# JUDGMENT OF THE COURT
5 December 1996 *

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

* Language of the case: English.

**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 Brattgård and Staffan Sandström, Departementsråd 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

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 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 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 år efter', 'bis zum Ende des dritten Jahres nachdem', 'μέχρι το τέλος του τρίτου έτους από', '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.

## 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.

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.**

Rodríguez Iglesias Mancini Murray

Sevón Kakouris Gulmann

Edward Puissochet Ragnemalm

Delivered in open court in Luxembourg on 5 December 1996.

R. Grass G. C. Rodríguez Iglesias

Registrar President