prices are fixed at a level such that the sale of imported products becomes either impossible or more difficult than that of domestic products.

3. Article 30 of the EEC Treaty precludes a Member State from introducing in respect of pharmaceutical products imported from other Member States specific legislation which refers to the manufacturer's basic prices usually charged for products intended for consumption within the territory of the Member State in which they are produced, where the legislation applicable to domestic production is based solely on a freeze of the level of prices at a given reference date.

A situation of that kind can have the effect of placing the sale of imported products at a disadvantage by rendering such sale more difficult, impossible or, in any event, less profitable than the sale of domestic products whenever the level of prices to which, as regards products from other Member States, the legislation of the Member State of importation refers, is lower than that applicable to products from that State.

In Case 181/82

REFERENCE to the Court of Justice under Article 177 of the EEC Treaty by the President of the Arrondissementsrechtbank [District Court], The Hague, for a preliminary ruling in the proceedings pending before that court between

ROUSSEL LABORATORIA BV, having its registered office in Hoevelaken,

DUPHAR BV, having its registered office in Amsterdam,

MERCK, SHARP & DOHME BV, having its registered office in Haarlem,

ESSEX (NEDERLAND) BV, having its registered office in Amstelveen,

KABIVITRUM BV, having its registered office in Amsterdam,

CN SCHMIDT BV, having its registered office in Amsterdam,

WILLPHARMA BV, having its registered office in Amsterdam,

TENDO-HACO FARMACIE BV, having its registered office in Wapenveld,

ACF CHEMIEFARMA NV, having its registered office in Amsterdam,

CLIN MIDY BV, having its registered office in Maassluis,

NEDERLANDSE ASSOCIATIE VAN DE FARMACEUTISCHE INDUSTRIE ("NEFARMA") [Netherlands Pharmaceutical Industry Association], having its registered office in Utrecht,

and

THE NETHERLANDS (Minister for Economic Affairs and Minister for Health and the Environment),

on the interpretation of various provisions of the EEC Treaty, in particular Articles 3, 5, 7, 30, 85 and 86 thereof, in the light of the Netherlands legislation on the prices of imported medicines,

THE COURT

composed of: J. Mertens de Wilmars, President, T. Koopmans, K. Bahlmann and Y. Galmot (Presidents of Chambers), P. Pescatore, Lord Mackenzie Stuart, A. O'Keeffe, G. Bosco and U. Everling, Judges,

Advocate General: S. Rozès
Registrar: P. Heim

gives the following

JUDGMENT

Facts and Issues

The facts of the case, the procedure and the written 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 procedure

1. As is clear from the judgment making the reference, in the Netherlands, the Prijzenwet [Prices Law] of 24 March 1961 (Staatsblad 1965, No 645) authorizes the public authorities to intervene in the free formation of prices in order to combat inflation or rigidity at the lower end of the price scale resulting from imperfect competition.

Article 2 (1) of that Law also authorizes the competent ministers, *inter alia*, to fix maximum prices if they consider that the public interest, both social and economic, so requires.

The decrees adopted on the basis of that provision expire automatically one year after their entry into force, unless they are repealed earlier. Article 3 of the Prijzenwet provides for the possibility of granting exemption, on request, from compliance with the rules thus laid down. Any conduct conflicting with those provisions is deemed to constitute an offence.

2. Since the beginning of the 1970s, the Netherlands Government has adopted a general decree on prices every year under Article 2 (1) of the Prijzenwet. The decree for 1982 — the Prijzenbeschikking Goederen en Diensten 1982 [Prices of Goods and Services Decree 1982] of 29 December 1981 (Staatscourant No 250 of 29 December 1981, p. 6) — prohibited producers from selling any goods on the domestic market at a price exceeding 100.9% of the reference price, namely the price, exclusive of turnover tax, charged for a product supplied before 28 November 1981, plus or minus an amount corresponding to the fluctuations in the purchase price of the raw materials and subsidiary materials and in transport costs as well as in excise duties and turnover tax. A comparable provision required traders to adhere to the purchase price of the goods, increased by 105% of the profit margin which they or their predecessors in title had applied before 28 November 1981 for identical goods, increased by the turnover tax payable.

Before June 1982, the rules of the Prijzenbeschikking Goederen en Diensten applied to domestic and imported medicines alike.

In June 1982, the Prijzenbeschikking Registergeneesmiddelen 1982 [Prices of Registered Medicines Decree 1982, hereinafter referred to as "the Prices of Registered Medicines Decree"] of 8 June 1982 (Staatscourant No 107 of 9 June 1982, p. 7) entered into force; that decree applies exclusively to the prices of imported registered medicines by derogating, as regards that category of product, from the provisions of the Prijzenbeschikking Goederen en Diensten. However, the latter decree still applies to medicines produced in the Netherlands.

The Prices of Registered Medicines Decree prohibits any person from selling on the Netherlands domestic market a registered medicine imported by him to any person other than a private individual at a price higher than the manufacturer's basic price last applicable in the country of origin before 15 May 1982 in a similar case for an identical medicine in the same package size, plus or minus the amount by which the manufacturer's basic price has risen or fallen since 15 May 1982, further increased by the direct costs, exclusive of turnover tax, by the profit margin which he or his predecessor in title last applied before 15 May 1982 in a similar case for an identical medicine or by the maximum profit margin which he or his predecessor in title was permitted to apply under the Prijzenbeschikking Goederen en Diensten, and by the turnover tax due. If the medicine is offered for sale in the country of origin in a different package size, the manufacturer's basic price is calculated on a proportionate basis. The effect of Article 3 of the Prices of Registered Medicines Decree is that a wholesaler retains his profit margin in absolute terms although he is obliged to adhere to the purchase price of the medicine before 15 May 1982.

It is clear from the explanatory memorandum to the Prices of Registered Medicines Decree, which is contained in the judgment making the reference, that the said Decree was adopted on the ground that the Prijzenbeschikking Goederen en Diensten provides only limited possibilities of controlling the prices of imported medicines. The prices of such medicines are often higher than those charged in certain countries from which those medicines are imported,

without its being possible to explain the disparities by variations between countries in the profit margins, exchange rates, transport costs or direct costs of importation. The importation of medicines is predominantly in the hands of multinational undertakings and the import price fixed by such undertakings for a given medicine is often determined by the internal pricing policy of the group to which they belong. The Prijzenbeschikking Goederen en Diensten permits the import price to be passed on subsequently. That is the result of insufficient price competition in the sector concerned since the final consumer has scarcely any influence on the type, quality, quantity and price of the medicine, the choice of which is determined primarily by the prescribing doctor, and since, moreover, as a result of the insurance system, his financial interest in the medicines which he uses is limited to the consideration that they should be as cheap as possible.

3. The plaintiffs in the main action, namely 10 pharmaceutical undertakings and the Nederlandse Associatie van de Farmaceutische Industrie ("Nefarma") [Netherlands Pharmaceutical Industry Association] instituted interlocutory proceedings against the Netherlands before the Arrondissementsrechtbank [District Court], The Hague, for an order rendering inoperative the Prices of Registered Medicines Decree.

In support of their claim, the plaintiffs in the main action maintain that the contested decree is contrary to the Prijzenwet and infringes the provisions of Article 30, Article 3 (f) in conjunction with Articles 85 and 86, and Articles 5 and 7 of the EEC Treaty as well as the general principles of Community law in regard to equality, proportionality, legal certainty and proper and exact preparation of legislation. The Netherlands, on the other hand, contends in particular that trade between States is not restricted by a national measure if its effect is to counter an artificial partitioning of the common market by a dual pricing system.

By interlocutory judgment of 14 July 1982, the President of the Arrondissementsrechtbank, The Hague, declared the application of Nefarma inadmissible and the complaint based on a breach of Article 2 (1) of the Prijzenwet unfounded on the ground that the contested decree was one of the measures for combating inflation covered by that provision. As regards the alleged incompatibility of the decree with Community law, the President of the Arrondissementsrechtbank, by the same judgment, stayed the proceedings and requested the Court under Article 177 of the EEC Treaty to give a preliminary ruling on the following questions:

"1. In the light of the argument put forward by the Netherlands, a Member State of the Community, is the Prices of Registered Medicines Decree 1982 to be regarded as:

A measure having an effect equivalent to a quantitative restriction on imports, prohibited by Article 30 of the EEC Treaty?

A form of discrimination prohibited by Article 7 of the EEC Treaty?

2. Do Articles 3 (f) and 5, in conjunction with Articles 85 and 86 of the EEC Treaty, have direct effect?

3. If Question 2 is answered in the affirmative, has the Netherlands by adopting the Prices of Registered Medicines Decree 1982 infringed those articles?

4. Do the principles of equality, proportionality, legal certainty and proper and exact preparation have direct effect in a case such as this?

5. If Question 4 is answered in the affirmative, has the Netherlands by adopting the Prices of Registered Medicines Decree 1982 contravened one or more of those principles?"

4. The interlocutory judgment was lodged at the Court Registry on 20 July 1982.

In accordance with Article 20 of the Protocol on the Statute of the Court of Justice of the EEC, written observations were lodged by: the plaintiffs in the main action, represented by B. H. ter Kuile, Advocate at The Hague; the Netherlands Government, represented by F. Italianer, Secretary-General at the Ministry for Foreign Affairs; and the Commission of the European Communities, represented by Rolf Wägenbaur, Legal Adviser to the Commission, and Thomas van Rijn, a member of its Legal Department, acting as Agents.

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. However, it requested the Commission to reply in writing to certain questions.

II — Written observations

The contested legislation in general

The *plaintiffs in the main action* observe that approximately 80% of the medicines used in the Netherlands are imported, largely from other Member States of the Community. Similarly, approximately 80% of the medicines manufactured in the Netherlands are exported, by and large to other Member States.

Although there is no common organization of the market in medicines involving a common pricing system, a common market in medicines has none the less come into existence as a result of the Council Directives on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (No 65/65/EEC of 26. 1. 1965, Official Journal, English Special Edition, 1965-1966 p. 20; No 75/318/EEC of 20. 5. 1975, Official Journal, L 147, p. 1; No 75/319/EEC of 20. 5. 1975, Official Journal, L 147, p. 13). That system precludes the adoption by the Member States of any measure which is capable of hindering the development of the pharmaceutical industry and trade in pharmaceutical products within the Community.

Domestic price levels for medicines vary appreciably within the Community from one Member State to another. As the Commission stated in its answer to a parliamentary question (Answer of 16. 3. 1978 to Written Question No 916/77 by Mr Cointat, Official Journal 1978, C 98, p. 9), such prices may vary for a number of reasons, such as price controls in force in some Member States but not in others, price reductions imposed by certain public authorities, obstacles to the free movement of medicines, the VAT rates applied to medicines, exchange rate fluc-

tuations and company pricing policies and the variations often reflect differences in the economic, monetary, financial and social policies of the Member States. Accordingly, such price variations are not the result of subjective manipulations by the suppliers of the medicines concerned.

In particular, certain Member States, namely Belgium, France and Italy, keep prices of medicines artificially low by means of legislation on prices and on refunds by sickness insurance schemes, thereby intervening to a substantial extent in the formation of prices under natural conditions on the market in proprietary medicinal products. That national pricing policy led the Commission to initiate a procedure, which is still in progress, in order to determine whether the policy of those States is permissible.

The effect of that policy is that the level of prices for a large number of wholly comparable medicines is considerably lower in the so-called "cheap" countries than it is in the Netherlands for domestic and imported products alike. As a result of those price differences, the Netherlands Government adopted measures designed to reduce the prices of medicines on the Netherlands market by artificial means, that is to say otherwise than by the natural price mechanism, to the relatively low level which exists in each of the cheap countries.

The Prices of Registered Medicines Decree is intended to operate in the following manner: if the foreign supplier, who is not affected by the contested decree, refuses to lower his selling price to the Netherlands importer in conformity with the decree, the importer will probably not purchase the medicine in question since his profit margin would, following the artificial reduction of the resale price and in view of the unchanged purchase price, be so small that he would no longer be able to carry out the transactions in question profitably. The foreign supplier will therefore consider to what extent he would prefer to forego the opportunity to sell his products on the Netherlands market rather than continue to sell them at the new reduced prices and thereby retain a competitive position for his products on the Netherlands market. If, in order to retain his competitive position on the Netherlands market, the foreign supplier decides to lower the selling price, in conformity with the criteria established by the contested decree, the importer will not be affected because the new prices enable him to retain his initial profit margin. The loss occasioned by the reduced price is borne almost entirely by the foreign supplier who might in consequence draw the conclusion that in the long term he will export medicines to the Netherlands in smaller quantities because the position of his product, as far as the price charged for it is concerned, has deteriorated artificially. It is quite conceivable that whilst a producer of medicines may be prepared to sell his medicines at economically unprofitable prices which are kept artifially low by the authorities only in the country of origin be will not be prepared to charge the same unprofitable prices in other Member States.

The *Netherlands Government* emphasizes that before the Prices of Registered Medicine Decree entered into force, there was a substantial difference in the exercise of control over the formation of prices of medicines manufactured in the Netherlands and of imported medicines. Whilst in the case of domestic products, only that proportion of production costs

which was constituted by the cost of imported raw materials and subsidiary materials — often representing less than 5 % of the final price — was not subject to the restriction laid down, in the case of imported medicines the formation of prices, including the price charged for goods delivered to the importer's premises, fell wholly outside the restrictions imposed by the public authorities.

Since the production and the sale of medicines are prèponderantly in the hands of multinational undertakings, which also include the supplier and the importer, it is impossible to speak, in this field, of normal price formation in the sense in which this takes place on the free market between independent parties. Where the importer does not form part of a multinational undertaking, he acts as an exclusive representative, with the result that in this case, too, normal price formation does not exist. The prices are fixed by a foreign supplier in a situation in which the decisive factor in the formation of the price is not the trend in production or distribution costs but the degree of competition on the market for which the product is intended and the "countervailing power" which exists there. On the Netherlands market in medicines, there is no price competition or "countervailing power" — or practically none — in view of the fact that the final consumer as a rule has no influence on the choice of medicine and has no direct financial interest in using cheap medicines.

Since approximately 80 % of the total quantity of medicines used in the Netherlands is imported, the pricing policy pursued before the contested decree entered into force affected only 20 % of domestic consumption.

In those circumstances, the Netherlands Government considered it necessary to increase its intervention in the formation of prices of imported medicines in order to achieve a more effective policy on prices.

Article 30 of the EEC Treaty

The *plaintiffs in the main action* observe that the facts relied upon by the Netherlands State in order to justify the contested decree have not been established on the basis of objective reasons in accordance with a proper procedure in the course of which the trade interests concerned would have been given an opportunity to make known their views. The facts relied upon by the Netherlands are fundamentally incorrect.

In seeking to prevent by means of the contested decree, on a national basis, the artificial partitioning of the Community market in medicines, the Netherlands State is acting primarily in the interests of the Community with a view to countering unilaterally and on a national basis alleged defects of the Community market in medicines. In a Community market in which directives have achieved a degree of harmonization of national laws, the Member States are not empowered to redress, by means of national measures, situations which they regard as contrary to the Community principle of the free movement of goods. The power to determine whether a situation is contrary to the Community interest and to adopt remedial measures is vested exclusively in the Community.

In any event, a Member State may not by its own actions bring about a situation in which a remedial measure itself comes into conflict with Article 30 of the EEC treaty or with another rule of Com-

munity law. The Prices of Registered Medicines Decree is contrary to Article 30 because it is capable of influencing trade between Member States and of affecting trade within the Community and because it does not apply to domestic products and to imported medicines without distinction.

Even on the assumption that the Member States may adopt pricing measures which restrict trade, the national authorities are in any event obliged to fix the maximum price of the imported product at a level which does not make the sale of the product impossible or more difficult than the sale of the domestic product (see judgments of the Court of 26 February 1976 in Case 65/75 *Tasca* [1976] ECR 291 and of 6 November 1979 in Joined Cases 16 to 20/79 *Danis* [1979] ECR 3327). The maximum price which the importer may charge under the contested decree in the event of the resale of medicines imported from so-called cheap countries does not satisfy that criterion. Although the importation and sale in the Netherlands of proprietary medicinal products from Belgium, France or Italy are not rendered impossible, these operations are rendered at least far more difficult than the marketing of corresponding domestic products which are governed only by the Netherlands pricing system embodied in the Prijzenbeschikking Goederen en Diensten.

The contested decree creates an obstacle to a change in patterns of trade since a change in the country of origin after the reference date of 15 May 1982 does not entail any alteration of the maximum price, regardless of the reason for the change in the country of origin. Accordingly, the relocation of centres of production of medicines in other Member States would serve no purpose in the case of medicines intended for the Netherlands market. For that reason, the contested decree is in contradiction with the very existence of a common market. Moreover, any increase in the Netherlands resale price for medicines imported into the Netherlands from countries with relatively high price levels is ruled out in advance by Article 2 (3) of the Prices of Registered Medicines Decree.

Variations in the prices of medicines within the Community are attributable not exclusively or primarily to subjective and arbitrary criteria applied by the suppliers concerned but to objective factors beyond their control. In any event, even if the price variations involved were regarded as arbitrary, that would be because certain Member States often adopt measures the effect of which is to fix and to maintain artificially prices of medicines in their States at a level different from what it would be if the mechanism of price formation were allowed to function normally. Artificial intervention of that kind naturally has an impact on the prices of medicines in other Member States. The distortion is "exported" from one Member State to all the others. In a common market, the Member States should refrain from any unilateral inteference with the mechanism of price formation where such interference would probably generate additional distortions within the Community.

Nor can a national measure such as that at issue in the present case fall outside the prohibition contained in Article 30 by

virtue of what is known as the "rule of reason" (judgment of the Court of 20 February 1979 in Case 120/78 *Rewe* [1979] ECR 649) since in this instance there is a Community system for the marketing of medicines which was introduced by certain directives, the contested decree does not apply to imported and to domestic products without distinction and it does not seek to attain an objective which is in the general interest and prevails over the free movement of goods.

Although the court making the reference did not submit any questions concerning Article 36 of the Treaty, it would be desirable, in order to avoid the need to submit a fresh reference for a preliminary ruling, to state that the contested decree cannot be justified on the basis of that article either since the decree has obviously not been adopted for the protection of health but constitutes an economic measure taken by the public authorities.

The *Netherlands Government* contends that, according to the case-law of the Court (see judgment of 9 December 1981 in Case 193/80 *Commission* v *Italy* [1981] ECR 3019), in the absence of relevant Community legislation the Member States are in principle free to adopt rules governing production and distribution on their territory. Similarly, the Member States in principle retain their power to adopt measures on prices. That approach is in conformity with the provisions of Article 103 of the EEC Treaty which proceeds on the assumption that the powers relating to conjunctural policy are vested primarily in the Member States.

As is apparent from the judgment making the reference, the Prices of Registered Medicines Decree is one of the measures involved in the fight against inflation under the general conjunctural policy pursued by the Netherlands Government. There is no Community legislation governing the prices of medicines. Coordination between the Commission and the Member States with a view to achieving greater transparency in the formation of prices on the market in medicines has not so far yielded any results.

As regards the possibility of restrictive effects on the level of prices fixed for the sale of imported products, it should be observed that the contested decree does not constitute an isolated measure but forms part of a general pricing system for medicines which includes provisions on the prices applicable to domestic products set out in the general Prijzenbeschikking Goederen en Diensten. There are sufficient reasons for subjecting imported medicines to distinct provisions, adopted to take account of the specific features of those medicines. Accordingly, the mere fact that the contested decree is concerned solely with imported medicines does not mean that it constitutes a measure having an effect equivalent to a quantitative restriction on imports.

The contested decree does not make it impossible to sell imported products. The manufacturer's basic price, charged on the foreign market, is also taken into account for the Netherlands market.

In order to examine the question whether the contested decree leads to less favourable treatment for imported products, it is possible to distinguish between, on the one hand, costs which the importer may include in his selling price and, on the other, the profit margin which he may incorporate in his selling price and the profit margins which may be applied at the next stage of distribution.

As regards the wholesaler's and the importer's margin, the Prices of Registered Medicines Decree refers to the margin applicable by virtue of the general Prijzenbeschikking Goederen en Diensten. Therefore, provided that the price of imported medicines is not affected by the contested decree, the profit margin remains the same as it was before, with the result that there is no difference in treatment between imported products and domestic products. If the price of the imported medicine falls as a result of the contested decree, the wholesaler and the importer can none the less retain their profit margin in absolute terms, with the result that imports are not affected by a fall in the purchase price imposed by the contested decree. Thus, as far as wholesalers' and importers' margins are concerned, imported medicines are by no means treated less favourably.

The purchase price of an imported medicine may be passed on in so far as it does not exceed the basic price charged by the foreign manufacturer. The other costs may be passed on in their entirety. The importer may also pass on in their entirety price increases occurring in the country of origin. The contested decree is therefore in conformity with the case-law of the Court (judgments of 26 February 1976 in Case 65/75 *Tasca* [1976] ECR 291 and in Joined Cases 88 to 90/75 *Sadam* [1976] ECR 323).

The contested decree proceeds on the assumption that if the common market operates properly, a supplier cannot charge different prices to purchasers established in different Member States where such divergences are not caused by variations in costs. Price variations attributable to the desire to exploit each national market to the limit of "what it can bear" create or reinforce a partitioning of national markets and accordingly constitute an obstacle to freedom of movement. The contested decree allows the importer to obtain supplies on the market of the country of origin at prices charged to wholesalers and to pass on those prices. A refusal to supply the medicines at that price cannot be regarded as a consequence of the Prices of Registered Medicines Decree but is the result of a decision freely taken by the supplier. Accordingly, a fall in trade resulting from such a refusal is not an effect which is contrary to Article 30. Any other view would lead to the conclusion that a Member State is obliged to accept any level, however arbitrary, of prices charged for imported products. Its effect would be to prevent the Member States from taking action any longer, in conformity with the objectives and the provisions of Article 85 et seq. of the EEC Treaty, against prices fixed by traders in breach of those provisions. Preference should be given to a more restricted, but natural, pattern of trade, as opposed to a more extensive pattern resulting from price discrimination practised by suppliers, which is itself made possible by the defective functioning of the market.

An undertaking should not use a *de facto* partitioning of the market in order to gain in the importing Member State an advantage which could not be obtained in the exporting Member State for a product marketed in the latter State by an undertaking to which the first undertaking is bound by a legal or economic relationship. An undertaking is at liberty to decide with full knowledge of the

facts whether or not to market its product in the exporting Member State. If it decides to market the product there, it must, in conformity with the proper functioning of the common market, fix its price without drawing any distinctions on the basis of what may happen to be the geographical destination of the product within that market. For a comparable case, reference may be made to the judgment of the Court of 14 July 1981 in Case 187/80 *Merck* [1981] ECR 2063, paragraph 11 of the decision.

The effect of the contested decree corresponds in substance to that of parallel imports. Once a product has been marketed in a Member State either by the manufacturer himself or with his consent, it must also be allowed to move freely within the common market: The effect of the contested decree is to enable a medicine marketed at a given price in any Member State to be sold on the Netherlands market at the same price without its encountering further obstacles.

The Netherlands Government therefore concludes that imported products are not treated less favourably than domestic products and that the measures in question are not contrary to Article 30.

The *Commission* observes that, according to the case-law of the Court (see the aforementioned judgments in the *Tasca*, *Sadam* and *Danis* cases as well as the judgments of 16 November 1977 in Case 13/77 *GB-Inno-BM* v *ATAB* [1977] ECR 2115 and of 24 January 1978 in Case 82/77 *Van Tiggele* [1978] ECR 25), national measures on prices must not in themselves be regarded as measures having an effect equivalent to quantitative restrictions. It may be otherwise if prices are fixed at a level which makes the sale of imported products impossible or considerably more difficult than the sale of domestic products. However, it must be pointed out that unlike the cases so far decided by the Court, this case involves legislation on prices which is not applicable to imported products and to domestic products without distinction, even though the domestic products are also covered by a system of rules on prices. In Directive 70/50/EEC (Official Journal, English Special Edition 1970 (I), p. 17), the Commission adopted a critical attitude with regard to measures on prices applicable exclusively to imported products.

In this case, the difficulty consists in ascertaining whether the linking of the maximum price of an imported product to the normal level of prices prevailing in the country of origin, by preventing undertakings from charging different prices on the basis of the country of destination, constitutes a hindrance to trade. As a rule, that question should be answered in the negative since the importation of goods is not rendered impossible or more difficult if it is borne in mind that the level of prices in the country of origin is such as to ensure an adequate economic yield for undertakings. If the maximum price in the importing country is fixed at a level which guarantees the producer the same economic yield as that which he obtains from sales in the country of origin and if additional costs incurred between the stage of production in the country of origin and that of sale in the importing country as well as a reasonable profit

margin for the importer can all be included in the maximum price, imports are rendered neither more difficult nor impossible.

However, the mechanisms of price regulation established by legislation may be such as to preclude, to a greater or lesser extent, the passing on of costs to the next supplier, with the result that the price charged to the wholesaler does not accord with that which is regarded, in economic terms, as the cost price of the product. In such a case, the effect of linking the maximum price in the importing country to the price charged in the country of origin is to compel the undertaking to sell its products also in the importing country at a price which does not properly reflect the actual cost price, which would be absurd in terms of profitability. In those circumstances, the effect of the legislation on prices may be to hinder imports.

Since it took the view that the level of prices in certain Member States, such as France, Italy and Belgium, was too low and was not in conformity with Community law as a result of the strict policy pursued with a view to controlling the prices of pharmaceutical products, the Commission approached the governments of those Member States in connection with their legislation on prices which, in its opinion, had led to an appreciable alteration in the prices charged in Italy and to the liberalization of prices in France. The Commission, however, is not in a position to state that the level of prices of pharmaceutical products in all the Member States is, at present, an accurate reflection of the real cost price of those products.

It is for the national court to take account of that state of affairs which characterizes the Community market in pharmaceutical products, by considering whether the legislation in question is compatible with Article 30. Legislation on prices must not have the effect of preventing manufacturers of proprietary medicinal products from selling such products in the Netherlands at a price which accurately reflects at least the real cost price of the product.

Article 7 of the EEC Treaty

The *plaintiffs in the main action* observe that the effect on proprietary medicinal products of the Netherlands policy on prices is that medicines which are comparable in every respect, are, as far as the price is concerned, treated differently according to whether they are imported from abroad or manufactured in the Netherlands. The criterion used to discriminate in this way between products and between suppliers is the country of origin of the medicines. That difference in the treatment of comparable articles and persons may be seen as discrimination on grounds of nationality within the meaning of Article 7 of the EEC Treaty, a provision in respect of which the Court, according to its case-law, may exercise its powers of direct review.

The *Netherlands Government* refers to its observations on Article 30 and states that it cannot be disputed that the imported product is not treated less favourably than the domestic product. Initially, the general rules embodied in the Prijzenbeschikking Goederen en Diensten relating to the calculation of prices differed in their effect on imported and domestic products and it was therefore justifiable not to subject the two categories of product to absolutely identical rules. Thus, in the present case, there is no compatibility with Article 7 of the EEC Treaty.

The *Commission* observes that the objections raised against the contested decree under Article 7 are identical to

those raised under Article 30. Since Article 30 contains more specific rules it is unnecessary to consider separately whether the contested decree is compatible with Article 7. Furthermore, discrimination occurs only if similar situations are treated differently or if different situations are treated in the same way. It is, where appropriate, for the national court to ascertain the extent to which price legislation relating to imported products and price legislation relating to domestic products are concerned with similar situations.

Articles 3 (f) and 5 in conjunction with Articles 85 and 86 of the EEC Treaty

The *plaintiffs in the main action* observe that as a result of various steps taken by the national authorities, including those of the Netherlands, in relation to the formation of the prices of medicines, the prices of proprietary medicinal products are kept at an artificially low level, even though that level may vary from one Member State to another. The effect of those national measures is that the price of medicines cannot find its natural level on the basis of supply and demand on the free market of the Community. That situation leads to a distortion of competition in the Community. The system of competition laid down in Article 3 (f) and set out in detail, *inter alia*, in Article 85 et seq. is one of the fundamental principles of the Community. The sovereign rights of the Member States in that area are definitively curtailed by the transfer of the rights and obligations of those States under the relevant provisions of the Treaty. Legal provisions which are unilaterally adopted by a Member State and are contrary to the system of competition are devoid of any effect. The contested decree therefore constitutes an infringement of Article 3 (f) and of Article 5, in conjunction with Articles 85 and 86 of the Treaty. A national of a Member State of the Community who considers that his rights under the Treaty or under secondary Community legislation are infringed by such national legislation may seek protection from the competent national court in respect of those rights where they have been so infringed. The direct effect of the provisions in question should be recognized.

The *Netherlands Government* observes that the contested decree does not require or encourage the undertakings to act in a manner which is contrary to Articles 85 and 86 of the Treaty, nor does it facilitate such conduct. The supply of products to foreign purchasers at the same price as that charged to domestic purchasers cannot be regarded as conduct conflicting with those provisions. A measure adopted by the public authorities which leads to the same result cannot therefore come into conflict with the combined provisions of Articles 5 and 85 et seq. of the Treaty. The third question raised by the court making the reference must therefore be answered in the negative, with the result that the second question loses its purpose. Should the Court none the less wish to answer that question, the Netherlands Government leaves it to the Court to determine whether or not Articles 3 (f) and 5 in conjunction with Articles 85 and 86 have direct effect.

The *Commission* observes that Article 3 (f) has no significance on its own and may therefore be relied upon only in conjunction with Articles 85 and 86. It is indisputable that individuals may rely on those articles before the national court. As regards Article 5, in so far as it is relied upon in conjunction with Articles

85 and 86, which have direct effect, individuals cannot be denied recourse to it before the national court. Since, however, the legislation on prices at issue in this case cannot be regarded as an agreement between undertakings, a decision by an association of undertakings, a concerted practice or an abuse of a dominant position, it does not come within the scope of Articles 85 and 86.

Direct effect of certain general principles of Community law

The *plaintiffs in the main action* consider that the general principles of Community law must, in view of their nature and scope, be of general and universal application and therefore have direct effect inasmuch as they may be relied upon by the Community institutions, the Member States and nationals of those States. The Court has already recognized in its case-law the direct effect of certain general principles of Community law in relation to secondary Community legislation. In view of the universal nature of those principles, it may be accepted that they are also applicable in cases in which national legislation comes into conflict with the principles of Community law. That would be of importance for the unity of Community law and of Community policy. The Member States would thus have fewer opportunities to adopt independent measures affecting Community policy. Rectification of such measures by the national court in proceedings brought by a national of a Member State of the Community would often be swifter and more appropriate than the procedure provided for in Article 169 of the EEC Treaty.

The *Netherlands Government* observes that the direct effect of certain general principles must not be confused with the direct effect of the articles of the Treaty which lay down such principles. According to the case-law of the Court, general legal principles are particularly relevant in connection with the appraisal of measures adopted by the institutions. In such cases, they are relied upon as a source of guidance for the interpretation of rules of Community law or in order to determine whether an institution has made proper use of the powers vested in it. However, the case-law of the Court contains no reference to general principles as independent criteria for the appraisal of measures and decisions adopted by the Member States, except possibly in relation to the action of a national authority in a situation governed specifically by Community law in which the national authority genuinely fulfils a function on behalf of the Community. The significance of the general legal principles referred to in the fourth question should not therefore be considered separately in this case. In any event, general principles of law cannot be regarded as having direct effect because they do not constitute an independent source of obligations.

The *Commission* observes that the applicability of general principles of law is recognized by the Court in the case of disputes in which the Community institutions are directly involved, where a

given provision of Community law is directly at issue or where the general principle of law is directly or indirectly incorporated in a provision of Community law. A measure adopted by a Member State in relation to its nationals is incompatible with the general principles of Community law only if it is based on a binding provision of Community law or if general principles of law are incorporated in such a provision. In the present case, therefore, the general principles of Community law are not applicable.

III — Oral procedure

At the sitting on 2 March 1983 oral argument was presented by the following: B. H. ter Kuile, of The Hague Bar, for the plaintiffs in the main action; A. Bos, acting as Agent, for the Netherlands Government; R. Wägenbaur and J. F. Verstrynge, acting as Agents, for the Commission of the European Communities.

The Advocate General delivered his opinion at the sitting on 11 May 1983.

Decision

1 By judgment of 14 July 1982, which was received at the Court on 20 July 1982, the President of the Arrondissementsrechtbank [District Court], The Hague, referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty several questions concerning the interpretation of Articles 3 (f), 5, 7, 30, 85 and 86 of the EEC Treaty and of certain principles of Community law in order to enable him to determine the compatibility with Community law of national legislation on prices for imported medicines.

2 Those questions were raised in interlocutory proceedings instituted against the Netherlands by 10 pharmaceutical undertakings and by the Nederlandse Associatie van de Farmaceutische Industrie ("Nefarma") [Netherlands Pharmaceutical Industry Association] for an order rendering inoperative the Prijzenbeschikking Registergeneesmiddelen 1982 [Prices of Registered Medicines Decree 1982, hereinafter referred to as "the Prices of Registered Medicines Decree"] of 8 June 1982 (Staatscourant No 107 of 9 June 1982, p. 7) adopted on the basis of the Prijzenwet [Prices Law] which authorizes the competent ministers to fix maximum prices if they consider that the public interest, both social and economic, so requires.

3 Before June 1982, the prices of medicines, whether produced in the Netherlands or imported, were regulated without distinction by the Prijzenbeschikking Goederen en Diensten 1982 [Prices of Goods and Services Decree 1982] (Staatscourant No 250 of 29 December 1981, p. 6)

which continues to apply to domestically-produced medicines. That decree prohibits producers from selling any goods on the domestic market at a price exceeding 100.9% of the reference price charged before 28 November 1981, plus or minus an amount corresponding to the fluctuations in the purchase price of the raw materials and subsidiary materials and in transport costs as well as in excise duties and turnover tax. Traders are required not to exceed the purchase price of the goods, increased by 105% of their profit margin before the reference date of 28 November 1981 and by turnover tax.

4 The Prices of Registered Medicine Decree introduced specific rules for imported medicines. It is clear from the explanatory memorandum to that decree, which is set out in the judgment making the reference, that the competent ministers took the view that the legislation formerly applicable provided only limited possibilities of controlling prices of imported medicines since the import prices of those products were often higher than the prices charged in certain countries of origin in which the level of medicine prices was lower and those high import prices might be passed on under the Prijzenbeschikking Goederen en Diensten. The Prices of Registered Medicines Decree therefore prohibited the sale of an imported medicine at a price higher than the manufacturer's basic price last applicable in the country of origin before 15 May 1982 in a similar case for an identical medicine in the same package size, plus or minus the amount by which the manufacturer's basic price has risen or fallen since that date, further increased by the direct costs and by the profit margin applied before the reference date of 15 May 1982 or by the maximum profit margin allowed under the Prijzenbeschikking Goederen en Diensten, and including turnover tax.

5 In the main proceedings, the plaintiffs claimed, in particular, that the legislation in question is contrary to Articles 30, 7, 3 (f), 85 and 86 of the EEC Treaty and to the general principles of Community law in regard to equality, proportionality, legal certainty and proper and exact preparation of legislation. In its defence of the contested Prices of Registered Medicines Decree, the Netherlands contended, in particular, that intra-Community trade was not affected where the national authorities adopted measures against an artificial division of the common market by a dual pricing system, as operated by certain pharmaceutical undertakings.

6 Taking the view that the decision in the case depended on the interpretation of various rules of Community law, the President of the Arrondissementsrechtbank referred to the Court the following questions for a preliminary ruling:

"1. In the light of the argument put forward by the Netherlands, a Member State of the Community, is the Prices of Registered Medicines Decree 1982 to be regarded as:

A measure having an effect equivalent to a quantitative restriction on imports, prohibited by Article 30 of the EEC Treaty?

A form of discrimination prohibited by Article 7 of the EEC Treaty?

2. Do Articles 3 (f) and 5, in conjunction with Articles 85 and 86 of the EEC Treaty, have direct effect?

3. If Question 2 is answered in the affirmative, has the Netherlands by adopting the Prices of Registered Medicines Decree 1982 infringed those articles?

4. Do the principles of equality, proportionality, legal certainty and proper and exact preparation have direct effect in a case such as this?

5. If Question 4 is answered in the affirmative, has the Netherlands by adopting the Prices of Registered Medicines Decree 1982 contravened one or more of those principles?"

The Netherlands market in medicines

7 Before those questions are answered, it is appropriate to consider, in connection with the main proceedings, certain characteristics of the Netherlands market in medicines to which the national legislation at issue refers.

8 It is common ground that the prices of medicines differ appreciably between one Member State and another. Whilst in certain Member States, including Belgium, France and Italy, the level of prices is low, the Netherlands is one of those Member States in which the level of prices of both domestic and

imported medicines is high. Those differences in prices are attributable, in particular, to legislation which allows certain Member States to intervene, either directly or by the adoption of measures in the field of social security, in the formation of prices.

9 The market in medicines is characterized by the presence of very large undertakings which operate in several States, or even on a world scale, and which are able to adjust their pricing policy to the conditions prevailing on a given national market. The ultimate consumer of a medicine generally exerts only a very limited influence on the choice of a medicine, which he most frequently uses after it has been prescribed by a doctor, and he normally has only a limited financial interest in using inexpensive medicines since his costs are covered by social security. In those circumstances, competition between pharmaceutical undertakings is scarcely concerned with the prices of medicines, and the differences in the prises charged by producers according to the country of destination of the medicines can, in principle, easily be passed on to the consumer.

10 On the Netherlands market, approximately 80% of the medicines used are imported from other Member States. On the other hand, approximately 80% of the medicines produced in the Netherlands are intended for export.

11 The contested provisions of the Prices of Registered Medicines Decree seek to reduce the high prices charged on the Netherlands market for imported medicines by depriving producers in Member States in which prices of medicines are low of the possibility of varying their prices from one Member State to another according to the destination of the medicines, in this case the Netherlands market. Foreign producers are placed in a situation in which they are compelled either to accept a reduction in their prices corresponding to the level prevailing in the country of origin or to forego the opportunity of selling their products on the Netherlands market.

Application of Article 30

12 The first part of the first question submitted by the President of the Arrondissementsrechtbank seeks in substance to ascertain whether Article 30 of the EEC Treaty must be interpreted as precluding the adoption of national legislation on the price of imported goods of the kind described above.

13 According to the plaintiffs in the main proceedings, Article 30 must be interpreted as meaning that legislation such as that contested in the present case constitutes a measure having an effect equivalent to a quantitative restriction because it restricts trade by preventing a supplier of medicines from selling his products at profitable prices, since the artificial intervention of certain Member States aimed at restricting the price of medicines makes it impossible in those Member States to charge prices which cover the real costs.

14 The Netherlands Government observes that in the absence of Community legislation in this area, the Member States may adopt rules regulating the prices of goods. The contested Prices of Registered Medicines Decree forms part of a general system concerning the prices of medicines. It does not treat imported medicines less favourably since importers can pass on the manufacturer's basic prices charged in respect of products intended for consumption within the territory of the Member State of manufacture and they can obtain the same trading margins. A Member State is entitled to combat differences in prices from one Member State to another resulting from the defective functioning of the common market and from the operation by certain manufacturers of a dual pricing system.

15 The Commission considers that national measures regulating the prices of imported products on the basis of the manufacturer's basic prices charged in respect of products intended for consumption within the territory of the Member State of manufacture do not constitute in themselves measures having an effect equivalent to quantitative restrictions. However, it would be otherwise if the sale of imported products were rendered impossible or appreciably more difficult than that of domestic products as a result of the price fixed in the Member State of manufacture being too low to cover the actual cost price. According to the Commission, it is for the national court to consider whether that is so in the present case, regard being had to the characteristics of the Community market in pharmaceutical products.

16 Article 30 of the EEC Treaty prohibits, in trade between Member States, all measures having an effect equivalent to a quantitative restriction. According to the well-established case-law of the Court, any measures which are capable of hindering, directly or indirectly, actually or potentially, trade between Member States are to be regarded as measures having such effect.

17 The Court has frequently had occasion to apply those principles to price control systems applicable to domestic products and imported products alike (see judgments of 26 February 1976 in Case 62/75 *Tasca* [1976] ECR 291 and in Joined Cases 88 to 90/75 *Sadam* [1976] ECR 323; judgment of 24 January 1978 in Case 82/77 *van Tiggele* [1978] ECR 25; judgment of 6 November 1979 in Joined Cases 16-20/79 *Danis* [1979] ECR 3277). The Court has held that although such systems do not in themselves constitute measures having an effect equivalent to a quantitative restriction, they may have such an effect when the prices are fixed at a level such that the sale of imported products becomes either impossible or more difficult than that of domestic products.

18 In circumstances such as those referred to in the question raised in the present case, the legislation in question does not apply to domestic products and imported products alike but consists of different sets of rules for the two groups of products, laid down by different decrees and different also as regards their substantive content. Whilst the legislation concerning domestic products freezes prices at a certain date, subject to increases which are permitted on certain conditions, the legislation concerning imported products fixes prices at the level of the selling prices charged by producers in the country of manufacture.

19 Legislation of that kind, which differentiates between the two groups of products, must be regarded as a measure having an effect equivalent to a quantitative restriction where it is capable of making more difficult, in any manner whatever, the sale of imported products.

20 It is in the light of the conditions prevailing on the market of the Member State of importation that it is necessary to assess the compatibility with the rules set out above of legislation such as that at issue in the present case.

21 It is true that legislation freezing prices at a certain date takes account, in substance, as regards domestic products, of the manufacturer's basic price for those products charged at that date to purchasers in the country of manufacture and that that price, in this case, is also the criterion for fixing the price of the imported products. However, the significance of the manufac-

turer's basic price as a criterion varies from one Member State of manufacture to another as a result of the legal provisions and economic conditions which govern the formation of that price in those countries. Thus, legislation such as that at issue in this case has different effects, first of all for the producers of a Member State which freezes prices at a level previously fixed by the producers themselves and, secondly, for the producers of a Member State which itself unilaterally lays down imposed prices.

22 Whilst producers of domestic products and imported products were able, until the entry into force of such differentiating legislation, to profit from the benefits available under the conditions prevailing on the import market, only producers of domestic products may continue to do so after the entry into force of that legislation. However, producers of imported products are bound by the prices fixed in the Member State in which the goods are produced.

23 A situation of that kind can have the effect of placing the sale of imported products at a disadvantage by rendering such sale more difficult, impossible or, in any event, less profitable than the sale of domestic products whenever the level of prices to which, as regards products from other Member States, the legislation of the Member State of importation refers, is lower than that applicable to products from that State. In those circumstances, therefore, it is capable of hindering trade between Member States.

24 That finding leaves intact the possibility which the Member States have of combating inflation and adopting measures intended to control increases in the price of medicines, whatever their origin, on condition that they do so by means of measures which do not place imported medicines at a disadvantage.

25 Accordingly, the answer to the first part of the first question should be that Article 30 of the EEC Treaty precludes a Member State from introducing specific legislation in respect of imported pharmaceutical products which refers to the manufacturer's basic prices usually charged for products intended for consumption within the territory of the Member State in which they are produced, where the legislation applicable to domestic production is based solely on a freeze of the level of prices at a given reference date.

26 In view of the answer given to the first part of the first question, it is no longer necessary to answer the other questions submitted by the President of the Arrondissementsrechtbank.

Costs

27 The costs incurred by the Netherlands Government and by the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. As these proceedings are, in so far as the parties to the main action are concerned, in the nature of a step in the action pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT

in answer to the question submitted to it by the President of the Arrondissementsrechtbank, The Hague, by judgment of 14 July 1982, hereby rules:

Article 30 of the EEC Treaty precludes a Member State from introducing specific legislation in respect of imported pharmaceutical products which refers to the manufacturer's basic prices usually charged for products intended for consumption within the territory of the Member State in which they are produced, where the legislation applicable to domestic production is based solely on a freeze of the level of prices at a given reference date.

Mertens de Wilmars Koopmans Bahlmann Galmot

Pescatore Mackenzie Stuart O'Keeffe Bosco Everling

Delivered in open court in Luxembourg on 29 November 1983.

P. Heim
Registrar

J. Mertens de Wilmars
President