Accordingly, the rules of 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 it 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.

In Case 187/80

REFERENCE to the Court under Article 177 of the EEC Treaty by the President of the Arrondissementsrechtbank [District Court] Rotterdam for a preliminary ruling in the action pending before that Court between

MERCK & Co INC., Rahway, New Jersey, United States of America,

and

1. STEPHAR BV, Rotterdam,

2. PETRUS STEPHANUS EXLER, residing at Capelle aan den IJssel,

on the interpretation of the rules of the EEC Treaty on free movement of goods and in particular Article 36 in relation to patent law,

THE COURT

composed of: J. Mertens de Wilmars, President, P. Pescatore, Lord Mackenzie Stuart and T. Koopmans (Presidents of Chambers), A. O'Keeffe, A. Touffait, O. Due, U. Everling and A. Chloros, Judges,

Advocate General: G. Reischl
Registrar: A. Van Houtte

gives the following

JUDGMENT

Facts and Issues

The facts of the case, the course of the procedure and the observations submitted under Article 20 of the Protocol on the Statute of the Court of Justice of the EEC may be summarized as follows:

I — Facts and written procedure

The plaintiff in the main action, Merck & Co Inc. (hereinafter referred to as "Merck") manufactures and markets in all the Member States a drug known as "Moduretic" intended mainly for the treatment of hypertension. It holds patents for this drug in all the Member States except Luxembourg and Italy and for its manufacturing process in all the Member States except Luxembourg, Italy, Denmark and the Federal Republic of Germany.

In the Netherlands Merck is the holder and registered proprietor of the Netherlands patents No 138819 of 18 September 1973 and No 142413 of 18 October 1974. The second patent protects diuretic drugs, that is to say such as cause increased elimination of urine, and the process for their manufacture whilst the first patent is based on a subsequent discovery and protects a compound preparation with diuretic effects and a manufacturing process for it involving a unit of dose combining:

1. A preparation protected by the other patent No 142413; and
2. Another preparation with diuretic effects which was already known previously, namely hydrochlorothiazide.

Since the product protected by patent No 142413 is part of the preparation protected by patent No 138819, acts infringing the latter patent automatically infringe the other patent.

Merck expressly stated before the court making the reference without being contradicted by the defendant in the main action that it manufactures Moduretic in the Netherlands and does so in the factory of its wholly-owned subsidiary, Merck, Sharp & Dohme BV, Haarlem.

Merck also markets its pharmaceutical product in Italy but has not been able to obtain a patent there, for on 3 October 1962, the date to which the priority right goes back, it was not possible to obtain patents for drugs and their manufacturing process as a result of Article 14 (1) of the Italian Patent Law (Royal Decree of 29 June 1939, No 1127). That article was subsequently declared unconstitutional and therefore inapplicable by a judgment given by the Italian Constitutional Court on 20 March 1978 so that since that date it has been possible to obtain patents in Italy for drugs and their manufacturing process. After that judgment however,

Merck could still not obtain a patent because the product no longer fulfilled the legal condition of novelty which is a condition for obtaining a patent. That is no doubt one of the reasons why the drug is cheaper in Italy than in the Netherlands.

The undertaking Stephar BV, whose business is *inter alia* the import of pharmaceutical products, imports Moduretic from Italy and re-sells it on the Netherlands market at prices lower than those charged by Merck.

Merck therefore applied to the President of the Arrondissementsrechtbank Rotterdam for an interim order against Stephar and its director for infringing the patents of which it is the proprietor. That action was based on Article 30 of the Netherlands Law on patents (Rijksoctrooiwet) pursuant to which the proprietor of a patent has the exclusive right of manufacturing, using, selling, licensing or putting into circulation the product protected by the patent "save if and in so far as such products have been marketed previously by or with the authority of Merck itself in another Member State of the Community where Merck is the proprietor of the patents" corresponding to the Netherlands patents.

In its application Merck relies on all the facts set out above and further on the fact that it has not been able to obtain patents for its products and their manufacturing process in Italy. It is that latter argument, which is challenged by the defendants and which has led the President of the Arrondissementsrechtbank Rotterdam to make an order dated 2 July 1980 in which it raises the following questions:

"In a case where:

1. an undertaking is the proprietor of a patent in a Member State of the European Communities for a drug and the processes for manufacturing it;

2. by or with the consent of that undertaking that drug is marketed in Italy where the undertaking could not by law acquire a patent for that drug by virtue of Article 14 (1) of the Italian Patent Law (Regio Decreto of 29 June 1939 No 1127), later declared unconstitutional by the Italian Constitutional Court in its judgment of 20 March 1978, which prohibited the grant of patents for drugs and processes for manufacturing them;

3. a third party imports the drug referred to in paragraph 2 above from Italy into the Member State referred to in paragraph 1 above and deals in them there;

4. and the patent legislation in that country gives the proprietor of the patent the right to oppose by legal action the marketing there by others of the products protected by the patent even if previously they had been lawfully marketed in another country by or with the consent of the proprietor of the patent,

do the rules contained in the EEC Treaty concerning the free movement of goods, notwithstanding the provisions of Article 36, then prevent the proprietor of the patent from availing himself of the right referred to in paragraph 4 above?"

The order for reference was lodged at the Court Registry on 15 September 1980.

Pursuant to Article 20 of the Statute of the Court of Justice of the European Economic Community written observations were lodged on 21 November 1980 by the Commission of the European Communities represented by Rolf Wägenbaur, Legal Adviser, acting as Agent, assisted by Thomas Van Rijn, a member of the Commission's Legal Department, on 2 December 1980 by Stephar BV, represented by D. den Hertog, Advocate at the Hoge Raad [Supreme Court] of the Netherlands, on 4 December 1980 by the French Government, represented by Thierry Le Roy, acting as Agent, on 11 December 1980 by the Government of the United Kingdom, represented by G. Dagtoglou, Treasury Solicitor's Department, acting as Agent, and on 30 December 1980 by Merck, represented by T. Schaper, Advocate of The Hague.

On hearing the report of the Judge-Rapporteur and the views of the Advocate General the Court decided to open the oral procedure without any preparatory inquiry, but it asked the Commission to forward all the documents relating to Article 81 (1) of the European Patent Convention and in particular the proposal by the Federal Republic of Germany and the minutes of the Luxembourg Conference on the Community Patent.

II — Written observations lodged pursuant to Article 20 of the Statute of the Court

A — Observations of the plaintiff in the main action

The *plaintiff in the main action* considers first of all the Netherlands legislation and in particular Article 30 of the national Law on patents (Rijksoctrooiwet) and the case-law of the Hoge Raad and comes to the conclusion "that according to Netherlands municipal law the proprietor of a patent has not exhausted his right by marketing his product in another country if he has a parallel patent there and *a fortiori* if he cannot obtain a patent in that other country because of the legislation on patents in force there".

Merck then considers the applicable Italian municipal law on patents. It recalls first of all that at the time when applications for patents in respect of the two Merck inventions might have been made drugs could not be patented in Italy and it was not until after 20 March 1978, the date of the judgment given by the Italian Constitutional Court which declared Article 14 (1) of the Italian Law on patents unconstitutional, that drugs and their manufacturing process were no longer excluded from the grant of patents in Italy. According to Merck however it is no longer possible to obtain a patent for the drug Moduretic "because of the absence of apparent novelty". It is true that there are two Italian draft laws of a transitional nature which might allow Merck to apply for the grant of a patent for its drug but the possibility of Merck's still obtaining Italian patents "has nevertheless no relevance to the present proceedings because any such patents cannot legally have retroactive effect" and in any event since Italy has still not introduced the transitional law allowing the Merck inventions to be patented it would in the meantime still be possible for Stephar to

import Moduretic products from Italy where they are marketed by Merck without patent protection. After those preliminary remarks Merck sets out the outline of its argument relating to the interpretation of Article 36 in the matter. It intends to show:

1. The action which it has brought against the imports by Stephar is "justified on grounds of ... the protection of industrial and commercial property" because of:

   (a) The divergence between the Netherlands and Italian laws on patents in relation to the patentability of drugs;

   (b) The specific object of the rights which it derives from its patents in the Netherlands;

2. This action does not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

1. (a) The disparity between the Netherlands and Italian laws on patents in relation to the patentability of drugs

Merck relies on paragraph 8 of the judgment of 20 February 1979 in Case 120/78 *Rewe* [1979] ECR 649, paragraph 6 of the judgment of 26 June 1980 in Case 788/79 *Gilli* [1980] ECR 2071 and on the "communication from the Commission" concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in Case 120/78 *(Cassis de Dijon)* (Official Journal of 3 October 1980, C 256, p. 2) to claim that according to the Court obstacles resulting from disparities between commercial and technical rules must be accepted if those rules are necessary to satisfy mandatory requirements. That case-law of the Court is applicable "if not directly at least in any event by analogy to the disparities between the laws on patents in Member States". Since it is part of industrial and commercial property, the protection of which is expressly referred to in the said Article 36, patent law must not be subject to more severe criteria than those of equity and proportionality "which in virtue of an unwritten 'rule of reason' applies to areas not referred to in Article 36 such as for example the effectiveness of revenue checks and the protection of the consumer". Merck recalls that in the judgment of 16 December 1980 in Case 27/80 *Fietje* (not yet published) the Court considered that it might be necessary in order to give consumers effective protection to adopt measures derogating from Article 30 and maintains that that case-law ought to be applied in the present case in which it is "certainly necessary" to ensure "effective protection" of industrial property especially as it is expressly referred to in Article 36.

Merck's intention is to show that the disparity it has referred to between the Italian and Netherlands laws is necessary to satisfy mandatory requirements or to ensure effective protection for industrial and commercial property. As a result that disparity meets the criteria laid down by the Court of Justice in the aforementioned judgments. In reliance on the communication from the

Commission (referred to above) it is also Merck's intention to show that in the present case it is not for the Netherlands to take account of the Italian law but on the contrary for the Italian legislature to take account of the criteria for protecting patents in the Netherlands in view of the fact that such criteria apply in all the other Member States and that under the Italian legislation on patents, at least as regards drugs and their manufacturing processes, not only are the means insufficient to attain the aim intended by the law, namely the protection of patents, but they do not even exist. As a result the difference in relation to that in the Netherlands law is "necessary" and "not excessive"; it serves a purpose in the general interest which is compelling enough to justify an exception to Article 30 pursuant to Article 36 and similarly is essential or constitutes "the most appropriate means" to ensure patent protection. In support of that argument Merck discusses at length the considerations put forward by the Italian Constitutional Court in its judgment of 20 March 1978. It considers that they "mean in substance that the Italian legislature has been guilty of a failure to act; according to contemporary opinion the non-patentability of drugs has no rational basis: it is incompatible with various constitutional principles including the obligation on the State to encourage scientific and technical research and is further incompatible with the relations which Italy has with the other Member States of the EEC".

Merck observes in that respect that the incompatibility with the various constitutional principles arises in every case from one and the same injustice: "the absence of a return to the inventor to compensate for the costs of research". Finally it deduces a number of principles from the considerations of the Italian Constitutional Court:

— In the present case and for the proper working of the Community market of the EEC Italy should take account of the "legitimate interests of the other Member States";

— Such conduct would be in accordance with the rules of harmonization as sought by means of the future Community patent elaborated in the Luxembourg Convention of 1975;

— The non-patentability in Italy is disproportionate;

— On the other hand the Netherlands patent law and the action by Merck based thereon are not incompatible with the principle of proportionality;

— Therefore the disparity between the two national laws in question should be accepted as "necesary" to satisfy "mandatory requirements" or to ensure "effective protection" for industrial property;

— Thus Merck's action is "appropriate" and "not excessive"; it is "essential" to ensure protection of Merck's patents and justifies an exception to the principle of the free movement of goods.

1. (b) The specific object of industrial property in relation to patents

On this subject Merck recalls first of all that according to the Hoge Raad the

principle that the rights are exhausted following marketing of the product of the proprietor of the patent abroad (that is to say outside the Netherlands):

"is not acceptable either, because without any further elimination it would lead to unacceptable results which are certainly not intended by the legislature".

According to Merck that applies *a fortiori* in a case such as the present where not only the proprietor of the patent does not have a patent in the exporting country but further that position arises because it is not legally possible to obtain patents for the product in question in that country. Merck wonders whether such a result, described by the Hoge Raad as unacceptable, must in fact be accepted on the ground that the exporting country is a Member State and even though the fact that the product is not patentable is incompatible with the constitution of that Member State. Such an inference may be drawn from the wording of paragraph 1 of the operative part of the judgment of the Court of Justice of 31 October 1974 in Case 15/74 *Centrafarm* [1974] ECR 1147, but Merck wishes to stress that although the operative part there simply mentions "which has been marketed in another Member State" without adding the qualification "where the proprietor of the patent has a parallel right", that judgment, relating to the questions put by the Hoge Raad, in which there was such a qualification, is confined to parallel patents.

In support of its argument Merck considers the reasoning of the Court's judgment and in reliance on paragraphs 9 to 12 it maintains that "as regards products of the proprietor of the patent himself the argument of the Court of Justice therefore applies only to the case of parallel patents and it is reasonable to assume that the Court of Justice intended its ruling to apply only to that case". Further it is only in that case that the argument logically fits the specific subject-matter of patents as defined by the Court in paragraph 9 as "the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention ..." whereas to accept that rights are exhausted where there is no opportunity to obtain parallel patents is incompatible with that definition.

It is also to be added in support of that argument that the Court devotes two paragraphs to considering whether there may indeed be parallel patents. In Merck's view such considerations "would have been quite useless if the existence or not of parallel patents had not been relevant to the decision of the Court of Justice". Finally Merck thinks that some importance should also be attached to the fact that the judgment was published in the reports of the Court of Justice under the title "Parallel patents".

Merck then considers the whole of the case-law of the Court in relation to industrial and commercial property, which it sub-divides into four categories. The first and second categories, relating respectively to "national trade-mark rights having what is called a common origin" and "the setting up of industrial and commercial property to obstruct the importation of a product originating in another Member State" where it has been marketed by independent competitors, are of no relevance in the present case. Merck simply points out that Mr Advocate General Roemer in his opinion in Case 24/67 *Parke Davis* said that the

essence of a patent was to give the patent-holder a "reasonable return on his outlay".

On the other hand the judgments which the Court of Justice has given in relation to copyright are of great relevance in the present case. Thus first of all in the judgment of 8 June 1971 in Case 78/70 *Deutsche Grammophon-Gesellschaft* v *Metro* [1971] ECR 487 the Court held that the fact that the plaintiff opposed the parallel import of gramophone records from France into Germany solely because such distribution did not occur within German territory was in conflict with the provisions prescribing the free movement of products within the Common Market. Merck opposes the parallel importations by Stephar not solely because the products are marketed in Italy but "in addition and above all" because Merck cannot obtain patents for its products in Italy.

It follows indirectly from the judgment of 18 March 1980 in Case 62/79 *Coditel* [1980] ECR 881 that it would be difficult to regard copyright in relation to a book or gramophone record as being exhausted by the sale in a country where protection of copyright is legally prohibited and the work must therefore be sold at prices competing with those of pirate editions.

Finally Merck refers to the opinion of Mr Advocate General Warner delivered on 11 November 1980 in Joined Cases 55 and 57/80 *GEMA*, which had not yet been decided by the Court when the written observations were lodged, to the effect that "there can be no exhaustion of rights when no rights exist". The fourth category of judgments of the Court relating to proceedings where trade-mark rights have been relied on to oppose parallel importations and especially the judgment of 10 October 1978 in Case 3/78 *Centrafarm* [1978] ECR 1823 provides important guidelines for the solution of the present case. In Case 3/78 the Court considered that it might be lawful for the manufacturer of a product to use in different Member States different marks for the same product especially if the trade-mark under which the product is already marketed in one of the Member States "is not lawfully available in another Member State when the product is subsequently marketed in that other Member State." It therefore recognized that the proprietor of a trade-mark was justified pursuant to Article 36 in setting up his Netherlands trade-mark to prevent parallel importations from a country where the proprietor of the trade-mark was not able lawfully to obtain that mark. In the same way Merck maintains that it ought in principle to be able to rely on its Netherlands patents to prevent the parallel importations by Stephar from a country where Merck has not been able lawfully to obtain patents and Merck concludes that its action is justified because it cannot obtain parallel patents in Italy. As a result the sole fact that the products are marketed in Italy by Merck itself is not sufficient to exhaust the patent right.

Apart from the case-law of the Hoge Raad of the Netherlands national patent laws and legal writers, especially British, reject the argument of the exhaustion of rights when the drug is marketed in another Member State where there is no patent protection. Finally although Article 81 of the Community Patent Convention states the principle of the exhaustion of the rights in Member States after the product has been put on the market in any Contracting State by the proprietor of the patent or with his express consent, it stipulates: "unless there are grounds which, under Community law, would justify the extension to such acts of the rights conferred by the patent". In Merck's view it is not possible to imagine clearer justification than where a Member State, contrary to its own constitution, makes the grant of patents legally impossible.

2. Arbitrary discrimination or disguised restrictions on trade between Member States

From this aspect it is necessary to consider whether Merck failed to make applications for patents in Italy as part of a practice pursued by it with a view to artificially partitioning the market. Merck considers that it may confine itself here to denying that there was any question of that: it failed to make applications simply because it knew that drugs and their manufacturing process were not patentable in Italy.

In conclusion Merck is of the opinion that the answer to be given to the question put to the Court of Justice must be in the negative.

B — Written observations of the French Government

The *French Government* puts forward a line of argument substantially similar to that of Merck. It considers that the *Centrafarm* v *Sterling Drug* case differs from this one; it also cites Case 3/78 as authority and maintains that there the Court recognized the existence of exceptional circumstances and for their appreciation referred to the essential function of the right in question. This case is concerned with an exceptional situation which it is therefore necessary to appreciate in relation to the function of the patent right as it is defined by the Court in paragraph 9 of the judgment in *Centrafarm* v *Sterling Drug,* namely in essence to reward the creative effort of the inventor. The company by which the invention was made does not receive the reward for its creative effort in Italy because it is subject there to competition from other companies which do not have research costs to cover. Therefore if products put into circulation in Italy in such conditions of competition were to find their way into the territory of States in which the company has obtained patents it would lose the reward for its creative effort in those countries too. Such a result would therefore not be compatible with the "essential function" of the patent right.

Further, because of the temporary disparity between laws, the Court of Justice accepted exceptions to free circulation of goods which were the subject of industrial property rights. It is important, in the view of the French Government,

not to distort the conditions for achieving the harmonization resulting from the coming into force of the European Patent Convention before the effects thereof are felt, for "the possible partial impairment of the content of the exclusive right given by patents for drugs in the countries of the Community other than Italy would have serious consequences upon the conditions of competition in the European pharmaceutical industry". By reason thereof the Italian pharmaceutical industry is on the one hand privileged in being able easily to conquer foreign markets and on the other hand at a disadvantage by being deprived of the consent, and even of the technological assistance, of the patentee for the manufacture of drugs not patented in Italy. From that point of view Community undertakings might refrain from setting up subsidiaries in Italy or might refuse to bind themselves by contracts involving transfers of technology or know-how with Italian partners, which would have serious consequences both for the free movement of goods and the pursuit of free competition within the Community albeit such activities are not formally contrary to Article 85 of the EEC Treaty.

Finally the French Government refers to the work of the Luxembourg Conference on the Community patent when Article 81 (1) and in particular the present type of case were discussed at length. The present wording of Article 81 (1), in particular the last sentence, is the result of a proposal by the Federal Republic of Germany which received general approbation and in particular that of the Commission as is evident from the minutes. As a result, in the opinion of the French Government, it was accepted that the "situation upon which the Court must give a ruling today constitutes an exceptional situation, derogating from the rule laid down by the judgment in *Centrafarm* v *Sterling Drug*". Moreover it is because of the agreement on the wording of Article 81 (1) that the Committee of the Whole agreed unanimously not to adopt a protocol on the deferred application of the provisions relating to the exhaustion of rights attached to Community and national patents.

As a result the French Government is of the opinion that "by reason of Article 36 of the EEC Treaty Community law does not prevent the proprietor of a patent in a Member State from opposing, pursuant to the applicable national legislation, the marketing of products protected by the patent in that State by others than himself where those products have been manufactured and marketed by him in another Member State the national law of which does not allow the product in question to tbe protected by patent".

C — Written observations of the United Kingdom

The *Government of the United Kingdom* comes to the same conclusion as Merck. It cites the same case-law set out above by the applicant to contend that the Court has evolved a Community doctrine of exhaustion of rights whilst allowing exceptions to the principle of free movement of goods under Article 36 solely where they are justified by the protection of rights which are the specific subject-matter of industrial property. The British Government refers

to the definition of the specific subject-matter of the patent given by the Court and stresses the concept of reward which in its view is "the ability of the patentee to fix the price of the patented product free from such competitive forces as would exist but for the exclusive rights given by the patent." The reward is an incentive to the production and marketing of inventions which often benefits the consumer by increasing the range of products available to him. The rationale of an exhaustion doctrine is that a patentee should be able to take a monopoly profit, but only once. It is sufficient therefore that he takes his reward in any one Member State where he owns the patent when the goods are first marketed there by him with his consent.

After recalling the examples of application of the Community doctrine of the exhaustion of rights given by the Court in the aforementioned Cases 15/74, 24/67 and 78/70 the Government of the United Kingdom maintains that those examples are not exhaustive and "that it is entirely consistent with the Community doctrine of exhaustion to hold that in the circumstances set out by the Dutch court, the patentee is entitled to assert the rights given under national law to prevent the marketing of the goods in question." Otherwise this would eliminate a significant part of the specific subject-matter of the patent which, as the Court has recognized, the Community rules on the free movement of goods respect.

The British Government then cites in support of its argument Article 81 of the Community Patent Convention and especially the minutes of the Luxembourg Conference from which it appears that the last sentence of Article 81 (1) was inserted into the Convention in order to extend its scope to the type of situation which is at present before the Court.

The British Government finally adds that protection of the patentee's reward is consistent with both the application of the Treaty rules relating to the free movement of goods and the practical considerations relating to the encouragement of inventions and their marketing within the Community. The absence of reward resulting from the Italian rules would leave the inventor with only one choice which might compel him to withdraw from the Italian market entirely and would be unfair both to the Italian consumer and to the inventor, who would be the only person effectively prevented from putting the goods on the Italian market. "This type of situation would become more common, and hence more serious, with the entry into the Community of Greece and the possible entry of Spain and Portugal, none of which grants patents for pharmaceutical products".

For those reasons, the United Kingdom "considers that the rules contained in the Treaty concerning the free movement of goods do not prevent the proprietor of a patent in one Member State from availing himself of the right to prevent, by legal action, the marketing there by

others of the products protected by the patent which have been lawfully marketed in another Member State where no such patent protection exists".

D — Written observations of the defendant in the main action

As regards facts the *defendant in the main action* maintains that Merck Sharp & Dohme markets Moduretic on the different markets of the Member States at very different prices, namely, if as a basis for reference the price in the Federal Republic of Germany is taken as 100, as follows:

— Netherlands: 140,

— Denmark: 76,

— Belgium: 102,

— United Kingdom: 58,

— France: 51,

— Italy: 56.

1. Stephar begins by placing the present case in the context of the previous case-law of the Court. It considers that the present case falls between the *Parke Davis* and *Sterling Drug* cases and that the problem put by the present case "has not yet effectively been referred to the Court of Justice". But that does not mean that the previous case-law of the Court of Justice does not offer, in this case to the national court, sufficient guide-lines to answer independently the questions of Community law which arise. The cases of *Deutsche Grammophon Gesellschaft* v *Metro* and *Sterling Drug* show that "Merck cannot rely on its patent in the Netherlands to oppose the importation of its original product from Italy". Stephar relies basically on the operative part of the judgment in *Sterling Drug* which, it is true, leaves a certain doubt as to whether at the time of that judgment the Court of Justice contemplated the situation in which a plaintiff who is proprietor of the patent in the country of importation has no parallel patent in the country of origin, but in Stephar's view that possible doubt is removed in the eleventh paragraph of the decision where the Court held that the action of the proprietor of the patent "may be justified against a product coming from a Member State where it is not patentable and has been manufactured by third parties without the consent of the patentee". That co-ordinating conjunction shows that in 1974 the Court of Justice also contemplated the case which presented itself in *Parke Davis* and that it also intended to resolve it.

Stephar finally stresses that, as regards the case-law of the Court of Justice, the national court itself found that such case-law "does not, in law, allow any other conclusion than that" referred to by Stephar above.

2. Stephar takes the view that Merck's argument is based on the fact that since pharmaceutical products were not patentable in Italy Merck had to market Moduretic in Italy in competition with third parties and therefore at lower prices. As a result the specific subject-matter of the patent which is to reward the creative effort of the inventor must include Merck's ability to oppose the marketing of its original product in the Netherlands. In any event it is necessary to take this view since the constitutional

court has declared Article 14 of the national law to be unconstitutional.

3. In order to answer that argument by Merck the defendant in the main action first of all considers the reasons for the Italian national provision which was declared unconstitutional. In its view it involves a price system laid down by the public authorities intended to ensure that pharmaceutical products are marketed at reasonable prices in the interests of public health. As regards price control, the Court expressly declared, in particular in the *Sterling Drug* case, that "the existence of factors such as these in a Member State, however, cannot justify the maintenance or introduction by another Member State of measures which are incompatible with the rules concerning the free movement of goods, in particular in the field of industrial and commercial property". Thus, in Stephar's view, the intervention of the Italian public authorities in the price mechanism is not decisive in this case especially as in that respect pharmaceutical brand products are subject in several Member States to direct or disguised intervention by the public authorities.

4. Stephar also stresses that the proprietor of the patent has a choice. Pursuant thereto he may very well not market the product for which a patent has been given to him in another Member State of the Community. As a result if the inventor chooses nevertheless to market the product in such a Member State, he recognizes by so doing that the price of the product gives him a reasonable return for his inventive activity. It would be quite different if the proprietor of the patent were actually forced to exploit his invention in the said Member State. There is no direct or indirect constraint upon the inventor in Italy and therefore Merck enjoyed complete freedom in deciding to market Moduretic in Italy. In any event Merck had a *de facto* monopoly as a result of the special know-how to manufacture the proprietary product and thus obtains a return for its inventive activity unimpeded by third parties.

5. Stephar is also concerned to observe that the fact that Merck prepares Moduretic itself in the Netherlands has no effect upon the wording of the question and it is irrelevant whether the Netherlands manufacturer is the same or whether he must be placed on an equal footing from the legal point of view and/or from the economic point of view with the Netherlands proprietor of the patent, as in this case.

6. Finally Stephar considers that the judgment of the Italian Constitutional Court constitutes "a legislative measure". It often happens that the national legislature fundamentally changes its view especially as regards patent rights. Thus for example in the Netherlands it was not possible to patent a "substance" until 1 July 1978 and only then was it possible to issue patents for substances. In Stephar's view "it would be bold to say that in doing so the Netherlands legislature refused the inventor his due for 68 years and that it thus maintained an unlawful situation".

In conclusion Stephar proposes that the question put by the President of the Arrondissementsrechtbank Rotterdam should be answered "to the effect that

in the circumstances as described, notwithstanding the provisions of Article 36, the rules in the EEC Treaty in relation to the free movement of goods prevent the proprietor of a patent from setting up his patent rights under the national legislation".

E — Written observations of the Commission

The *Commission* shares on the whole the opinion of the defendant in the main action.

1. The Commission recalls first of all the case-law on the relationship between national patent law and Articles 30 and 36. Although the situation at the root of the present case has already been the subject of a reference for a preliminary ruling in Case 24/67, the judgment given by the Court in that case does not offer "a real guide to the answer to be given to the question put in the present case" concerning the situation in which the pharmaceutical product has been put into circulation in Italy by the proprietor of the patent whereas in Case 24/67 the product in question had been manufactured and marketed in Italy without the authority of the proprietor of the patent in the other Member States. Although Case 78/70 involved a similar case it concerned an industrial property right akin to copyright and not patent right.

The most important case in the Commission's view is Case 15/74 *Sterling Drug*. The basic principle followed by the Court as regards the relationship between the rules of the Treaty on free movement of goods and national patent law are shown in paragraphs 4 to 12. It follows that even if Article 36 contains an exception to the prohibition in Article 30 for *inter alia* industrial property rights the only impediments to free movement of goods allowed are those justified by the protection of the rights which constitute the specific subject-matter of that property. An obstacle to the free movement of goods of this kind may be justified only where such protection has been invoked against a product coming from a Member State where it is not patentable and has been manufactured by third parties without the consent of the patentee. On the other hand no derogation from the principle of free movement of goods is justified where the product has been lawfully marketed in a Member State whence it is imported by the patentee himself or with his consent especially in the case of a proprietor of parallel patents.

2. In the Commission's view that case-law contains "certain important guide-lines for the solution of the problem which has been put", the main one being free movement of goods. To answer the question put, it is necessary first of all to take note, in the Commission's view, that the territory to be taken into account regarding the first marketing is not the national territory but the whole Common Market in view of the principle of free movement of goods. In those circumstances "as soon as the product protected by a patent is put into circulation for the first time in the Community by the proprietor of the patent himself or with his consent the right of the proprietor of the patent is exhausted and it is no longer possible to prevent the importation and marketing of the product in question in another

Member State in reliance on the patent right". That is also how it is necessary to interpret paragraph 11 of the judgment in Case 15/74. That paragraph lays down the general principle to the effect that derogation from free movement is not justified either in the case where the proprietor of the patent puts the product into circulation in a country where he enjoys patent protection or in the case where he puts the said product into circulation in a country where he does not enjoy such protection. The inclusion in the last part of the sentence of the words "in particular in the case of a proprietor of parallel patents" shows that it is simply a special case of the specific application of the general principle which has been enunciated.

It is true that it may be contended that such a conclusion is not compatible with the view that the protection of rights is the specific subject-matter of the patent right but only if those rights are to include the obtaining of profits from monopolies on the basis of reward for the creative effort of the inventor. In its opinion of 26 September 1975 on the draft Convention for the European Patent for the Common Market (Official Journal L 261 of 9 October 1975, p. 26) the Commission already stated that "it is not however the purpose of the law of patents to guarantee to the patentee a higher profit than that which can be derived from the market price. A patentee is only granted, for a certain period, the exclusive right to forbid anybody to make and market the subject of his invention."

According to the Commission that point of view was adopted by the Member States and written into Article 81 (1) of the Community Patent Convention which makes no distinction between the case where the product has been put into circulation in a country which does not provide for patents and that where it has been put into circulation in a country offering patent protection. The last sentence of Article 81 (1), which is a political compromise, was justified in the view of the Member States by the fact that "in certain cases it may be unfair to take away a patentee's right to prohibit importation from a Member State which does not give patent protection". In the Commission's view "the Member States did not put forward arguments to the effect that in a case such as the present special interests of proprietors of patents may lead to the conclusion that it would be incompatible with the general principles referred to above for the proprietor of the patent not to be able to avail himself of his right of prohibition".

The Commission repeats that in its view to resolve the problem posed in the present case it is irrelevant whether the product in question was put into circulation by the proprietor of the patent or with his consent either in a country where it is impossible to protect the said product by a patent or in a country where such protection is possible.

As a result it proposes that the question put should be answered as follows:

"The exercise by the proprietor of a patent of the right conferred upon him by the legislation of a Member State lawfully to oppose the putting into circulation by third parties in the said State of products protected by the patent which have been marketed by the proprietor of the patent or with his consent in another Member State where they are not patentable is incompatible with the rules of the EEC Treaty on the free movement of goods within the common market".

III — Oral procedure

Merck & Co Inc., the plaintiffs in the main action, represented by T. Schaper of the Hague Bar, Stephar, one of the defendants in the main action, represented by D. den Hertog of the Hague Bar, the Government of the United Kingdom, represented by G. Dagtoglou, acting as Agent, and by R. Jacob, Barrister, and the Commission, represented by Rolf Wägenbaur, acting as Agent, assisted by Thomas Van Rijn, presented oral argument and their replies to the questions put to them by the Court at the sitting on 7 April 1981.

The Advocat General delivered his opinion at the sitting on 3 June 1981.

Decision

1 By a judgment of 2 July 1980 which was received at the Court on 15 September 1980 the President of the Arrondissementsrechtbank Rotterdam referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty a question on the relationship between the provisions of the Treaty concerning free movement of goods, in particular Article 36, and the protection of industrial and commercial property afforded by national laws.

2 In the judgment making the reference the President of the Arrondissementsrechtbank described the elements of fact and national law constituting the background to the question substantially as follows:

— Merck & Co Inc. (hereinafter referred to as "Merck") is the proprietor of two Netherlands patents protecting a drug, Moduretic, and its manufacturing process, by virtue of which pursuant to Netherlands law it has a legal remedy against the protected product's being marketed in that country by other persons, even when that product has been marketed in a different Member State by or with the consent of the holder of the patent.

— The company markets the drug in Italy where it has not been able to patent it owing to the fact that at the time when the drug was sold in Italy the Italian Patent Law (Regio Decreto [Royal Decree] No 1127 of 29 June 1939) — which was subsequently declared unconstitutional by a judgment of the Italian Corte Costituzionale [Constitutional Court] delivered on 20 March 1978 — prohibited the grant of patents for drugs and their manufacturing processes.

— Stephar imports the drug from Italy into the Netherlands and markets it there in competition with Merck.

3 On the basis of those facts the court has asked whether in such circumstances the general rules of the Treaty concerning the free movement of goods, notwithstanding the provision of Article 36, prohibit the proprietor of a patent who sells a drug protected by that patent in a Member State (The Netherlands) from preventing, as he may under the national legislation of that Member State, the drug which he himself sells freely in another Member State where no patent protection exists (Italy), from being imported from that other Member State and marketed by other persons in the first Member State (The Netherlands).

4 The parties to the proceedings commenced their discussion of the question by emphasizing that the Court has already stated, in its judgment of 31 October 1974 *(Sterling Drug,* Case 15/74 [1974] ECR 1147), that inasmuch as it provides an exception, for reasons concerned with the protection of industrial and commercial property rights, to one of the fundamental principles of the Common Market, Article 36 admits of such a derogation only in so far as it is justified for the purpose of safeguarding rights which constitute the specific subject-matter of that property, which as far as patents are concerned is in particular to 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".

5 In the same judgment the Court declared that an obstacle to the free movement of goods may be justified on the ground of protection of industrial property where such protection is invoked against a product coming from a Member State where it is not patentable and has been manufactured by third parties without the consent of the patentee.

6 The parties are in agreement as to the fact that the situation under consideration in the present instance differs from that which was the subject of that decision because, although it concerns a Member State where the product in question is not patentable, that product has been marketed not by third parties but by the proprietor of the patent and manufacturer of the product himself; however, from that statement they draw opposite conclusions.

7 Stephar and the Commission conclude that once the proprietor of the patent has himself placed the product in question on the open market in a Member State in which it is not patentable, the importation of such goods into the Member State in which the product is protected may not be prohibited because the proprietor of the patent has placed it on the market of his own free will.

8 In contrast Merck, supported by the French Government and the Government of the United Kingdom, maintains that the purpose of the patent, which is to reward the inventor, is not safeguarded if owing to the fact that the patent right is not recognized by law in the country in which the proprietor of the patent has marketed his product he is unable to collect the reward for his creative effort because he does not enjoy a monopoly in first placing the product on the market.

9 In the light of that conflict of views, it must be stated that in accordance with the definition of the specific purpose of the patent, which has been described above, the substance of a patent right lies essentially in according the inventor an exclusive right of first placing the product on the market.

10 That right of first placing a product on the market 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.

11 It is for the proprietor of the patent to decide, in the light of all the circumstances, under what conditions he will market his product, including the possibility of marketing it in a Member State where the law does 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 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.

12 That is borne out, moreover, by the statements of the Court in its judgments of 22 June 1976 *(Terrapin,* Case 119/75 [1976] ECR 1039) and 20 January 1981 *(Musik-Vertrieb membran and K-tel,* Joined Cases 55 and 57/80 (not yet published) inasmuch as "the proprietor of an industrial or commercial property right protected by the law of a Member State cannot rely on that law to prevent the importation of a product which has been lawfully marketed in another Member State by the proprietor himself or with his consent".

13 Under those conditions to permit an inventor, or one claiming under him, 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 is not patentable would bring about a partitioning of the national markets which would be contrary to the aims of the Treaty.

14 The reply to the question which has been raised therefore should be 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.

Costs

15 The costs incurred by the French Government, the Government of the United Kingdom and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. As this case is, in so far as the parties to the main proceedings are concerned, in the nature of a step in the proceedings before the national court, the decision as to costs is a matter for that court.

On those grounds,

THE COURT,

in answer to the question referred to it by the President of the Arrondissementsrechtbank Rotterdam by an order dated 2 July 1980, hereby rules:

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.

Mertens de Wilmars Pescatore Mackenzie Stuart Koopmans O'Keeffe

Touffait Due Everling Chloros

Delivered in open court in Luxembourg on 14 July 1981.

A. Van Houtte
Registrar

J. Mertens de Wilmars
President