meets those criteria has different effects on the cost prices of the various undertakings by reason of particular features of the economic structure of such undertakings which manufacture or market such products is irrelevant to the application of that provision.

In Case 32/80

REFERENCE to the Court under Article 177 of the EEC Treaty by the Arrondissementsrechtbank [District Court] Roermond, The Netherlands, for a preliminary ruling in the action pending before that court between

OFFICIER VAN JUSTITIE [Public Prosecutor]

and

J. A. W. M. J. KORTMANN

on the interpretation of Article 36 of the EEC Treaty,

THE COURT

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

Advocate General: F. Capotorti
Registrar: A. Van Houtte

gives the following

JUDGMENT

Facts and Issues

The judgment making the reference 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 procedure

In this case a preliminary question has been referred to the Court of Justice by the Arrondissementsrechtbank Roer-

mond, The Netherlands, before which criminal proceedings were instituted against Mr Kortmann, a Netherlands trader, who was charged with infringing certain requirements of the rules on the manufacture and marketing of medicinal products.

The basis of those rules is the law relating to the supply of medicinal products (Wet op de Geneesmiddelenvoorziening) of 28 July 1958 (Staatsblad 408). It lays down as a requirement of the production and supply of pharmaceutical preparations and proprietary medicinal products the prior registration of such products and preparations by a board which approves them and authorizes their uses.

An order of 8 September 1977 (Staatsblad 537) on the registration of medicinal products (Besluit Registratie Geneesmiddelen, hereinafter referred to as "the Registration Order") governs the implementation of the required registration. The procedure for registration is the same whether it is requested by the manufacturer of the product or the manufacturer's appointed importer in the Netherlands. On the other hand different procedures are laid down where the registration is requested by a "parallel importer". These specific procedures are described in Article 23 of the Registration Order, which was adopted following the judgment of the Court of Justice of 20 May 1976 (Case 104/75 *De Peijper* [1976] ECR 613) in order to comply with that judgment.

That article provides that where an importer intends to effect parallel imports of pharmaceutical products from another Member State they must first be registered, albeit in a simplified form, since they have previously been registered and checked at the request either of the manufacturer or of the duly appointed importer.

The essential provisions of the simplified system of monitoring thereby brought into force are formed by the said Article 23 (2) and (3) of the Registration Order which reads as follows:

Article 23 (2)

"Any person wishing to import from a Member State a pharmaceutical product as marketed in that Member State may, on application, and in accordance with the following provisions be entered by the Board in the register in question as the holder of the registration:

(a) Where the product in question:

(1) either has the same qualitative and quantitative composition as a pharmaceutical product registered in accordance with an application within the meaning of Article 3 (1) of the Law or is practically the same and has the same effect as such registered pharmaceutical product;

(2) is prepared either by the manufacturer of the registered product or by another manufacturer of the group to which the manufacturer of the registered product belongs or by a licensee of the manufacturer of the registered product;

(3) is made up in the same pharmaceutical form as the registered products referred to in subparagraph (1);

(b) Where the product is a proprietary medicinal product which has been authorized both in the Netherlands and in the Member State concerned in accordance with Articles 9 and 11 of Directive 75/319/EEC."

Article 23 (3)

"An application within the meaning of paragraph (2) submitted in respect of a product referred to in subparagraph (a) therefore must contain the following information:

(a) the name and address of the applicant;

(b) the name of the Member State from which the pharmaceutical product is to be imported;

(c) the name under which the product to be imported is marketed in the Member State referred to in subparagraph (b);

(d) the name and address of the person who is responsible for the marketing of the product in the Member State referred to in subparagraph (b);

(e) a statement of the pharmaceutical form of the product to be imported;

(f) the name of the registered pharmaceutical product referred to in paragraph (2) (a) (2) and the number under which that product is entered in the register;

(g) the name under which the product to be imported is to be marketed."

Pursuant to Article 4 (6) and Article 5 (2) of the Law of 1958 the Registration Order provides for the collection of various charges *inter alia* from traders who have requested and obtained a registration of medicinal products.

The scale of these charges was fixed by an order *(Vergoedingsbesluit)*, hereinafter referred to as "the Charges Order", of the Secretary of State for Health and the Environment of 15 December 1977 (Staatscourant, 251). Two of these charges are at issue in the main action:

(a) a *single* fee charged on the registration of a pharmaceutical product. It amounts in principle to HFL 2 668 for the manufacturer or authorized importer; it is reduced to HFL 667 in the case of the simplified registration by parallel importers (Charges Order, Articles 6 and 7);

(b) an *annual* fee of HFL 890 (proprietary medicinal product) or HFL 71.50 (preparation) for each product registered, which is intended to cover the costs of monitoring and is imposed at the same rate on manufacturers, authorized importers and parallel importers (Charges Order, Article 9).

Mr Kortmann is charged with marketing pharmaceutical products which he imported in parallel from other Member States without applying for or obtaining the simplified registration for them. In his defence he argues that the acts with which he is charged do not constitute offences because the provisions of the Registration Order, read together with those of the Charges Order, are incompatible with Article 30 *et seq.* of the EEC Treaty.

The Arrondissementsrechtbank Roermond, to which the matter was referred on appeal, considered that the action raised questions on the interpretation of Community law and, by a judgment of 4 December 1979, submitted a request to the Court of Justice of the European Communities for a preliminary ruling on the following question:

"Given that:

(a) certain pharmaceutical products are lawfully in free circulation in one or more Member States in the sense

that the permits required under national law for those pharmaceutical products have been issued to the manufacturer or, where appropriate, to those who are responsible for putting the pharmaceutical products into circulation in each of the Member States; and

(b) third parties may be aware that such permits have been granted in each of the Member States because the fact has been officially published or has become generally known by some other means; and

(c) a (parallel) importer of medicinal products established in one of the Member States imports into the Member State in which he is established the pharmaceutical products which are in circulation as described above,

do the exceptions to the rules relating to the free movement of goods within the EEC, particularly Article 36 of the EEC Treaty in so far as it relates to the protection of health and life of humans, justify the authorities of the importing Member State permitting imports of those pharmaceutical products only on payment of a registration charge, and if so, what standards should be applied to the amount and frequency of the payments and the system governing payments?"

The judgment making the reference was received at the Court Registry on 24 January 1980.

In accordance with Article 20 of the Protocol on the Statute of the Court of Justice of the EEC observations were submitted by the Netherlands Government, represented for that purpose by Mr Italianer, and by the Commission of the European Communities, represented for that purpose by Mr Beschel, a member of its Legal Department, assisted by A. F. de Savornin Lohman of the Rotterdam Bar.

On hearing the report of the Judge-Rapporteur and the views of the Advocate General the Court decided to open the oral procedure without holding a preparatory inquiry.

II — Written observations submitted under Article 20 of the Protocol on the Statute of the Court of Justice of the EEC

A — Observations of the Netherlands Government

(a) Examination of the rules at issue

The Netherlands Government first of all gives an account of the national legislation on the registration of medicinal products as enacted following the judgment of the Court of Justice of 20 May 1976 in the above-mentioned Case 104/75, *De Peijper*. The Registration Order requires medicinal products which an importer proposes to import in parallel to be registered although by definition such products have already been registered by the manufacturer or by his authorized distributor. However, this procedure constitutes a simplified registration which is intended to establish whether the product to be imported in parallel and whose marketing has been authorized in another Member State has a composition identical or virtually identical, qualitatively and quantitatively,

to that of the product which has previously been registered in the Netherlands. That prior check on the identity of a product is necessary in view of the fact that manufacturers of pharmaceutical products sometimes vary the composition or packaging of the same product from one Member State to another. When a parallel importer submits an application for the registration of a product he is required to supply only a limited number of facts permitting the College ter Beoordeling van Geneesmiddelen [medicinal products registration board] to check that the product imported in parallel is identical with that already registered in the Netherlands. Furthermore each consignment of medicinal products imported in parallel undergoes a check when it is actually imported in order to establish that it corresponds to the registered product. That separate check was established following the said *De Peijper* judgment as a substitute for the documents relating to the first check which a parallel importer is not in a position to submit. Neither that second check nor the fee collected therefor is at issue in this case. Finally the medicinal products imported either in parallel or officially by or in the name of the manufacturer also undergo a disqualifying inspection relating to the conditions of storage and must comply with other conditions laid down by law for the supply of medicinal products.

The registration and monitoring entail considerable expense which justifies the payment of a fee which, furthermore, covers only a part of the expenses actually incurred. In its examination of the Charges Order the Netherlands Government stresses the distinction between the annual fees and the initial registration fee.

The initial *registration fee* fixed for the parallel importer at the lowest rate, HFL 667, and calculated on the basis of the average cost takes account of the fact that such importations are less onerous for the registration board since the therapeutic effect and the relative harmlessness of the medicinal products in question have already been checked although the products still require a number of investigations and administrative measures.

The *annual fee,* which is also calculated on the basis of the average cost, is in principle identical for all applicants and there is a possibility of an exemption or a reduction in the amount without discrimination for parallel importers as well as for other persons liable.

(b) Examination of the question submitted

The Netherlands Government states first of all that the payment of fees does not and cannot affect consideration of the application for registration or the final registration of medicinal products imported in parallel. The medicinal product imported in parallel must be registered even though the single fee has not been paid and the registration, which includes the right of marketing the product, cannot be cancelled if the annual monitoring fee remains unpaid. Mr Kortmann, by adopting the view that he could not and should not pay the fee, was thus wrong in considering himself released from the duty to apply for and obtain the registration.

Turning next to the question submitted, the Netherlands Government observes that it falls into two parts: the Arrondissementsrechtbank asks: (1) whether Article 36 authorizes a Member State to make the importation of a medicinal product conditional on payment of a fee for its registration. (2) If so, whether that fee must be examined in the light of certain rules and what those rules are. Nevertheless it is not clear whether the first part of the question concerns the fact that the importation of products is *subject to* the collection of a fee (point (1) (a)) or whether it refers to the fact that the fee must have been *paid before* the importation can be effected (point (1) (b)). Since those two aspects give rise to separate problems the Netherlands Government considers them separately.

Point (1) (a): May importation be made conditional on the collection of a fee?

The Netherlands Government observes that although the registration and monitoring prescribed by the above-mentioned legislation constitute measures having an effect equivalent to a restriction on imports within the meaning of Article 30 they are nevertheless justified under Article 36 of the Treaty.

Furthermore such measures are applied to all medicinal products, both those produced on the national territory and those imported directly or in parallel. In addition they form part of a system of registration and monitoring set up by Council Directives 65/65/EEC of 26 January 1965 (Official Journal, English Special Edition 1965-1966, p. 20) and 319/75/EEC (Official Journal 1975, L 147, p. 13) on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. Finally the above-mentioned judgment in the case of *De Peijper* does not preclude the registration of pharmaceutical products imported in parallel.

The Government of the Netherlands nevertheless concedes that the fact that the measures in question are in accordance with Article 36 is not by itself sufficient to justify the charging of the fees at issue since the exception laid down in Article 36 relates solely to the quantitative restrictions and measures having an equivalent effect referred to in Article 30 *et seq.* and not to charges having an equivalent effect as was stated in the judgment of the Court of Justice of 10 December 1968 (Case 7/68 *Commission* v *Italy* [1968] ECR 423). It follows from that judgment that in considering whether the fees at issue are in accordance with Community law regard must be had both to Article 12 *et seq.* (charges having an effect equivalent to customs duties) and to Article 95 (discriminatory internal taxation). The Netherlands Government considers on the basis of the judgment of the Court of 15 December 1976 (Case 35/76, *Simmenthal* [1976] ECR 1871) that the fees at issue do not constitute charges having an effect equivalent to customs duties within the meaning of Article 12 of the Treaty as they are applied in accordance with the same criteria to imported products and to products manufactured on the national territory. They accordingly constitute internal taxation within the meaning of Article 95 of the Treaty.

The reply to the first part of the first question might thus be that:

"The fees charged for the registration and monitoring of imported medicinal products are compatible with Community law in so far as similar fees are charged in accordance with the same criteria for medicinal products manufactured on the national territory. Such fees constitute internal taxation within the meaning of Article 95 of the Treaty

even though under national law they amount to payment for a service (vergoedingen)."

Point (1) (b): May the importation be made conditional upon the prior payment of the fee?

Consideration of this aspect of the problem appears less essential in view of the fact that the rules in question do not, either in law or in fact, make the payment of the various fees a condition of the registration of medicinal products imported in parallel. Nevertheless having regard to the case-law in accordance with which the Court of Justice refrains from appraising the relevance of questions submitted by the court making the reference the Netherlands Government proceeds to consider the question. It considers on the basis of the judgment of the Court of 29 June 1978 (Case 142/77 *Statens Kontrol med ædle Metaller* [1978] ECR 1543) that the reply must be that it is in principle in accordance with the Treaty to make the marketing of the products in question conditional on the payment of internal taxation within the meaning of Article 95 of the Treaty, subject to the prohibition of discrimination.

Point (2): The criteria which the amount of the fee must meet

Since the above examination has shown that the question submitted by the Arrondissementsrechtbank relates to internal taxation the provision to which reference must be made is Article 95. That provision requires that taxation must be imposed in accordance with the same criteria and on the same basis for imported products as for domestic products and excludes all discrimination. On the other hand within the framework of Article 95 the question whether or not the fee charged corresponds to the costs actually incurred is irrelevant. Since in the case of both domestic and imported products the registration fee is calculated on the basis of the costs of registration and monitoring the requirements of Article 95 are met. It might nevertheless be possible to detect discrimination if the products for which the same fee is charged were so different one from another that equality of treatment in fact constituted discrimination. That aspect of the problem was taken into account since the *single payment* charged on submission of the application for registration of medicinal products imported in parallel is much lower than that charged for the first registration precisely because it is a simplified registration. On the other hand since the *annual* monitoring fees are in principle the same for all medicinal products no objection can be advanced on the basis of Article 95.

The Netherlands Government accordingly considers that with regard to the second part of the question the reply might be as follows:

"Article 95 prohibits all discrimination against imported products and requires that taxation should be imposed in accordance with the same criteria and on the same basis for imported products and domestic products; these requirements are in particular fulfilled where considerable differences in the processes to be carried out with regard to a given category of imported products, as distinct from other products, are reflected in a general difference in the fees charged for the various categories of products; these requirements are also fulfilled where the tax rules make provision for the possibility of an exception in cases in which a system of payments on the basis of the average amount of such expenses would produce a completely unreasonable result and where advantage is in fact taken of that provision."

B — Observations of the Commission

(1) The state of harmonization of the market in medicinal products

After describing the state of the market in medicinal products the Commission proceeds to analyse the directives on harmonization adopted in this sphere. It observes first of all that the authorizations for placing such products on the market of a Member State do not concern the manufacturer or his importer but the proprietary medicinal product as such following its examination and approval by the national authorities. It observes secondly that the system adopted in the directives on harmonization is directed neither towards the establishment of a system of central authorizations at Community level nor towards a system of reciprocal recognition of national authorizations but to a system "in which the national authorizations from one Member State to another form the basis of participation in the national markets". The national (territorial) authorizations are thus accepted as the basis and the directives are intended only to remove obstacles arising from that system of national authorizations. The Commission observes finally that the problems raised by parallel imports were not dealt with in the directives in question.

(2) The question submitted

According to the Commission a procedure for authorization of the kind established by the national provisions in question constitutes a measure having an effect equivalent to a quantitative restriction within the meaning of Article 30. Such a measure can be justified only under Article 36 of the Treaty. If it is not so justified it follows automatically that all related financial charges are also *ipso facto* incompatible with the Treaty. Where on the other hand, as in this case, the lawfulness of the measure is not directly called in question the lawfulness of the fees must be appraised in the light of Article 9 *et seq.* (prohibition of customs duties and of charges having equivalent effect) and of Article 95 of the Treaty (prohibition of discriminatory internal taxation). The Commission accordingly proceeds to consider whether the two fees at issue are in accordance with this point of Community law.

The single registration fee in the case of parallel imports

(a) With regard to Articles 9 and 12 of the Treaty

Proceeding on the basis of the idea expressed in the case-law of the Court of Justice that the prohibition of charges having an effect equivalent to customs duties is intended to prevent in trade between Member States the imposition of any pecuniary charge based on the fact of crossing the frontier of a Member State by goods moving within the Community, two criteria must be examined, the "importation of goods" and the "crossing of frontier". According to the Commission the registration procedure consists, in the case of a second applicant for registration, in checking by means of a sample, whether the goods may be marketed in the Netherlands. In the case of a product already lawfully marketed in another Member State with an identical form and composition any pecuniary charge imposed on the occasion of its crossing the frontier constitutes a charge having

an equivalent effect and it is of little relevance whether that charge is imposed when the frontier is crossed or at another stage.

The position would be different only if that charge constituted the consideration for a specific service actually rendered to the importer. However, that is not the case here as the acts of an administration adopting measures of control in the general interest of the protection of health cannot be considered, according to the case-law of the Court, as a service rendered to the importer.

(b) Article 95 of the Treaty

A fee charged on an imported product on the occasion of its crossing the frontier also falls outside the concept of a tax having an effect equivalent to a customs duty if it comes within a general system of internal taxation systematically embracing domestic and imported products in accordance with the same criteria. In that case regard must be had to Article 95 in judging whether it is in accordance with the Treaty.

Two criteria must be taken into consideration for the purposes of Article 95. First the revenue from the tax must do no more than cover the costs. On the basis of the above-mentioned case of *De Peijper* the Commission maintains that the national authority must in the first place justify the amount of its expenses. In the second place the rules may not draw a distinction between the first person to be registered and other applicants. If a comparison is made between the first and subsequent registrations in the Netherlands rules it may be seen that in both cases the basic factor is the protection of public health and that on each occasion the registration is intended to ensure that those provisions are in fact observed. Nevertheless certain specific features of the rules in question may give rise to discrimination:

(a) If the position were that the person first registered was merely required to contribute to the costs whilst the second and subsequent applicants were required to meet the entire costs, there might be discrimination;

(b) The Netherlands rules set up a system of fees in order to cover the costs incurred by the authorities in checking an application for registration. When an application for registration is submitted for a number of packagings of the same product the rules prescribe a reduction of 50% for the first registration because the checks carried out on the second and subsequent packagings are more restricted than on the first (Article 6 (2) of the Charges Order). It might be expected on the basis of that principle that the second and subsequent applicants would enjoy corresponding reductions of 50% in the initial rate. However, according to Article 7 of the Charges Order that is not so;

(c) In accordance with Article 4 (3) of the Registration Order the Minister is empowered in certain special conditions to grant at the request of the first person registered partial exemption from the fee payable for the first registration. No such provision is made for the second and subsequent persons registered.

The Commission considers that there does not exist in this case a general system of internal taxation applying systematically and on the same criteria to domestic and imported products. It considers, on the basis of the judgment of the Court of 5 February 1976 (Case 87/75 *Bresciani* [1976] ECR 129), that it is necessary to ascertain whether the imported product and the national product are taxed at a similar stage of production and distribution. Each occasion on which a sufficient degree of similarity cannot be established constitutes a breach of the principle of non-discrimination laid down by Article 95 and the charge in question has an effect equivalent to a customs duty.

In this case scrutiny of the system shows appreciable differences. The first application for registration concerns the authorization of a specific medicinal product as such, the characteristics of which must be established since the national authorities cannot be deemed to know them. Furthermore the examination covers all the properties of the medicinal product for which the registration is requested and finally, following the examination, the medicinal product in question is authorized as such on the national market.

On the other hand the registration of parallel products concerns the registration of a trader in relation to a medicinal product which, by reason of the presumption that it meets the requirements, must be deemed to be known in all its details to the national authorities so that the examination may be limited to the finding that a medicinal product meets those requirements and more detailed examination is required only in exceptional circumstances.

On those grounds the Commission tends to the view that the very stringent criteria adopted by the Court for the application of Article 95 are not met so that the matter must be approached on the basis of Article 9 *et seq.* of the Treaty.

The annual monitoring fee

This fee, which is the same for the person first registered, the importer and the parallel importer, appears formally to comply with the criterion of identical treatment under Article 95 of the Treaty.

The question submitted by the national court however concerns the amount and frequency of the payments. Its purpose is to enquire whether under the Netherlands system the parallel importer is placed on an equal footing with the person first registered. In this respect the Commission finds appreciable differences.

Whilst the person first registered possesses a file for each packaging of his product on the basis of which he is entitled to market it in the Netherlands regardless of the Member State in which the product was manufactured or from which it was imported, the files of the second and subsequent persons registered cover only importation of the product from a specified Member State. In extreme cases parallel importers must thus effect eight registrations for each packaging of the same product and pay the annual fee eight times. This provision is discriminatory in itself and it is necessary further to consider whether the fee constitutes a covering of the relevant costs. The Commission considers that whilst it may be possible for the Netherlands authorities to justify a fee in this connexion of HFL 890, on the other hand it would be difficult to concede that the multiplication of that amount is justified by a corresponding increase in the burden of work. The Commission

raises the point whether the derogative provision in Article 15 (4) of the Registration Order sufficiently offsets that factor since no parallel importer is entitled to an exemption from or a reduction in the annual fee payable by him.

For the sake of completeness the Commission raises the question whether regard should not be had to the fact that the position on the market of the parallel importer is adversely affected, as compared with that of the person first registered, by his obligation to pay other dues charged by the same authorities in addition to the fees which are at issue in the main action. According to the Commission's information parallel importers are liable to pay substantial sums pursuant to Article 47 (1) of the Besluit Farmaceutische Produkte [Pharmaceutical Products Order] (Staatsblad 538) read together with Article 13 of the Charges Order. The Commission has begun an investigation into this matter but it appears at present that, even on the supposition that such checks may be authorized otherwise than by sampling, the relative charges would have to be considered contrary to Community law. Although this is not a point to be settled during the present proceedings it may be difficult for the national court to disregard such charges in the course of a detailed appraisal of the parallel importer's marketing opportunities.

The Commission refrains from making specific suggestions as to the wording of the reply to the question submitted but requests the Court to have regard to the considerations which it has set out.

III — Oral procedure

At the sitting on 1 October 1980 the defendant in the main action, represented by H.P. Ruysink, of the Maastricht Bar, the Commission of the European Communities, represented by M. Beschel, acting as Agent, assisted by A. F. de Savornin Lohman, of the Rotterdam Bar, and the Netherlands Government, represented by A. Bos, acting as Agent, assisted by R. Drost, acting as expert adviser, presented oral argument.

The Advocate General delivered his opinion at the sitting on 29 October 1980.

Decision

1 By a judgment of 4 December 1979, which was received at the Court on 24 January 1980, the Arrondissementsrechtbank [District Court], Roermond, referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty a question which relates to the interpretation of Article 36 of that Treaty and which is worded as follows:

"Given that:

(a) certain pharmaceutical products are lawfully in free circulation in one or more Member States in the sense that the permits required under national law for those pharmaceutical products have been issued to the manufacturers or, where appropriate, to those who are responsible for putting the pharmaceutical products into circulation in each of the Member States; and

(b) third parties may be aware that such permits have been granted in each of the Member States because the fact has been officially published or has become generally known by some other means; and

(c) a (parallel) importer of medicinal products established in one of the Member States imports into the Member State in which he is established the pharmaceutical products which are in circulation as described above,

do the exceptions to the rules relating to the free movement of goods within the EEC, particularly Article 36 of the EEC Treaty in so far as it relates to the protection of health and life of humans, justify the authorities of the importing Member State permitting imports of those pharmaceutical products only on payment of a registration charge, and if so, what standards should be applied to the amount and frequency of the payments and the system governing payments?"

2 That question has been raised in the context of criminal proceedings instituted against a Netherlands trader who is a "parallel importer" of pharmaceutical products in the Netherlands and who has been charged with having held for sale, or having sold, delivered or dealt in, a certain number of proprietary medicinal products within the meaning of Article 1 (1) (h) of the Netherlands Law relating to the supply of medicinal products (Wet op de Geneesmiddelenvoorziening) which had not first been registered as required by Article 3 of that Law. It is apparent from both the considerations set out in the judgment making the reference and the wording of the question that the accused did not comply with that requirement because two fees, one single and the other annual, are payable on registration, and because he considers that the requirement of registration in conjunction with the

requirement to pay the said fees, which he considers excessive, constitutes a measure having an effect equivalent to a quantitative restriction on imports which is incompatible with Article 30 of the Treaty and which does not qualify for the exception laid down in Article 36 of the Treaty.

3 The Arrondissementsrechtbank has submitted the question set forth above in order to be in a position to decide whether the national rules, in so far as they require payment of these fees, are in accordance with Community law.

4 In order to provide a reply which may be of assistance to the national court it is necessary to take into account the fact that the provisions in question were enacted by the Netherlands authorities following the judgment delivered by the Court on 20 May 1976 in Case 104/75 *De Peijper* [1976] ECR 613.

5 That judgment also concerned parallel imports of pharmaceutical products and it found that such imports were rendered impossible in practice by the fact that the Netherlands authorities made the authorization to place such products on the market conditional upon the production of documents, intended to enable medical checks to be carried out, which were identical with the documents already lodged by the manufacturer or his duly appointed importer. The judgment found that if the manufacturer or his duly appointed importer refused to provide the parallel importer with a copy of those documents, which they alone held, the parallel importer could not meet the requirements of the national authorities and his request for registration was accordingly refused.

6 On the basis of those findings of fact the Court declared that national rules or practices which make it possible for a manufacturer and his duly appointed representatives to enjoy a monopoly of the importation and marketing of a pharmaceutical product simply by refusing to produce the documents relating to the pharmaceutical product in general or to a particular consignment thereof must be regarded as being unnecessarily restrictive and cannot therefore come within the exception specified in Article 36 of the Treaty, unless it can be proved that any other rules or

practices would obviously be beyond the means which can be reasonably expected of an administration operating in a normal manner.

7 The Court added that if a number of variants of a medicinal preparation exist which differ from one Member State to another and if those differences have a therapeutic effect there is justification for treating those variants as different medicinal preparations for the purposes of authorizing them to be placed on the market and as regards the requirement of producing the relevant documents enabling medical checks to be carried out, it being understood that for each of the authorization procedures the answer provided above remains valid if there is only a single version of the medicinal preparation.

8 After that judgment the Netherlands authorities enacted rules, namely Article 23 of the Besluit Registratie Geneesmiddelen of 8 September 1977 (Staatsblad 1977, No 537), which provided the parallel importer of a proprietary medicinal product previously registered at the request of the manufacturer or his appointed representative with a simplified procedure for registration intended solely to ascertain whether the composition of the product which the parallel importer proposes to import is "the same" or "practically the same" as that of the product which has already been registered.

9 In view of the simplified nature of that second registration the parallel importer is required to pay a single fee amounting to 25% of that charged when the medicinal product was first registered at the request of the manufacturer or his duly appointed representative. The second registration also entails payment of an annual fee amounting to HFL 687 which is intended to cover the costs of inspecting the products in question after they are placed on the market. The amount of this annual fee is the same for domestic products and imported products alike and in the case of imported products no distinction is made depending on whether they were imported in parallel or directly by the foreign manufacturer or his duly appointed representative.

The interpretation of Article 36

10 As the Court held in the above-mentioned *De Peijper* judgment, in the case of imported pharmaceutical products which have already been registered at the request of the manufacturer or the duly appointed importer, Article 36 does not prevent national authorities from checking whether the products imported in parallel are identical to those which have already been registered or, where variants of the same medicinal products are placed on the market, whether the differences between those variants have no therapeutic effect. That check must however extend only to verifying whether the products so conform and the Member State in question must have required the manufacturer or authorized importer to provide full information regarding the different forms in which the medicinal products in question are manufactured or marketed in the various Member States by either the manufacturer himself, subsidiary or related undertakings, or undertakings manufacturing such products under licence.

11 A monitoring procedure which is in accordance with the requirements of Article 36 is not deprived of its justification, within the meaning of that provision, by virtue of the fact that it gives rise to the collection of fees of the kind described by the national court. On the other hand such fees may not be considered compatible with the Treaty on the sole ground that they are charged in consequence of a measure adopted by a State which is justified within the meaning of Article 36. The exemption provided for in Article 36 in fact relates exclusively to quantitative restrictions on imports or exports or measures having equivalent effect. It may not be extended to customs duties or to charges having equivalent effect which, as such, fall outside the compass of Article 36.

12 It follows that the question whether such fees are permissible must be appraised in relation to Articles 9 and 13 or, where appropriate, Article 95 of the Treaty.

13 It thus appears that, in order to provide the national court with a reply which is of assistance to it, it is necessary to consider whether fees of the kind in question fall under the prohibitions laid down in those provisions.

The interpretation of Article 13 of the Treaty

14 According to the settled case-law of the Court of Justice the prohibition, in trade between Member States, of all customs duties and of all charges having equivalent effect refers to all charges demanded on the occasion of or by reason of importation and which are imposed specifically on imported products and not on similar domestic products.

15 Since this prohibition does not admit of any distinction according to the aim in view in levying the pecuniary charges for the abolition of which it provides, it also includes fees demanded for public health inspections carried out by reason of the importation of goods.

16 The position would be different only if the pecuniary charges related to a general system of internal dues applied systematically to categories of products in accordance with objective criteria without regard to the origin of the products.

17 It is apparent from the foregoing considerations that fees of the type referred to by the national court do not display the essential features of charges having an effect equivalent to a customs duty. In fact fees demanded of a parallel importer of pharmaceutical products either in the form of a single fee on the occasion of the registration of the pharmaceutical products which he proposes to import or in the form of an annual fee charged in order to meet the costs of procedures intended to check whether the products subsequently marketed are identical to the registered product do not constitute such charges where those fees form part of a general system of internal fees charged both on the occasion of the registration of medicinal products produced in the Member State in question and on the occasion of the registration of medicinal products imported either directly by the manufacturer or his appointed importer or as so-called "parallel imports" and where such fees are charged, in the case of parallel imports, in accordance with criteria identical or comparable to the criteria employed in determining the fees on domestic products.

18 Contrary to the views of the Commission, it is not the case that "each occasion on which a sufficient degree of similarity cannot be established constitutes a breach of the principle of non-discrimination laid down by

Article 95 and the charge in question has an effect equivalent to a customs duty". A discriminatory internal tax does not automatically constitute a charge having an effect equivalent to a customs duty. A charge in the form of an internal tax may not be considered as a charge having an effect equivalent to a customs duty unless the detailed rules governing the levying of the charge, or its use if the charge in question is allocated to a particular use, are such that in fact it is imposed solely on imported products to the exclusion of domestic products.

Article 95 of the Treaty

19 The national court observes that the accused maintains that the system of fees only appears to accord equal treatment to producers and authorized importers on the one hand and parallel importers on the other and that in reality it discriminates against the latter and in fact re-establishes for the benefit of the former the monopoly in imports of which the Court disapproved in its judgment of 20 May 1976.

20 The issue which has thus been raised prompts the Court to point out first of all that for the proper application of Article 95 of the Treaty it is the treatment of the imported product as opposed to the domestic product which must be compared and not the treatment of two imported products, identical or similar, depending on whether they are imported by means of one form of trading rather than another. However, so far as the disposal of the case submitted to the national court is concerned, the result is the same since, in order to satisfy the requirements of Article 95, it is necessary that domestic products on the one hand and imported products in general on the other hand should be subject to a system of internal taxation which is imposed on them in accordance with criteria which do not discriminate against imported products.

21 The papers in the case and the statements in the judgments making the reference show that both the single fee and the annual fee required for registration apply to both domestic pharmaceutical products and products from other Member States, whether imported in parallel or not. The detailed rules which are laid down for parallel imports are, however, different.

22 It is therefore necessary to consider whether those rules are compatible with the prohibition of discrimination contained in Article 95.

23 With regard to the single fee two rules have been mentioned by the national court. The first is that the fee is reduced to 25% of the amount of the fee charged on the occasion of the first registration of the product by the national or foreign manufacturer or the appointed importer having regard to the fact that the registration in question is simplified.

24 A national system of fees which, for pharmaceutical products as a whole, draws a distinction between the amount of the fees charged on the occasion of a first registration and the amount charged on the occasion of a second registration by reason of the simplified nature of the latter is not incompatible with Article 95 of the Treaty. That provision does not require the abolition of all fees in the second case provided that, having regard to the difference in the two registrations, a reasonable proportion is maintained in fixing the amount of such fees.

25 The second rule mentioned by the national court consists in the fact that the competent authority may reduce the amount of the single fee at the request of domestic or foreign manufacturers or appointed importers but that is not possible in the case of products imported in parallel.

26 The Netherlands Government disputes that the national legislation in question in fact draws such a distinction whilst the Commission appears to accept that this is the case. It is for the national court to settle this matter. If the reduction granted in respect of the first registration is so large that it in fact eliminates the difference between the fees charged for the two registrations, it is necessary, if Article 95 is to be correctly applied, that the reduction be taken into account, where the importer in question so requests, in fixing the fee charged in respect of a second registration.

27 With regard to the annual fees, whose amount is recognized to be the same for all products, the alleged discrimination against parallel importers consists in the circumstance that, whilst national manufacturers, manufacturers in

other Member States and appointed importers are able to market a small number of types of registered products since each type is marketed in a large number of units which gives a large turnover, the parallel importer must import a very much wider variety of types of different products in order to attain a reasonable turnover and each type is liable to a reduced single fee but to an annual fee at the full rate. In the case of the parallel importer the burden of such fees is thus shared by a very much smaller number of units so that importation is no longer profitable.

28 Article 95 is complied with where a tax of the same amount affects the cost prices of different undertakings unequally by reason of particular features of their economic structure. It is sufficient that the internal tax applies in accordance with the same criteria, objectively justified by the purpose for which the tax was introduced, to domestic products and imported products so that it does not result in the imported product's bearing a heavier charge than that borne by the similar domestic product.

29 The reply to the question submitted should therefore be:

1. A monitoring procedure which is in accordance with the requirements of Article 36 is not as such deprived of its justification within the meaning of that provision by virtue of the fact that it gives rise to the collection of fees of the kind described by the national court.

2. Such fees are not justified on the sole ground that they are charged in consequence of a measure adopted by a State which is justified within the meaning of Article 36.

3. Fees demanded of a parallel importer of pharmaceutical products either in the form of a single fee on the occasion of the registration of the pharmaceutical products which he proposes to import or in the form of an annual fee charged in order to meet the costs of procedures intended to check whether the products subsequently marketed are identical to the registered product do not constitute charges having an effect equivalent to customs duties where those fees form part of a general system of internal fees charged both on the occasion of the registration of medicinal products produced in the Member State in question and on the occasion of the registration of medicinal products imported either directly by the manufacturer or his appointed importer or as what are known as parallel

imports and where such fees are charged, in the case of parallel imports, in accordance with criteria identical or comparable to the criteria employed in determining the fees on domestic products.

4. Article 95 is complied with where an internal tax applies in accordance with the same criteria, objectively justified by the purpose for which the tax was introduced, to domestic products and imported products so that it does not result in the imported product's bearing a heavier charge than that borne by the similar domestic product. The fact that a charge which meets those criteria has different effects on the cost prices of the various undertakings by reason of particular features of the economic structure of such undertakings which manufacture or market such products is irrelevant to the application of that provision.

Costs

30 The costs incurred by the Government of the Netherlands and 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 Arrondissementsrechtbank, Roermond, by judgment of 4 December 1979, hereby rules:

1. **A monitoring procedure which is in accordance with the requirements of Article 36 of the EEC Treaty is not as such deprived of its justification within the meaning of that provision by virtue of the fact that it gives rise to the collection of fees of the kind described by the national court.**

2. **Such fees are not justified on the sole ground that they are charged in consequence of a measure adopted by the State which is justified within the meaning of Article 36 of the EEC Treaty.**

3. **Fees demanded of a parallel importer of pharmaceutical products either in the form of a single fee on the occasion of the registration of the pharmaceutical products which he proposes to import or in the form of an annual fee charged in order to meet the costs of procedures intended to check whether the products subsequently marketed are identical to the registered product do not constitute charges having an effect equivalent to customs duties where those fees form part of a general system of internal fees charged both on the occasion of the registration of medicinal products produced in the Member State in question and on the occasion of the registration of medicinal products imported either directly by the manufacturer or his appointed importer or as what are known as parallel imports and where such fees are charged, in the case of parallel imports, in accordance with criteria identical or comparable to the criteria employed in determining the fees on domestic products.**

4. **Article 95 of the EEC Treaty is complied with where an internal tax applies in accordance with the same criteria, objectively justified by the purpose for which the tax was introduced, to domestic products and imported products so that it does not result in the imported product's bearing a heavier charge than that borne by the similar domestic product. The fact that a charge which meets those criteria has different effects on the cost prices of the various undertakings by reason of particular features of the economic structure of such undertakings which manufacture or market such products is irrelevant to the application of that provision.**

Mertens de Wilmars Pescatore Mackenzie Stuart Koopmans

O'Keeffe Bosco Touffait

Delivered in open court in Luxembourg on 28 January 1981.

A. Van Houtte
Registrar

J. Mertens de Wilmars
President