (iii) labelling in foreign languages; (iv) reluctance of some pharmacists to dispense such parallel imports unless there is sufficient price incentive; (v) obstacles flowing from dosage differences (of individual tablets); (vi) similar obstacles caused by differences in sizes of packs.
(53) - It speculates that most Spanish parallel imports are likely to be substitutions for existing sources of parallel imports in Italy or France rather than net additions to the market, because prices in Spain are not necessarily very different from price levels in Italy and France.
(54) - Primecrown notes that Article 27(1) provides for all signatory countries to provide patent protection for pharmaceutical products, and that its provisions on pat-

entability and term of protection are modelled on the provisions of the EPC. A transitional period of ten years for product patents is provided in favour of developing countries under Article 65(4). For an overview of TRIPS see, for example, Demaret, `The Metamorphoses of the GATT: From the Havana Charter to the World Trade Organization' (1995) 34 Columbia Journal of Transnational Law 123, pp. 162 to 169.

(55) - Citing, in particular, Marenco and Banks, `Intellectual Property and Community Rules on Free Movement: Discrimination Unearthed' (1990) 15 E.L. Rev., 247, the Commission enumerates four principal criticisms: (i) the rule deprives the patentee of the opportunity to obtain a full reward for his creative effort; (ii) the rule rests on the fallacious idea that a right can be exhausted where, in fact, it does not exist; (iii) it involves a misplaced notion of consent, namely consent to marketing rather than consent to the exercise of an intellectual property right; (iv) it paradoxically distinguishes between the effects of a decision of an undertaking which enjoys patent protection in a Member State not to market there but where a compulsory licence is issued by the State, from that of the same undertaking which cannot obtain patent protection and may be forced to sell into that market at a price fixed by the State. At the hearing, however, the Commission's agent refused to accept that any of these criticisms would justify renouncing Merck v Stephar.

(56) - They were: (i) that it was inherent in the ratio decidendi of Merck v Stephar; (ii) that it would be consistent with the evolution of recent case-law, particularly the decision in Pharmon v Hoechst; (iii) that it would tend to maintain the patent proprietor's right to obtain a full reward for its creative effort while simultaneously respecting the essence of the exhaustion of rights principle.

(57) - In its written observations, the Commission had submitted that while the existence of an ethical obligation is for the national court to determine, it would, nevertheless, suggest that such an obligation would exist where public health considerations in a Member State create a demand for a particular pharmaceutical product and where, for reasons relating solely to a perceived need to protect its position against parallel imports into another Member State, the proprietor of a patent would find it difficult to refuse to meet that demand.

(58) - The Commission accepts that it is unclear whether the plaintiffs in the main proceedings would actually be in a dominant position on the markets in question and, furthermore, whether their potential refusal to supply the market could be characterized as an abuse according to Article 86.

(59) - It should be noted that the Commission submits that the Merck v Stephar rule should continue to apply to cases where the product was patentable but, for whatever reason, the patentee did not actually obtain patent protection.

(60) - The Commission pointed out that Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (hereinafter the `Transparency Directive'); OJ 1989 L 40, p. 8, whose object is principally `to obtain an overall view of national pricing arrangements' (see recital 5), is not a harmonization measure.

(61) - As stated in footnote 1 above, I use interchangeably the terms `pharmaceutical' or `medicinal products/preparations'. Both the Court and Advocates General have in the three previous most relevant cases also used other terms including `medicaments' and `drugs' while some of the observations submitted in this case refer to `pharmaceuticals'. These terms can all be understood as referring to proprietary medicinal products for human use which essentially were the subject of the Parke, Davis v Centrafarm (Case 24/67 [1968] ECR 55, hereinafter simply referred to as `Parke, Davis'), Centrafarm v Sterling Drug and Merck v Stephar cases and are again at issue in the present cases. The words `proprietary medicinal product' are borrowed from Council Directive 65/65/EEC of 26 January 1965 (hereinafter `the 1965 Directive') on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, OJ, English Special Edition 1965-1966 (I), p. 20. The term `patentee' is used for convenience to describe the person who is entitled to the benefit of a patent right, whether as the proprietor of the patent, his assignee or licensee.

(62) - COM(93) 718 final.

(63) - Ibid., first paragraph on p. 5. In its resolution in response to the Commission communication, the European Parliament stated that it `expects' the development by the Commission of guidelines for `a realistic industrial policy' that will `direct European research more towards real innovation' through, inter alia, `protecting new medicinal products by intellectual property rights both in the EU and in third countries' (point 10); adopted at the plenary session of 16 April 1996, to date not yet published in the Official Journal. See also generally the Economic and Social Committee's Opinion on the `Free Movement of Medicines in the European Union - Abolition of Existing Barriers', OJ 1996 C 97, p. 1.

(64) - Acetylene Illuminating Company Ltd v United Alkali Co. Ltd [1905] RPC 145 and 153, House of Lords. This judgment would, at the time, also have been applicable in Ireland and would have remained a persuasive authority after independence in 1922.

(65) - Federal German Patent Law of 9 May 1961, Section 1(1)(2) as amended by the Law on the Amendment of the Patent Law, Trademark and other Laws of 4 September 1967, Bundesgesetzblatt I, No 56, p. 953.

(66) - Order of the Ministry of Industry No 450 of 16 December 1983.

(67) - Article 1(3) of Resolution 1043 of 13 October 1989.

(68) - See Articles 1 and 2 of Decree 932/1987, a decree concerning the granting of patents to nutritive and medicinal substances.

(69) - Royal Decree of 29 June 1939, No 1127.
(70) - For a full discussion, see Merck v Stephar, pp. 2065 to 2067.
(71) - European Intellectual Property Review Supplement, Volume 16, Issue 11, November 1994. Article 27(1) provides that `Patents shall be available for any inventions, whether products or processes in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application'. While it is arguable that Merck v Stephar is inconsistent with this provision, this issue is not raised by the questions referred. It should be noted that on 22 December 1994, the Council adopted Decision 94/800/EC concerning the conclusion on behalf of the European Community, as regards matters falling within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994); OJ 1994 L 336, p. 1. In Opinion 1/94 [1994] ECR I-5267 the Court declared that the Community and its Member States were jointly competent to conclude TRIPS.
(72) - The 1994 Report, loc. cit., footnote 62 above, p. 14.
(73) - These concerns are equally reflected in Council Regulation (EEC) No 2309/93 of 22 July 1993 (`the 1993 Regulation') laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products; OJ 1993 L 214, p. 1.
(74) - Loc. cit., footnote 61 above.
(75) - OJ 1987 L 15, p. 36.
(76) - See Article 1 at point 8(a)(iii) as introduced into the 1965 Directive.
(77) - COM(90) 101 final - SYN 255.
(78) - Ibid., paragraph 1.
(79) - See paragraph 5 of the memorandum.
(80) - Loc. cit., footnote 13 above.
(81) - See, for example, Joined Cases C-241/91 P and C-242/92 P RTE and ITP v Commission (hereinafter `Magill') [1995] ECR I-743.
(82) - See the Opinion of Advocate General Jacobs in Case C-10/89 HAG GF (hereinafter simply referred to as `HAG II') [1990] ECR I-3711, paragraph 10 of the Opinion.
(83) - Ibid., paragraph 9 of the Opinion.
(84) - The Court appears to have used these terms interchangeably in its case-law but, henceforth, the expression `specific subject-matter' will be used in this Opinion.
(85) - 12th ed. (London, 1980), p. 1016.
(86) - The same principle applies mutatis mutandis for patents. Thus, for example, in Ireland Section 40 of the Patents Act 1992 provides that `[A] patent while it is in force shall confer on its proprietor the right to prevent all third parties not having his consent from doing in the State all or any of ...' a number of things which constitute the essential protection of the patent. See also the references to the words `in the United Kingdom' concerning infringement actions brought before courts in that Member State under Section 60 of the Patents Act 1977.
(87) - Machlup, `An Economic Review of the Patent System', Study of the Committee on Patents, Trademarks and Copyrights of the Committee of the Judiciary, US Senate, 85th Congress, Study No 15 (Washington), p. 21. See the interesting examination of this and other formulations of the policy justification underlying patent systems by the late René Joliet, Professor and Judge of the Court (hereinafter `Professor Joliet'), in `Patented Articles and the Free Movement of Goods within the EEC' 28 Current Legal Problems (1975) 15, pp. 30 to 32.
(88) - In answer to a question put at the hearing, there was general agreement that the patent monopoly enjoyed in national law applies to the first sale of each individual batch or unit of the patented product produced by or with the consent of the patentee.
(89) - See the extensive study carried out by Demaret in Patents, Territorial Restrictions and EEC Law, IIC Studies in Industrial Property and Copyright Law, Vol. 2 (Munich, 1978), Ch. 3.
(90) - Such restrictions must be explicit: `When a man has purchased an article he expects to have control of it, and there must be some clear and explicit agreement to the contrary to justify the vendor in saying that he has not given the purchaser his licence to sell the article, or to use it wherever he pleases as against himself'; see the speech of Lord Hatherley in Betts v Willmott (1871) LR 6 Ch App, 239, p. 245. This principle was approved in Irish law by the judgment of the Supreme Court in Hunter v Fox [1965] RPC 416. The law of the United Kingdom and Ireland assumes that where a patentee markets patented products abroad, it cannot oppose the subsequent importation of those products into the United Kingdom or Ireland, unless a clear and express embargo on their import is imposed at the time of sale: `Thus, the English common law did not (contrary to the position in other countries) recognize a doctrine of automatic and obligatory exhaustion of rights upon sale of a patented article by a patentee or with his consent ...', Chartered Institute of Patent Agents, C.I.P.A. Guide to the Patent Acts, 4th ed. (London, 1995), p. 420.
(91) - See Demaret, loc. cit., footnote 89 above, and Alexander, `L'établissement du Marché commun et le problème des brevets parallèles' (1968) RTDE 513, pp. 516 to 521. In the law of the United Kingdom (and Ireland), a more restrictive view is taken of sales by a licensee under a foreign patent than of domestic sales, whereby the goods cannot enter the United Kingdom (or Ireland) unless there is a licence (express or implied) from the holder of the United Kingdom (or Irish) patent; see Cornish, Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights (London 1981), p. 199, who refers, inter alia, to Mr Justice Rudd's statement in Beecham v International Products [1968] RPC 129: `In the case of a sale by a licensee the matter must depend on the extent of the authority conferred on the licensee by the licensor under the licence or other agreements between them'; p. 135.
(92) - Loc. cit., cited in the issues of law and of fact, [1968] ECR 55, p. 67.

(93) - Although Centrafarm alleged at the hearing that an Italian company was manufacturing the product under licence from Parke, Davis.
(94) - Grounds of judgment, paragraphs 4 and 5.
(95) - See Professor Joliet, op. cit., footnote 87 above, p. 18. Deutsche Grammophon (`DG') produced phonographic recordings which it distributed under, inter alia, the Polydor trade mark in Germany and, through a subsidiary, in France. German retailers were required to sign an undertaking regarding minimum resale prices in order to obtain supplies. Supplies were discontinued to the defendant Metro for a breach of this obligation. Metro succeeded in obtaining records in Germany which had originally been supplied by DG to its French subsidiary. The records at issue in this case were actually sold by the French subsidiary to an undertaking in a third country, which subsequently supplied them to the undertaking in Hamburg from which Metro then acquired them. DG sought an injunction in the German courts prohibiting Metro from reselling or otherwise distributing the relevant records in Germany.
(96) - Deutsche Grammophon, paragraph 4 of the judgment.
(97) - Ibid., paragraph 11 of the judgment.
(98) - I agree with those who question the logical basis of the distinction: in particular I agree that `a right cannot consist of more than the ways in which it can be exercised'; see, for example, initially Korah, `Dividing the Common Market through national Industrial Property Rights' (1972) MLR 634, p. 636 and more recently the criticisms of Marenco and Banks, op. cit., footnote 55 above, pp. 224 to 226. I endorse the view expressed by Advocate General Gulmann in `Magill', loc. cit., footnote 81 above, that `an exercise of rights that falls within the specific subject-matter of an intellectual property right will relate to its existence. In other words the distinction between the existence and the exercise of rights and the application of the concept of the specific subject-matter are basically expressions of the same conceptual approach [and that] the distinction between the existence and exercise of rights has no independent significance for resolving specific questions of delimitation'; paragraph 31 of the Opinion. See also, for example, the Irish High Court judgment of Mr Justice Kenny in Central Dublin Development Association v Attorney General (1975) 109 ILTR 69, defining the ownership of property as `a bundle of rights'.
(99) - Advocate General Roemer in his Opinion in Deutsche Grammophon considered the distinction between copyright and patents to be `irrelevant'; [1971] ECR 487, p. 508. He stated that `copyright is certainly more closely related to a patent right than to a trade mark right'. Professor Joliet (op. cit., footnote 87 above, p. 20), referring to the legislative history of the German law which introduced the disputed right, points out that it was granted because of the quality of the technical service and in view of the considerable economic expenditure required to produce sound recordings suitable for marketing and that `this function made the monopoly at issue quite similar to a patent'.
(100) - Loc. cit., paragraph 12 of the judgment.
(101) - Advocate General Roemer, in his Opinion, referred to the exhaustion of rights in circumstances such as those of Deutsche Grammophon: `Here it should be decisive that the objective of the industrial property was attained when the goods were first placed on the market, since it was possible to use the monopolistic opportunity for gain. On the other hand, it would undoubtedly go beyond the objective of that right if the holder was permitted to control further marketing, in particular re-importation, and the free movement of goods was impeded. Thus in view of the reservation contained in Article 36, the fundamental aims of the Treaty and the principles of the common market, and in spite of the guarantee of the subsistence of industrial property rights, in a situation such as that in the present case it may be held that the right has been exhausted ... '; [1971] ECR 487, p. 508. It was thus clear even from this case that the version of the exhaustion doctrine which Community law was in the process of adopting bore essentially only a nominal resemblance to the Dutch and German laws which largely inspired it.
(102) - Ibid., paragraph 8 of the judgment.
(103) - `The real essence of the protection conferred on the patent owner is the exclusive right to manufacture and market the patented product, given to compensate him as the inventor of a process and bring him a financial reward for his efforts and the commercial risks he runs, and it is recognized on a purely temporary basis ...'; paragraph 4 of his Opinion.
(104) - Paragraph 9 of the judgment.
(105) - See paragraphs 10 and 11 of the judgment.
(106) - Paragraph 11 of the judgment.
(107) - Paragraph 12 of the judgment. Advocate General Trabucchi was equally emphatic: `It is certainly not compatible with the basic principle of the Community system governing the circulation of goods for a company, which is the owner of a patent in force in more than one State of the Community and, through a company wholly under its control, joins in putting the said product on sale in a Member State, to block its importation by third-party purchasers into another Member State for the purpose of ensuring a commercial monopoly there for another of its subsidiary companies'; paragraph 5 of his Opinion.
(108) - This was the principal criticism of the Centrafarm v Sterling Drug judgment made by Professor Joliet, op. cit., footnote 87 above, p. 37, when he stated: `to say that the product has been manufactured by the patentee is irrelevant if someone else could have manufactured it as well. The test of whether the manufacturing took place with the consent of the patentee implies in my view, that the patentee could control it, i.e. that he enjoyed a parallel patent in the exporting country. Needless to say that consideration of the patent function also justifies a restriction on imports in such a situation'. Demaret also accepted this view of the judgment by stating that, in the case of marketing in a country of origin by a patentee or with his consent but without patent protection, it was unlikely, following Centrafarm v Sterling Drug, that the Court would permit an import restriction; see `Le brevet

communautaire après Centrafarm: un instrument dépassé ou inachevé?' (1977) RTDE 1, p. 33.
(109) - He correctly acknowledged that this consideration was not treated as relevant by the Court in Deutsche Grammophon; see paragraph 98 above.
(110) - Opinion, p. 2088.
(111) - Ibid., p. 2090 (emphasis in original).
(112) - Ibid., p. 2091.
(113) - Loc. cit., paragraphs 9 and 10 of the judgment.
(114) - Ibid., paragraph 11 of the judgment.
(115) - Paragraph 11 of the judgment.
(116) - Case 192/73 [1974] ECR 731, hereinafter referred to simply as `HAG I'.
(117) - In earlier case-law, for example, Parke, Davis, loc. cit., the Court referred to the fact that: `The national rules relating to the protection of industrial property have not yet been unified within the Community ... '; paragraph 4 of the grounds of judgment.
(118) - The Court has always accepted that national industrial property rights are not exhausted by exploitation outside the Community; see, initially, Case 51/75 EMI Records v CBS [1976] ECR 811, which concerned trade marks, but repeated in the context of the Act of Accession and patents in Generics, loc. cit., footnote 43 above. Some national courts have taken the view that the importation of patented products from a third country via another Member State will not exhaust the patentee's national patent right in the Member State of destination; see, for example, the cases cited by Tritton, Intellectual Property in Europe (London, 1996), who notes that the Hanseatisches Oberlandesgericht, Hamburg in its judgment in Re Patented Bandages Material [1988] 2 CMLR 359 `held that the patentee has not exhausted its rights where the patentee does not enjoy a parallel patent in the intermediate Member State'; p. 317.
(119) - Koch, loc. cit., footnote 32 above, describes the lack of discrimination succinctly: `The conditions of marketing in the two Member States concerned are not comparable, and the exercise of the patent does not discriminate against the foreign as compared to the domestic placing on the market'; p. 620.
(120) - Many commentators have criticized the option contained in paragraph 11 of Merck v Stephar; see, for example, Korah, EC Competition Law and Practice, 3rd ed. (London 1994), p. 193, who states that `[T]o discourage the patentee from selling in countries where it can obtain no protection may in theory lead to the products being sold only where they are protected by patent, and this might divide the market even more seriously than does differential pricing', and Marenco and Banks who remark that `[I]t is indeed ironical that provisions aimed at promoting market freedom should be interpreted in such a way as to penalise the exercise of such freedom'; loc. cit., footnote 55 above.
(121) - The plaintiffs have never claimed that they are not profiting from marketing the relevant products on the Spanish and Portuguese markets: I do not believe, however, that this fact eliminates the large difference in principle between sale with and without the benefit of patent protection.
(122) - Article 129(1) of the Treaty.
(123) - See Centrafarm v Sterling Drug, paragraph 9 of the judgment, quoted at paragraph 95 of this Opinion.
(124) - See paragraphs 9 and 10 of the judgment.
(125) - At the time of the Court's judgment in Merck v Stephar, the patentability of pharmaceuticals in Europe was the exception rather than the rule as, apart from Spain and Portugal, Austria, Denmark, Finland, Greece and Italy have only recognized such patentability within the last 15 years; see paragraph 79 above.
(126) - Loc. cit., p. 2095.
(127) - While this statement is certainly correct, the right of a patentee resides in the opportunity of making the monopoly profit, which is clearly evidenced by the determination exhibited by patentees in the defence of this opportunity.
(128) - Korah, op. cit., footnote 120 above.
(129) - Paragraph 1 of Protocol No 8 and of Protocol No 19.
(130) - Musik-Vertrieb Membran, paragraphs 25 and 26 of the judgment.
(131) - Opinion, p. 180. He did not simply propose that GEMA could claim `crudely ... the difference between the United Kingdom statutory rate of 6.25% and a royalty calculated according to its own scales'. Classifying GEMA's royalty scales as `irrelevant' he recommended that the extent of the restriction would be `the difference between the royalty actually paid in the United Kingdom ... and the royalty that could have been negotiated in the absence of Section 8 and on the footing that records in respect of which that royalty had been paid could be freely marketed anywhere in the Community'; Opinion, p. 179.
(132) - Similar views have been expressed by various academic commentators: see, for example, Marenco and Banks, op. cit., footnote 55 above, pp. 246 to 248; Demaret, `Industrial Property Rights, Compulsory Licences and the Free movement of Goods under Community Law' (1987) 18 IIC 161, p. 176; White, case note on Pharmon v Hoechst 23 CMLR 721, pp. 722 and 723; Gotzen, `La libre circulation des produits couverts par un droit de propriété intellectuelle dans la jurisprudence de la Cour de Justice', Revue trimestrielle de droit commercial et de droit économique 1985, p. 467, at p. 471.
(133) - Loc. cit., Opinion, p. 2285, original emphasis.
(134) - Paragraphs 25 and 26 of the judgment.
(135) - Paragraph 29 of the judgment.
(136) - See Gormley, (1985) 10 E.L. Rev., 447, p. 449.
(137) - Pharmon v Hoechst, paragraph 26 of the judgment (emphasis added).
(138) - `Industrial Property Rights, Compulsory Licences and the Free Movement of Goods under Community Law' (1987) Vol. 18 IIC No. 2 161, at p. 175.
(139) - It is interesting to note that even strident academic supporters of Merck v Stephar were not convinced that the effects of Pharmon v Hoechst were compatible with the logic underlying Merck v Stephar; see, for example, the strong approval of Merck v Stephar articulated by Bonet, Revue trimestrielle de

droit européen 1982, pp. 161 to 166 and contrast that approbation with his critical comments on Pharmon v Hoechst, Revue trimestrielle de droit européen 1986, pp. 281 to 286.
(140) - See Demaret, `Industrial Property Rights, Compulsory Licences and the Free Movement of Goods under Community Law', op. cit., footnote 138 above, p. 177.
(141) - Report for the Hearing, p. 2611, paragraph 25 is quoted at paragraph 118 above.
(142) - Ibid., p. 2611.
(143) - Loc. cit., p. 2623.
(144) - Loc. cit., Opinion, p. 2623.
(145) - Ibid., paragraphs 15 and 16 of the judgment, emphasis added.
(146) - Paragraph 18 of the judgment, emphasis added.
(147) - See the economic rationale underlying paragraphs 15, 16 and 18 of the judgment, quoted above at paragraph 132, and, in particular, the emphasis which I have added to those paragraphs.
(148) - Profits on the British market were probably greater than on similar sales in Denmark. However, in response to a question from the Court, the Government of the United Kingdom produced no figures to substantiate the extent of the `copyright component', stated to be more than 25% of the `trade' price (see Warner Brothers, Report for the Hearing, p. 2616) in sales of video-cassettes in the United Kingdom.
(149) - `Geistiges Eigentum und freier Warenverkehr' (1989) GRUR Int. 177, p. 179, paraphrased English translation cited in Marenco and Banks, loc. cit., footnote 55 above, p. 250; see also (1989) RDAI 7, p. 815 for a French version of this article.
(150) - In so far as the exhaustion of the trade mark was concerned the Court held that `[T]he consent implicit in any assignment is not the consent required for application of the doctrine of exhaustion of rights. For that, the owner of the right in the importing State must, directly or indirectly, be able to determine the products to which the trade mark may be affixed in the exporting State and to control their quality. That power is lost if, by assignment, control over the trade mark is surrendered to a third party having no economic link with the assignor'; paragraph 43 of the judgment.
(151) - See paragraph 52 of the judgment.
(152) - Per Mr Justice Kingsmill Moore delivering the judgment of the Supreme Court in Attorney General v Ryan's Car Hire [1965] IR 642, 654; see generally Kelly, The Irish Constitution, Third edition by Hogan and Whyte, Butterworths, Dublin and London, 1994, pp. 532 to 539.
(153) - Practice statement on judicial precedent of 26 July 1966 [1966] 1 WLR 1234, [1966] 3 All ER 77; for a recent application of this statement, see Pepper v Hart [1993] 2 WLR 1035, [1993] 1 All ER 42.
(154) - Joined Cases 28/62 to 30/62 Da Costa v Nederlandse Belastingadministratie [1963] ECR 31, section II of the Opinion.
(155) - Case 26/62 Van Gend en Loos v Nederlandse Administratie der Belastingen [1963] ECR 1; this had been decided seven weeks before judgment in Da Costa.
(156) - Da Costa, loc. cit., footnote 154 above, pp. 37 to 39.
(157) - Case 66/80 International Chemical Corporation v Amministrazione delle Finanze dello Stato [1981] ECR 1191, paragraph 13 of the judgment.
(158) - Case 283/81 [1982] ECR 3415, paragraph 14 of the judgment.
(159) - Case 302/87 Parliament v Council (`Comitology') [1988] ECR 5615, paragraph 28 of the judgment; while this was a direct action rather than a reference for a preliminary ruling, the same question of principle arose.
(160) - Case C-70/88 Parliament v Council (`Chernobyl') - admissibility - [1990] ECR I-2041, paragraph 16 of the judgment.
(161) - Joined Cases C-267/91 and C-268/91 [1993] ECR I-6097.
(162) - Loc. cit., footnote 31 above, paragraph 8 of the judgment.
(163) - Keck and Mithouard, paragraph 16 of the judgment.
(164) - Case 8/74 Procureur du Roi v Dassonville [1974] ECR 837, paragraph 5 of the judgment.
(165) - He also noted that the doctrine of common origin had not been taken up in later legislation, and in particular the First Council Directive (89/104/EEC) of 21 December 1988 to approximate the laws of the Member States relating to trade marks (OJ 1989 L 40, p. 1), though he considered that such silence could be interpreted as either approbation or condemnation (paragraph 53 of the Opinion).
(166) - HAG II, cited in footnote 82 above, paragraph 10 of the judgment.
(167) - Ibid., paragraphs 16 and 17 of the judgment.
(168) - This issue is discussed at paragraphs 167 to 170 below.
(169) - Loc. cit., paragraph 11 of the judgment.
(170) - Centrafarm v Sterling Drug, paragraph 26 of the judgment.
(171) - Ibid., paragraphs 27 to 29 of the judgment.
(172) - Loc. cit., Opinion, p. 1178.
(173) - See paragraph 24 of the judgment. See also Musik-Vertrieb Membran at paragraphs 20 to 26. The only Community measure which has been introduced in respect of pharmaceutical price controls is the Transparency Directive, loc. cit., footnote 60 above. It has not been suggested by the national court or in the observations submitted to this Court that the controls operated by the relevant Spanish or Portuguese authorities infringe the requirements of that Directive.
(174) - See Case C-350/92 Spain v Council [1995] ECR I-1985; Beecham pointed in particular to paragraph 31 of the judgment where the Court refers to Spain's argument that the prolongation of the marketing monopoly enjoyed by a patentee through the supplementary certificate `has the effect of preventing the generic medicines industry from competing freely with [patentees], to the obvious detriment of consumers,

who would be able to obtain the medicines at better prices from the moment the monopoly situation ended'.
(175) - The Commission, for example, referred to the following special features of such products: (i) the fact that the patient (the consumer) has little choice or influence over the product that is prescribed for him; (ii) the limited amount of substitutability between products; (iii) the crucial fact that the cost of medicinal products is largely borne by the social security system of the State of the patient.
(176) - Case 24/86 Blaizot v Université de Liège and Others [1988] ECR 379, paragraph 28 of the judgment.
(177) - See, for example, Case 43/75 Defrenne v Sabena [1976] ECR 455, paragraphs 72 to 74 of the judgment and Case C-262/88 Barber v Guardian Royal Exchange [1990] ECR I-1889, paragraph 41 of the judgment.
(178) - See Joined Cases C-485/93 and C-486/93 Simitzi v Kos [1995] ECR I-2655, paragraph 17 of the Opinion (quoting from paragraph 30 and referring to paragraphs 31 and 32 of the Court's judgment in Case 163/90 Administration des Douanes et Droits Indirects v Legros and Others [1992] ECR I-4625); see also the Opinion of 30 April 1996 of Advocate General Elmer in Case C-228/94 Stanley Charles Atkins v Wrekin District Council and Department of Transport, paragraph 63; and the judgment of 30 April 1996 in Case C-308/93 Bestuur van de Sociale Verzekeringsbank v J M Cabanis-Issarte [1996] ECR I-0000, paragraph 47 of the judgment.
(179) - See Hyland, `Temporal limitation of the effects of judgments of the Court of Justice - A review of recent case-law' (1995) 4 IJEL 208, who argues that the alteration by the Court of its previous case-law should be considered an independent ground for limiting the temporal effect of its judgment.
(180) - Case 61/79 Amministrazione delle Finanze dello Stato v Denkavit Italiana [1980] ECR 1205; paragraph 16 of the judgment, emphasis added.
(181) - The national court's comment is quoted at paragraph 21 above.
(182) - In Case C-415/93 Union Royale Belge des Sociétés de Football Association ASBL and Others v Jean-Marc Bosman [1995] ECR I-4921, the Court was satisfied that a temporal limitation of the direct effect of Article 48 to transfer rules was held to be justified because `the specific features of the rules laid down by the sporting associations for transfers of players between clubs of different Member States, together with the fact that the same or similar rules applied to transfers both between clubs belonging to the same national association and between clubs belonging to different national associations within the same Member State, may have caused uncertainty as to whether those rules were compatible with Community law'; paragraph 143 of the judgment. In the present cases the arguments in favour of a temporal limitation are different but, if anything, stronger because legal relationships may have been entered into on the basis of what was an unambiguous interpretation of the Treaty.
(183) - It is noteworthy that counsel for Beecham conceded at the hearing that the Court could consider delimiting the retroactivity of the judgment.
(184) - Official Journal of the European Patent Organization 7/86, p. 200.
(185) - EPC, Article 167(2)(a).
(186) - This is the date fixed in accordance with Article 169 of the EPC for its entry into force.
(187) - Decision of the Administrative Council of 5 December 1986. Official Journal of the European Patent Organization 3/87, p. 91 et seq.
(188) - Spanish Patent Law of 20 March 1986, Transitional Provisions, paragraph 1 of the First Part, p. 176.
(189) - Article 167(5) of the EPC.
(190) - See, for example, paragraph 2 of Protocol No 8 concerning postponement in part of provisions on shifting the burden of proof in cases of infringement of process patents to 7 October 1992 and similar provisions regarding effective dates for judicial procedure known as `distraint - description'.
(191) - Article 54 of the EPC provides that his invention is new if `it does not form part of the state of the art' (at paragraph 1), which comprises `everything made available to the public ... before the date of filing of the European Patent application'.
(192) - The protection permitted for industrial and commercial property generally, and for patents in particular, by Article 36 `inasmuch as it provides an exception to one of the fundamental principles of the common market ... admits of derogations from the free movement of goods only in so far as they are justified for the purpose of safeguarding rights which constitute the specific subject-matter of that property'. See, for example, Case 434/85 Allen and Hanburys v Generics [1988] ECR 1245, paragraph 10 of the judgment, and the discussion above (paragraph 94 et seq.) of the specific subject-matter of a patent.
(193) - It is being assumed, for this purpose, that Merck v Stephar continues to govern such a prohibition.
(194) - Joined Cases 194/85 and 241/85 Commission v Greece [1988] ECR 1037, paragraph 20 of the judgment; Case 231/78 Commission v United Kingdom [1979] ECR 1447, paragraph 12.
(195) - See Generics, loc. cit., footnote 43 above; paragraph 41 of the judgment.
(196) - Summarized at paragraph 24 of this Opinion for Merck and paragraph 28 for Beecham.
(197) - Article 4, cited at paragraph 188 below.
(198) - See paragraph 26 above.
(199) - See footnote 17 above.
(200) - See, for example, Article 112 on intervention weights for barley; Article 128 on `the end of the 1992/93 marketing year' for aid for grape musts; Article 122(2) on `1986/87 to 1990/91 wine-growing years'.
(201) - This part of the Act of Accession applies to both Spain and Portugal, although Merck describes this as Article 379 of Spain's Act of Accession.
(202) - OJ 1989 L 401, p. 1.
(203) - European Treaty Series No 76, Council of Europe, Strasbourg 1975, Vol. III.

(204) - Article 1(1).
(205) - The countries are Austria, Belgium, France, Germany, Italy, Luxembourg and Sweden.
(206) - See footnote 24 above.
(207) - Spanish Civil Code, Article 5.1.