where such derogations are justified for the purpose of safeguarding rights which constitute the specific subject matter of this property.

2. The exercise, by the patentee, of the right which he enjoys under the legislation of a Member State to prohibit the sale, in that State, of a product protected by the patent which has been marketed in another Member State by the patentee or with his consent is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the Common Market. In this connexion, it is of no significance to know whether the patentee and the undertakings to which the latter has granted licences do or do not belong to the same concern. It is also a matter of no significance that there exist, as between the exporting and importing Member States, price differences resulting from governmental measures adopted in the exporting State with a view to controlling the price of the product.

3. The proprietor of a patent relating to a pharmaceutical product cannot avoid the incidence of Community rules concerning the free movement of goods for the purpose of controlling the distribution of the product with a view to protecting the public against defects therein.

4. Article 42 of the Act concerning the Conditions of Accession and the Adjustments to the Treaties cannot be invoked to prevent importation into the Netherlands, even before 1 January 1975, of goods put onto the market in the United Kingdom by the patentee or with his consent.

5. Article 85 of the Treaty is not concerned with agreements or concerted practices between undertakings belonging to the same concern and having the status of parent company and subsidiary, if the undertakings form an economic unit within which the subsidiary has no real freedom to determine its course of action on the market, and if the agreements or practices are concerned merely with the internal allocation of tasks as between the undertakings.

In Case 15/74,

Reference to the Court under Article 177 of the EEC Treaty by the Hoge Raad of the Netherlands, for a preliminary ruling in the action pending before that court between

CENTRAFARM BV, with registered office in Rotterdam, with ADRIAAN DE PEIJPER, resident at Nieuwerkerk aan de IJssel,

and

STERLING DRUG INC., with registered office in New York,

on the interpretation of the rules of the EEC Treaty on the free movement of goods, in conjunction with Article 42 of the Act annexed to the Treaty concerning the accession of the new Member States to the Economic Community, and on the interpretation of Article 85 of the EEC Treaty, in relation to patent rights,

THE COURT

composed of: R. Lecourt, President, C. Ó Dálaigh and Lord Mackenzie Stuart, Presidents of Chambers, A. M. Donner, R. Monaco, J. Mertens de Wilmars, P. Pescatore, H. Kutscher and M. Sørensen (Rapporteur), Judges,

Advocate-General: A. Trabucchi
Registrar: A. Van Houtte

gives the following

JUDGMENT

Facts

The decision making the reference and the written observations submitted pursuant to 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. Sterling Drug Inc., a company incorporated according to the law of the State of New York, is the titular holder of national patents in several countries — including the Netherlands (patent No 125 254) and Great Britain (patent No 1 000 892) — relating to the mode of preparation of a medicament named *acidum nalidixicum*, for the treatment of infections of the urinary passages.

For this product the trade-mark 'Negram' is the property, in Great Britain, of the company Sterling-Winthrop Group Ltd. and, in the Netherlands, of a subsidiary of the latter, Winthrop BV.

Centrafarm, of which Mr de Peijper is a director, imported medicinal preparations manufactured according to the patent method, some of which bore the trade-mark Negram, without the agreement of Sterling Drug, from England and the Federal Republic of Germany, where they had been put onto the market in a regular manner by subsidiaries of Sterling Drug Inc., into the Netherlands where they were offered for sale.

By importing the goods from Great Britain Centrafarm took advantage of a considerable price differential. It appears that in Great Britain the product is sold for half the price at which it sells in the Netherlands.

2. On 16 June 1971 Sterling Drug submitted to the president of the Arrondissements-Rechtbank at Rotterdam, sitting in chambers, an application for the immediate adoption of measures of conservation against the actions of Centrafarm and of its director, and requiring them to refrain from any further infringement of the patent belonging to Sterling Drug, together with several subsidiary requests. The president of the court rejected the application, on the grounds of an interpretation of the law on patents (Octrooiwet) according to which a product is held to have been put into

circulation in a regular manner even if it is put into circulation abroad by the titular holder of a Dutch patent. Sterling Drug thereupon brought an appeal before the Gerechtshof (Court of Appeal) at The Hague, which found in favour of Sterling Drug, with the exception of certain of its subsidiary requests.

Centrafarm and de Peijper brought an appeal on a point of law before the Hoge Raad against the judgment of the Gerechtshof.

3. Before deciding further, the Hoge Raad stayed the proceedings and requested the Court of Justice, pursuant to Article 177 of the EEC Treaty, to give a preliminary ruling on the following questions:

I. As regards the rules concerning the free movement of goods:

(a) Assuming that:

1. a patentee has parallel patents in several of the countries belonging to the EEC,
2. the products protected by those patents are lawfully marketed in one or more of those countries by undertakings to whom the patentee has granted licences to manufacture and/or sell,
3. those products are subsequently exported by third parties and are marketed and further dealt in in one of those other countries,
4. the patent legislation in the lastmentioned country gives the patentee the right to take legal action to prevent products thus protected by patents from being there marketed by others, even where these products were previously lawfully marketed in another country by the patentee or by the patentee's licencee,

do the rules in the EEC Treaty concerning the free movement of goods, notwithstanding what is stated in Article 36, prevent the patentee from exercising the right under 4 above?

(b) If the rules concerning the free movement of goods do not under all circumstances prevent the patentee exercising the right mentioned under (a) 4 above,

do they however so prevent him if the exercise of that right arises exclusively or partially from an attempt to partition the national markets of the relevant countries from each other for products protected by the patent, or at least has the effect of thus partitioning those markets?

(c) Does it make any difference to the reply to the questions under (a) and (b) above that the patentee and the licencee do or do not belong to the same concern?

(d) Can the patentee successfully rely in justification of the exercise of the abovementioned right on the fact that the price differences in the relevant countries which make it profitable for third parties to market in one country products originating in another country and give the patentee an interest in taking action against such practices, are the consequence of governmental measures whereby in the exporting country the prices of those goods are kept lower than would have been the case in the absence of those measures?

(e) At any rate where the patent relates to pharmaceutical products, can the patentee successfully rely in justification of the exercise of his patent rights on the fact that the state of affairs described under (a) above prevents him from controlling the distribution of his products, such control being considered by him essential so that measures for the protection of the public can be taken in the event of defects appearing?

(f) Is it a consequence of Article 42 of the Treaty of Accession that, if the rules of the EEC Treaty relating to the free movement of goods prevent the exercise of a patent right as before mentioned, those rules cannot be invoked in the Netherlands until 1 January 1975 insofar as the relevant goods originate in the United Kingdom?

II. As regards Article 85:

(a) Does the fact that a patentee owns parallel patents in different countries belonging to the EEC and that he has in those countries granted to different undertakings associated with the patentee licences to manufacture and sell (assuming that all the agreements entered into with such licencees are exclusively or in part designed to regulate differently for the different countries the conditions on the market in respect of the goods protected by the patent) mean that this is a case of agreements or concerted practices of the type prohibited by Article 85 of the EEC Treaty, and must an action for infringement as referred to under I (a) above — to the extent that this must be regarded as a result of such agreements or concerted practices — for that reason be held impermissible?

(b) Is Article 85 also applicable if, in connexion with the agreements or concerted practices referred to above, it is only undertakings belonging to the same concern that are involved?'

4. The interlocutory judgment of the Hoge Raad of 1 March 1974 was registered at the Court on 4 March 1974.

Pursuant to Article 20 of the Protocol on the Statute of the Court of Justice of the EEC, written observations were submitted on behalf of Sterling Drug Inc. by T. Schaper, of The Hague, Advocate with the Hoge Raad, and by A. Deringer, of Cologne, Advocate with the Oberlandesgericht, on behalf of Centrafarm BV and Adriaan de Peijper by L. D. Pels Rijcken, of The Hague, Advocate with the Hoge Raad, and A. F. de Savornin Lohman, Advocate at Rotterdam, on behalf of the Government of the Kingdom of Denmark by Mr Ersböll and on behalf of the Commission by its Legal Adviser, Bastiaan van der Esch, acting as agent.

Having heard the report of the Judge-Rapporteur and the opinion of the Advocate-General the Court decided to open the oral procedure without any preparatory inquiry.

II — Written observations submitted to the Court

Observations submitted by Sterling Drug Inc.

1. Sterling Drug Inc. recalls that a patentee has, in general, the exclusive right, over the territory of the country in question, to manufacture the patented product and to put it onto the market. However, once he has put the product into circulation in that country his right is held to be 'exhausted' and he can no longer prevent resale of the product in that country.

The company claims that no national law at present in force contains a provision under the terms of which marketing in a foreign country involves the exhaustion of the patent right. The Hoge Raad has again declared in this case that the meaning of Article 30 (2) of the 'Rijksoctrooiwet' 'is not open to doubt', and has confirmed its earlier case law according to which a Dutch patent is exhausted only by the act of marketing 'within the Kingdom'.

The Draft Convention on a European patent for the Common Market (Article 32) is also based upon the idea that only acts which take place within the territory covered by the EEC patent can exhaust the latter.

2. The right to challenge parallel imports can accordingly be refused to a patentee only if it must be held that national law has been modified in this respect by the coming into force of Community law.

Article 30 of the EEC Treaty prohibits 'quantitative restrictions on imports and all measures having equivalent effect', but must be read in conjunction with Article 36 which contains exceptions; the question which arises is whether the legal provision of Dutch national law on patents in issue:

— is justified on the grounds of protection of industrial property rights, and particularly patent rights, and if it

— constitutes neither a means of arbitrary discrimination, nor a disguised restriction on trade between Member States.

In this connexion the company examines the Judgments of the Court of 29 February 1968 (Case 24/67, *Parke Davis,* Rec. 1968, p. 81) and of 8 June 1971 (Case 78/70, *Deutsche Grammophon Gesellschaft,* Rec. 1971, p. 487).

(a) In the company's opinion distinctions should be drawn between the Deutsche Grammophon case and the present case. Firstly, in Deutsche Grammophon, the German copyright law, which dates from 1965, must be considered as a 'new' measure having equivalent effect, whereas the legal provision applicable in the present case, which dates from 1910, constitutes an 'existing' measure.

(b) Secondly, copyrights differ fundamentally from patent rights, given the characteristics of the latter. A patent is a monopoly, granted in each case by a specific State, with the aim of promoting, in the public interest, research investment and the publication of inventions, at the same time as giving the inventor a fair reward.

Until such time as the laws on patents are harmonized, the very nature of the present patent right implies the existence of several completely distinct categories of territorial validity. The right to challenge the importation of products put into circulation within a separate territory where those products are also patented therefore depends upon the nature of the patent.

The 'existence' of patents is fundamentally affected if a patentee can no longer prevent the importation into one Member State of products put into circulation in another Member State under a so-called 'parallel' patent. In fact, there are no true parallel patents. The legislations of the Member States with regard to patents are so different that even patents issued for the same inventions cannot be considered identical or 'parallel'.

Sterling Drug underlines in this respect, *inter alia,* that the period for which a patent is granted varies according to the legislations, and that, in certain States, patents are granted without any prior examination whereas in others the request for the grant of a patent is so examined. Requests for the grant of a patent for the same invention submitted in several countries may display differences.

If it is supposed that a patentee may challenge parallel imports of a product coming from another Member State, where that product is not protected by one of its patents, these differences can raise serious problems for the national court of the importing country which has to determine the degree of protection conferred by the patents in the exporting country or countries. It can happen that where the judge is unable satisfactorily to determine this complex question of the extent of protection, the patent is in practice not protected. This consequence affects the existence of the patent.

If it is supposed, on the other hand, that every time a patentee puts a product into circulation, even in a Member State where that product has never been patented and is not patentable, or in which the patent has come to an end, he is prevented from challenging importa-

tion, this interpretation affects the protection conferred by patents for that product held by the person concerned in other Member States. This amounts to saying that only the legal provision which is the least favourable to a patentee, contained in one of the legislations, determines in each case the protection attaching to all patents granted within the EEC.

The company concludes that the consequences of the numerous divergences between the national legislations cannot be avoided by the direct application of Community law, but solely by harmonization or unification, which is the objective of the Draft Convention on a European patent for the Common Market.

(c) Furthermore, the company mentions the preliminary studies for this Draft Convention and a report by the Assembly of the Secretaries of State to the governments of the Member States, on fundamental problems relating to the protection of industrial propetry — a report which must be considered as an authentic interpretation of Articles 30 and 36 — as well as several communications from the Commission up to 1970, and deduces that the national legal provisions on the basis of which parallel imports may be prevented by virtue of a patent are included in the exception laid down by Article 36, first sentence.

3. If it is supposed, on the other hand, that the exception laid down at Article 36 does not apply to these provisions, the question arises (a question which was not postulated in the Deutsche Grammophon case, as the Advocate-General rightly observed) whether Articles 30 et seq. are directly applicable.

The company refers in particular to the Judgment of 19 December 1968 (Case 13/68, *Salgoil,* Rec. 1968, p. 661).

Since the transitional period has ended the question arises, whether Article 30 and Article 32, second paragraph, first sentence, have become directly applicable as from 1 January 1970.

In this connexion the company recalls that in the Deutsche Grammophon case a 'new' law was involved, whereas the present case concerns an 'existing' law. Article 32, second paragraph, first sentence, which provides that measures having equivalent effect shall be abolished by the end of the transitional period at the latest, clearly constitutes an obligation to be fulfilled, which leaves the Member States a measure of discretionary power. The mere abolition of national provisions on patents allowing parallel imports to be prevented would affect the 'existence' of the patents and such abolition could not therefore be decided upon except in conjunction either with the simultaneous elimination of the very great differences existing between patent laws by harmonizing the latter or with the creation of a uniform EEC patent.

The company next claims that even the Commission does not seem to have considered it a reasonable proposition that Article 32, second paragraph, first sentence, should become directly applicable at the end of the transitional period. This is made clear by its Directive of 22 December 1969, based upon Article 33 (7) (70/50/EEC, OJ L 13/29).

Furthermore, it is often impossible to distinguish cases where Article 30 applies from those covered by Article 100 of the EEC Treaty and since, moreover, the legal provisions which are the subject of Article 100 remain in force until such time as the Council issues a directive, recognition of the direct applicability of Article 30, as from 1 January 1970, would lead to a large measure of legal uncertainty.

To deny the direct effect of Article 2, second paragraph, is also in line with the case law of the Bundesverfassungsgericht of Germany when seized of cases where the national legislature has not fulfilled obligations imposed upon it by the Constitution.

Finally, the company refers to Article 42 of the Act of Accession, according to which measures having an effect equivalent to quantitative restrictions shall be abolished by 1 January 1975 at the latest; since the company considers it unrealistic to suppose that the Member States will in fact be able to abolish all such measures before 1 January 1975, it would be difficult to require this on pain of automatic abrogation as from that date.

4. As regards question I (d), the company states that one of the fundamental objectives of the EEC is 'the institution of a system ensuring that competition in the common market is not distorted' (Article 3 (f)) and that such a system presupposes that artificial differences existing in interconnected fields must be jointly abolished according to an agreed timetable.

Measures with regard to prices adopted in an exporting country for reasons of social policy, the effect of which is to maintain prices of certain pharmaceutical products at a lower level within that country than prices which would have been in force in the absence of such measures, constitute artificial differences.

The alteration of market conditions is clearly observed where a manufacturer must compete with an importer who is not himself a producer, and who — without himself running the least commercial risk — restricts his activity to profiting from the price differential.

In the present case, unlike the Deutsche Grammophon case, the Dutch price is governed by free market forces, whereas the English price is artificial. Although nalidixic acid is patented in the Netherlands, its price is nevertheless governed by the laws of the market, because various competing medicinal preparations which also serve to treat infections of the urinary passages are to be found on the Dutch market.

The company adds that price differentials as between Great Britain and the other Member States also result from a factor which is completely outside the control of Sterling Drug, that is to say substantial changes in exchange rates.

5. As regards question I (e), the company recalls that it is not merely adducing, in support of its action, the fact that the products were not put into circulation in the Netherlands by itself or in its name. One of the decisive reasons why it has brought an action is that the behaviour of Centrafarm makes it impossible for it to control the distribution of its products. Such control is necessary above all to enable measures to be taken to protect the public in the event of a consignment of medicinal preparations proving defective.

The very existence of parallel imports renders any control impossible since one or more intermediaries, whose behaviour is beyond the control of the manufacturer, are involved in the process. With regard to this matter the company refers to a reply given in the same terms by the Dutch Secretary of State for Public Health on 18 September to the questions of a member of the Second Chamber.

The company concludes that in the event of the action brought by Sterling Drug against Centrafarm not being considered to be founded on its patent alone, it is however justified to the extent that it concerns a very urgent problem with regard to the protection of health.

6. As regards question I (f), concerning Article 42 of the Act of Accession, the company claims that measures having equivalent effect which have not been abrogated will in any case remain in force until 1 January 1975 at the earliest. It refers to the criteria for direct effect as defined by the Court in its Judgments of 4 February 1965 (Case 20/64, *Albatros*, Rec. 1965 — 3, p. 1) and of 19 December 1968 *(Salgoil,* aforementioned). It follows that the legal provision of Dutch patent law which allows parallel imports to be prevented can, at the present time, be invoked in

respect of parallel imports from Great Britain.

7. Finally, Sterling Drug claims that Article 85 of the EEC Treaty is not applicable in the present case, by reason of the fact that Sterling-Winthrop Group Ltd. is a wholly-owned subsidiary of Sterling Drug Inc. and that, as regards its power of decision — in particular for the operations in issue in this case — it is completely dependent upon Sterling Drug.

Observations submitted by Centrafarm

Centrafarm first examines the premises upon which the questions of the Hoge Raad are based. The protected products were lawfully marketed in the exporting country, that is to say that they were marketed either by the patentee itself, or with the latter's consent by a licencee. It emphasises that the facts as a whole differ from those of Case 24/67 *(Parke Davis,* aforementioned) which was concerned with a medicinal preparation imported into the Netherlands from Italy, where it was not protected by patent.

The company recalls that all countries tend to establish a balance within their national legal territory between the private interest of the patentee and the public interest of freedom of trade. This balance is achieved because the patentee draws advantage from the monopoly based upon his patent right while at the same time being subject to certain limitations. The most important restriction lies in the fact that when a product has been lawfully marketed within the territory of the country it may be freely resold without hindrance from the patentee.

The first question asks whether, under European law, a single limitation on the monopoly based upon the patent must be recognized, where that limitation is however not restricted to products lawfully marketed within the legal territory of each country considered separately, but extends to products lawfully marketed within the territory of the Community.

In the opinion of Centrafarm the Judgment in Case 78/70 *(Deutsche Grammophon)* constitutes an important precedent. The situation behind that case displays a marked similarity with the facts of the present case. The company concludes that the recitals of the Deutsche Grammophon Judgment, insofar as they are based upon 'the essential objective' of the EEC Treaty and upon the rules with regard to the free movement of goods which are contained therein, are entirely applicable, *mutatis mutandis,* to the present case.

The company emphasises that the exclusive right exercised pursuant to paragraph 85 of the German copyright law is very largely similar to the patent right. That right is granted to manufacturers of sound recordings not because the manufacture of such recordings is a service of an artistic nature, but because the manufacture of products of this type requires advanced technical know-how and a high level of investment which justify the protection granted to the manufacturer against the reproduction of those products, which could simply be effected in the form of magnetic tape recordings.

The company cannot see how question I (a) differs in scope from question I (b). It cannot understand how the attempt by a patentee to exercise his right in circumstances such as those of the present case can be anything but the direct consequence of a wish to partition off national markets for the products protected by a patent or, at least, how that attempt could fail to result in such a partition.

Question I (c) as to membership of the same concern is irrelevant in connexion with the free movement of goods within the Community.

As regards question I (d), the company claims that the price differentials ascertained are entirely extraneous to the protection due to the patentee. The latter is not granted exclusive rights for

the purpose of maintaining, for the product patented, price differentials depending upon the country of the EEC where the product is marketed; the exercise of a patent right for such an object cannot, *a fortiori,* be considered the 'specific subject matter' of that right. On no account therefore can the exception laid down in Article 36 of the Treaty be invoked on the basis of the circumstances set out in this question.

As to question I (e), the company states that the patent can in no circumstances permit the patentee more effectively to control the distribution of a patent medicinal preparation, with respect to possible defects in that product. Unpatented medicinal preparations may also be defective. If it is necessary to exercise control over pharmaceutical products, or to improve such control, this can be done in ways other than by means of patents.

In relation to the questions concerning Article 85 of the EEC Treaty Centrafarm notes that the present situation is identical to that of Case 40/70 *(Sirena,* aforementioned), and that that Judgment is of decisive importance for an answer to question II (a). The company refers in particular to recitals 9 to 12 of that Judgment, the substance of which applies almost word for word to the circumstances set out in question II (a). In order to apply Article 85 it is not important to know whether the agreements referred to are agreements concluded between a patentee and licencees in several countries of the EEC, given that such agreements are intended, above all, to regulate, in a way which varies from country to country, marketing conditions for products protected by patent. This implies in effect that such agreements 'may affect trade between Member States and ... have as their object or effect the prevention, restriction or distortion of competition within the common market'.

Even if links exist between these legal entities within a single group thereby excluding competition between them, contracts for the grant of licences must be considered as agreements prohibited by Article 85 where they are intended, above all, to regulate marketing conditions for products protected by patents in ways which differ from one country to another. It is not sufficient merely to consider the rights and obligations flowing from the provisions of the agreement. The economic and legal context within which the agreement is situated must also be considered, and it must be ascertained, in particular, whether parallel imports from one country to another may be prevented, on the one hand, by the existence of the agreements concluded with the various licencees and, on the other hand, by the effect of national patent legislation.

With reference in this connection to the Judgment of the Court of 25 November 1971 (Case 22/71, *Béguelin,* Rec. 1971, p. 949) and recalling that the Court found that the relationship between a parent company and a subsidiary cannot be taken into consideration in ascertaining the validity of an exclusive dealing contract concluded between a subsidiary and a third party, Centrafarm nevertheless emphasizes the substance of the Court's statement in recitals 12 to 14, and draws the following conclusions thereform. Since an exclusive dealing agreement may be covered by the prohibition contained in Article 85 of the Treaty on the grounds set out in those recitals, it must be conceded that Article 85 also applies where a patentee concludes agreements with licencees in various countries of the EEC, the essential object of which is to regulate differently for the different countries the conditions under which the product protected by the patent is marketed.

Observations submitted by the Danish Government

The Danish Government is of the opinion that a distinction must be made according to whether the products emanate from the same producer or are

manufactured in various countries of the Community. Thus Article 30 et seq. of the EEC Treaty do not allow the licencee of a sales agency who himself covers the home market by means of imports to invoke a patent right in order to prevent other imports of products put on sale in another Member State by the foreign producer. The abovementioned Articles also prohibit a patentee in a given Member State from invoking his right in order to prevent the importation into that State of products which he himself has put into circulation in another State of the EEC. The Government refers to the Judgments of the Court of 13 July 1966 (Joined Cases 56 and 58/64, *Grundig*, Rec. 1966, p. 429) and of 8 June 1971 (*Deutsche Grammophon*).

On the other hand, the Deutsche Grammophon Judgment cannot be followed where a patentee or a licencee, manufacturing products in his own country, invokes his patent right in order to prohibit the importation of products manufactured in another country of the EEC by the patentee himself, or by an undertaking which is associated with the patentee or by another licencee.

The exclusion of the possibility of preventing imports under these circumstances alters decisively the legal basis for and the conditions of the industrial exploitation of patents. This is the underlying reason for the Draft Convention on a European patent for the Common Market, which provides that the principle of international exhaustion of patent rights within the Community will come into force only after a transitional period, which has been judged to be necessary by the governments. Furthermore, this Draft Convention will enable conflicts which might arise from the obligation to use inventions for national production to be avoided, this obligation being laid down by the provisions of national legislations at present in force with regard to patents, since this problem has been solved by Article 47 of the Convention.

The Danish Government further notes that, in the present case, a patentee may justifiably claim that disparities between prices are the consequence of acts of the public authorities and that, where the patents concern pharmaceutical products, the patentee has a particular legitimate interest in being able to control the distribution of his products.

Observations submitted by the Commission

The Commission makes the following observations on the various questions put:

1. Question I (a)

In the case envisaged by the Hoge Raad, the incompatibility of the protection granted by national law to the patentee with the rules of Community law relating to the free movement of goods is already apparent in the Judgment given by the Court in Case 78/70 *(Deutsche Grammophon)*. Judgments given by national courts constitute measures having equivalent effect within the meaning of Article 30 where they prohibit the importation of goods from one Member State into another.

In the abovementioned Judgment the Court defined the exception laid down by Article 36, noting that the latter allows derogations from the principle of the free movement of goods only to the extent that they are justified in the interest of those rights which are the specific subject matter of industrial and commercial property. This definition, given in relation to a right akin to copyright, must apply equally to a patent right. In either case, the specific subject matter of the property consists in the exclusive right to manufacture or reproduce and to put into circulation for the first time a specific product of the human intellect or of industry. Where legal remedies before national courts make it possible to hinder imports of products manufactured in a regular manner under patent and then put into circulation this constitutes the creation

of a right extending beyond the specific subject matter of ownership of a patent.

This concept corresponds directly with the operative part of the Judgment given by the Court in the Deutsche Grammophon case. Whereas the Court seems to consider that the measure having equivalent effect consists in the exercise by the party concerned of exclusive rights, in the Commission's view the essential element consists rather in the decision of the national court enabling such rights to be exercised.

2. Question I (b)

The determining factor for the application of the prohibition contained in Article 30 consists not in the efforts made to partition off national markets but in the fact that such a partition in fact exists. Insofar as the question is also concerned to ascertain the limits to Article 36, the latter may be invoked as an exception to the rule constituted by Article 30 where the imported products have not been manufactured or put into circulation by the patentee, by the licencee or by other persons duly authorized to do so.

3. Question I (c)

It is of little importance to know whether, as the national court asks, the patentee and licencee belong to the same concern; it is however important to know whether the products have been put into circulation within the Common Market by the patentee or with his consent.

4. Question I (d)

The considerable price differential with regard to the same product as between two countries is not a ground for prohibiting the importation of products from that country where the level of prices is lowest by claiming the protection granted by the patent.

One of the essential aspects of the Common Market is that it offers the possibility of manufacturing products at the place where production proves to be least expensive. If, in a given Member State, a fixed price were imposed or subsidies were granted to certain undertakings this could provoke differences which would have an effect upon trade between the Member States. It is however the task of the Community authorities to frustrate such a development, wherever necessary, by introducing, for example, a scheme for the harmonization of legislations.

However, if the Community authorities fail in their duty the national courts are nevertheless not entitled to bring judgments which conflict with the provisions of Article 30 by invoking a patent right.

5. Question I (e)

The production and marketing of medicinal preparations give rise to the problem of the control of medicinal preparations which display certain defects. Various measures have already been adopted with a view to solving this problem. As concerns the Netherlands, the legal basis for these measures is Article 18 (2) of the Decree concerning proprietary medicinal products. It is not necessary, for the application of these measures, that the manufacture or marketing of a medicinal preparation be carried out by a single undertaking; control may also be exercised where several parallel importers are involved. The prohibition contained in Article 30 is therefore still applicable to the situation in question.

6. Question I (f)

Article 42 of the Act of Accession lays down the period within which measures having equivalent effect *already in force* must be abolished. For this reason these provisions are not concerned with the problem of *new* measures having equivalent effect, which must arise in this case if the Hoge Raad finds in favour of Sterling Drug in its action to

prevent imports of the medicinal preparation in question. The question referred should therefore be answered in the negative.

7. Question II (a)

The Hoge Raad postulates the regulation of market conditions, which differ from one country to another, and appears to refer thereby to the pursuit by the undertakings concerned of a policy of price differentials. In order to put this policy into effect the undertakings are invoking rights which in their belief flow from their industrial property. By behaving in this way the parties concerned ensure that their licencing agreements have a more marked effect upon the partitioning of the different markets, an effect which is accordingly contrary to the provisions of the first paragraph of Article 85 of the Treaty. The actual terms of the contract are of lesser importance. The exercise of rights derived from industrial property is subject to the prohibition contained in Article 85 whenever it appears to be the object, the means or the consequence of an agreement. This line of thought is confirmed by various judgments of the Court. The Commission refers to the Judgments of 13 July 1966 and 18 February 1971 (Case 56 and 58/64, *Consten,* Rec. 1966, p. 429, and Case 40/70, *Sirena,* Rec. 1971, p. 69).

As to whether, in the circumstances under consideration, an action for infringement based upon a patent right must be held impermissible, it seems evident that the prohibition contained in Article 85 (1) cannot be avoided by such an action.

8. Question II (b)

Article 85 does not apply to agreements involving undertakings belonging to the same concern, the sole object of which is the allocation of tasks within one and the same economic unit. However, if agreements concluded within a concern are of wider scope — if for example they restrict possibilities open to undertakings outside that concern of penetrating a given market — such agreements must be held to be covered by the provisions of Article 85 (1).

In view of its remarks on Article 30 et seq. the Commission confines itself to these theoretical observations. The question whether Article 85 (1) is applicable must be answered in relation to each case as it arises; in view of the documents relating to the proceedings it would appear that the question should be answered in the affirmative.

Following the conclusion of the written procedure the oral procedure was opened on 3 July 1974. The company Sterling Drug Inc. was represented by Advocates Deringer and Schaper, the company Centrafarm and Adriaan De Peijper by Advocates Pels Rijcken and de Savornin Lohman and the Commission by its Legal Adviser, Mr van der Esch.

During the course of the oral procedure, in reply to a question put by the Court, the two companies and the Commission gave their explanations with regard to the substantial differences existing between prices in Great Britain and those in the Netherlands.

The company *Sterling Drug Inc.* points out that the product 'Negram' was put onto the European market in 1963. The company claims that the price difference can be imputed to the following factors:

1. changes in exchange rates (accounting for about 60 % of the difference),
2. freight, import duties, importer's profit margin (accounting for about 15 % of the difference) and
3. the fact that prices of pharmaceutical products are kept at a low level by artificial means by the authorities in Great Britain.

In this respect the company refers to the booklet entitled 'International price comparison'. It is stated therein that the level of prices for pharmaceutical products in Great Britain is, in general, 30 % lower than that in countries of a

comparable size, due to the current system of regulation of prices. In this report, produced by a semi-official body, it is stated that international companies pursuing research projects are dependent upon profit margins which are sufficiently high to enable them to absorb the rise in the cost of research, whereas the British system merely allows current research costs to be covered.

The company *Centrafarm* claims, firstly, that the booklet mentioned by Sterling Drug appears to have been compiled as a defence of the British pharmaceutical industry. For its part, the company refers to three official reports, in particular the 1973 Report of the Monopolies Commission with regard to Roche products. The company gives a brief survey of the voluntary price regulation scheme as practised in Great Britain and concludes that, with the exception of a single case, the British Government has never imposed any sale price, either upon manufacturers, or on importers or on wholesalers, and that prices are established by the industry in consultation with the Health Ministry.

The company further remarks that although Negram is not a unique medicinal preparation, it can be said that, over a limited field, it occupies a central position, not to say a dominant position. The company also claims that there is a very powerful system of agreements in the Dutch pharmaceutical trade, to which 95 % of manufacturers and dealers are associated.

Finally, Centrafarm sets out the difficulties which would face national courts in the event of an affirmative answer to the question referred. Would they be able to enforce the prohibition whenever it appeared that, in the exporting country, there existed a measure the effect of which was to lower the price of a good below the level at which it would have been fixed by the free play of competition? The company also claims that since price formation is far from free in most countries an affirmative answer to the question put by the Hoge Raad would leave the present situation within the Community unchanged. It is to be expected that, in most cases, patentees could claim that price differentials are the consequence of measures adopted by the public authorities.

The *Commission* claims that it appears from the documents at its disposal that the main objective of the British rules on the subject is the achievement of a certain transparency of manufacturing costs, including costs of research and development.

In the Commission's opinion, price differentials as between Great Britain and the Netherlands are to be explained in terms of perfectly normal factors, such as a greater volume of sales in Great Britain and slightly less intense competition on the Dutch market.

Upon discovering that, at the present time, Negram is not produced in the Netherlands, a Member of the Court asked if, from the point of view of legal analysis, the situation would be different if the patentee itself produced the product in question within the importing country.

Both companies answered this question in the negative. The *Commission* was of the opinion that this question raises a number of particularly complex problems. The question is under discussion at the Commission. Although it is a natural first reaction to say that there is no difference between the two situations, arguments can be found in support of protection for the producer in the importing country against imports of the same product manufactured by others.

The Advocate-General delivered his opinion at the hearing on 18 September 1974.

Law

1 By interim decision of 1 March 1974, registered at the Court on 4 March, the Hoge Raad der Nederlanden (Dutch Supreme Court) referred certain questions, by virtue of Article 177 of the EEC Treaty, on patent rights in relation to the provisions of the Treaty and of the Act concerning the Accession of the three new Member States.

2 In the decision making the reference the Hoge Raad set out as follows the elements of fact and of national law in issue in relation to the questions referred:

— a patentee holds parallel patents in several of the States belonging to the EEC,

— the products protected by those patents are lawfully marketed in one or more of those Member States by undertakings to which the patentee has granted licences to manufacture and/or sell,

— those products are subsequently exported by third parties and are marketed and further dealt in in one of those other Member States,

— the patent legislation in the lastmentioned State gives the patentee the right to take legal action to prevent products thus protected by patents from being there marketed by others, even where these products were previously lawfully marketed in another country by the patentee or by the patentee's licencee.

3 It appears from the proceedings that the main action is concerned with the rights of a proprietor of parallel patents in several Member States who grants an exclusive licence to sell, but not to manufacture, the patent product in one of those States, while at the same time the patentee does not manufacture the patent product in that same Member State.

As regards question I(a)

4 This question requires the Court to state whether, under the conditions postulated, the rules in the EEC Treaty concerning the free movement of goods prevent the patentee from ensuring that the product protected by the patent is not marketed by others.

5 As a result of the provisions in the Treaty relating to the free movement of goods and in particular of Article 30, quantitative restrictions on imports and all measures having equivalent effect are prohibited between Member States.

6 By Article 36 these provisions shall nevertheless not include prohibitions or restrictions on imports justified on grounds of the protection of industrial or commercial property.

7 Nevertheless, it is clear from this same Article, in particular its second sentence, as well as from the context, that whilst the Treaty does not affect the existence of rights recognized by the legislation of a Member State in matters of industrial and commercial property, yet the exercise of these rights may nevertheless, depending on the circumstances, be affected by the prohibitions in the Treaty.

8 Inasmuch as it provides an exception to one of the fundamental principles of the Common Market, Article 36 in fact only admits of derogations from the free movement of goods where such derogations are justified for the purpose of safeguarding rights which constitute the specific subject matter of this property.

9 In relation to patents, the specific subject matter of the industrial property is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements.

10 An obstacle to the free movement of goods may arise out of the existence, within a national legislation concerning industrial and commercial property, of provisions laying down that a patentee's right is not exhausted when the product protected by the patent is marketed in another Member State, with the result that the patentee can prevent importation of the product into his own Member State when it has been marketed in another State.

11 Whereas an obstacle to the free movement of goods of this kind may be justified on the ground of protection of industrial property where such protection is invoked against a product coming from a Member State where it

is not patentable and has been manufactured by third parties without the consent of the patentee and in cases where there exist patents, the original proprietors of which are legally and economically independent, a derogation from the principle of the free movement of goods is not, however, justified where the product has been put onto the market in a legal manner, by the patentee himself or with his consent, in the Member State from which it has been imported, in particular in the case of a proprietor of parallel patents.

12 In fact, if a patentee could prevent the import of protected products marketed by him or with his consent in another Member State, he would be able to partition off national markets and thereby restrict trade between Member States, in a situation where no such restriction was necessary to guarantee the essence of the exclusive rights flowing from the parallel patents.

13 The plaintiff in the main action claims, in this connection, that by reason of divergences between national legislations and practice, truly identical or parallel patents can hardly be said to exist.

14 It should be noted here that, in spite of the divergences which remain in the absence of any unification of national rules concerning industrial property, the identity of the protected invention is clearly the essential element of the concept of parallel patents which it is for the courts to assess.

15 The question referred should therefore be answered to the effect that the exercise, by a patentee, of the right which he enjoys under the legislation of a Member State to prohibit the sale, in that State, of a product protected by the patent which has been marketed in another Member State by the patentee or with his consent is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the Common Market.

As regards question I (b)

16 This question was referred to cover the possibility that Community rules do not under all circumstances prevent the patentee from exercising the right, under his national law, to prohibit imports of the protected product.

17 It follows from the answer given to question I (a) above that question I (b) has become devoid of object.

As regards question I(c)

18 This question requires the Court to state whether it makes any difference to the answer given to question I (a) that the patentee and the licencees do or do not belong to the same concern.

19 It follows from the answer given to question I (a) that the factor which above all else characterizes a restriction of trade between Member States is the territorial protection granted to a patentee in one Member State against importation of the product which has been marketed in another Member State by the patentee himself or with his consent.

20 Therefore the result of the grant of a sales licence in a Member State is that the patentee can no longer prevent the sale of the protected product throughout the Common Market.

21 Accordingly, it is of no significance to know whether the patentee and the licencees do or do not belong to the same concern.

As regards question I (d)

22 This question requires the Court to state, in substance, whether the patentee can, notwithstanding the answer given to the first question, prevent importation of the protected product, given the existence of price differences resulting from governmental measures adopted in the exporting country with a view to controlling the price of that product.

23 It is part of the Community authorities' task to eliminate factors likely to distort competition between Member States, in particular by the

harmonization of national measures for the control of prices and by the prohibition of aids which are incompatible with the Common Market, in addition to the exercise of their powers in the field of competition.

24 The existence of factors such as these in a Member State, however, cannot justify the maintenance or introduction by another Member State of measures which are incompatible with the rules concerning the free movement of goods, in particular in the field of industrial and commercial property.

25 The question referred should therefore be answered in the negative.

As regards question I (e)

26 This question requires the Court to state whether the patentee is authorized to exercise the rights conferred on him by the patent, notwithstanding Community rules on the free movement of goods, for the purpose of controlling the distribution of a pharmaceutical product with a view to protecting the public against the risks arising from defects therein.

27 The protection of the public against risks arising from defective pharmaceutical products is a matter of legitimate concern, and Article 36 of the Treaty authorizes the Member States to derogate from the rules concerning the free movement of goods on grounds of the protection of health and life of humans and animals.

28 However, the measures necessary to achieve this must be such as may properly be adopted in the field of health control, and must not constitute a misuse of the rules concerning industrial and commercial property.

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

30 The question referred should therefore be answered in the negative.

As regards question I (f)

31 This question requires the Court to state whether Article 42 of the Act concerning the Conditions of Accession of the three new Member States implies that the rules of the Treaty concerning the free movement of goods cannot be invoked in the Netherlands until 1 January 1975, insofar as the goods in question originate in the United Kingdom.

32 Paragraph 1 of Article 42 of the Act of Accession provides that quantitative restrictions on imports and exports shall, from the date of accession, be abolished between the Community as originally constituted and the new Member States.

33 Under paragraph 2 of the same Article, which is more directly relevant to the question, 'measures having equivalent effect to such restrictions shall be abolished by 1 January 1975 at the latest'.

34 In the context, this provision can refer only to those measures having an effect equivalent to quantitative restrictions which, as between the original Member States, had to be abolished at the end of the transitional period, pursuant to Articles 30 and 32 to 35 of the EEC Treaty.

35 It therefore appears that Article 42 of the Act of Accession has no effect upon prohibitions on importation arising from national legislation concerning industrial and commercial property.

36 The case under consideration is therefore subject to the principle enshrined in the Treaty and in the Act of Accession, according to which the provisions of the Treaties establishing the European Communities concerning the free movement of goods and, in particular, Article 30, are applicable, from the date of accession, to the new Member States, save where contrary is expressly stated.

37 It follows that Article 42 of the Act of Accession cannot be invoked to prevent importation into the Netherlands, even before 1 January 1975, of goods put

onto the market in the United Kingdom under the conditions set out above by the patentee or with his consent.

As regards questions II (a) and (b)

38 These questions require the Court to state whether Article 85 of the Treaty is applicable to agreements and concerted practices between the proprietor of parallel patents in various Member States and his licencees, if the objective of those agreements and concerted practices is to regulate differently for the different countries the conditions on the market in respect of the goods protected by the patents.

39 Although the existence of rights recognized under the industrial property legislation of a Member State is not affected by Article 85 of the Treaty, the conditions under which those rights may be exercised may nevertheless fall within the prohibitions contained in that Article.

40 This may be the case whenever the exercise of such a right appears to be the object, the means or the consequence of an agreement.

41 Article 85, however, is not concerned with agreements or concerted practices between undertakings belonging to the same concern and having the status of parent company and subsidiary, if the undertakings form an economic unit within which the subsidiary has no real freedom to determine its course of action on the market, and if the agreements or practices are concerned merely with the internal allocation of tasks as between the undertakings.

Costs

42 The costs incurred by the Government of the Kingdom of Denmark and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable.

43 As these proceedings are, insofar as the parties to the main action are concerned, a step in the action pending before the Hoge Raad der Nederlanden, costs are a matter for that court.

On those grounds,

THE COURT,

in answer to the questions referred to it by the Hoge Raad der Nederlanden, by interim decision of 1 March 1974, hereby rules:

1. The exercise, by the patentee, of the right which he enjoys under the legislation of a Member State to prohibit the sale, in that State, of a product protected by the patent which has been marketed in another Member State by the patentee or with his consent is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the Common Market.

2. In this connection, it is of no significance to know whether the patentee and the undertakings to which the latter has granted licences do or do not belong to the same concern.

3. It is also a matter of no significance that there exist, as between the exporting and importing Member States, price differences resulting from governmental measures adopted in the exporting State with a view to controlling the price of the product.

4. The proprietor of a patent relating to a pharmaceutical product cannot avoid the incidence of Community rules concerning the free movement of goods for the purpose of controlling the distribution of the product with a view to protecting the public against defects therein.

5. Article 42 of the Act concerning the Conditions of Accession and the Adjustments to the Treaties cannot be invoked to prevent importation into the Netherlands, even before 1 January 1975, of goods put onto the market in the United Kingdom by the patentee or with his consent.

6. Article 85 is not concerned with agreements or concerted practices between undertakings belonging to the same concern and having the

status of parent company and subsidiary, if the undertakings form an economic unit within which the subsidiary has no real freedom to determine its course of action on the market, and if the agreements or practices are concerned merely with the internal allocation of tasks as between the undertakings.

Lecourt Ó Dálaigh Mackenzie Stuart Donner Monaco
Mertens de Wilmars Pescatore Kutscher Sørensen

Delivered in open court in Luxembourg on 31 October 1974.

A. Van Houtte
Registrar

R. Lecourt
President

OPINION OF MR ADVOCATE-GENERAL TRABUCCHI DELIVERED ON 18 SEPTEMBER 1974 [1]

Mr President,
Members of the Court,

1. The Joined Cases 15 and 16/74 on which the Hoge Raad of the Netherlands has referred for a preliminary ruling are concerned with similar subjects. The first case deals with patent rights, the second with the right to a trade mark.

The questions from the Dutch court concern the relationship between these two rights and, against the background of a complicated situation, whose salient features are described below, Community rules governing the free movement of products between the Member States and those prohibiting conduct in restraint of competition. These features may be summarized as follows:

(a) an American company, which owns parallel patent rights in several Member States, has, in each of them, granted a licence for manufacture or merely for sale to its subsidiary companies, which are entirely under its control;

(b) the product, which is regularly sold in one State by the manufacturer who is the patent owner and holder of the trade mark in that country, is exported and resold by third-party purchasers in another Member State where the parent company also owns the patent but does not make use of it for production, whereas a local company under its control, which owns the right to the same trade mark which the product bears in the country where it is

1 — Translated from the Italian.