provisions of a Member State which give a patent proprietor the right to prevent the marketing in that State of a product which has been manufactured in another Member State by the holder of a compulsory licence granted in respect of a parallel patent held by the same proprietor. In that respect, it makes no difference whether a prohibition on exportation is attached to the compulsory licence, whether that licence fixes royalties payable to the patentee or whether the patentee has accepted or refused such royalties.

Where a compulsory licence is granted to a third party the patent proprietor is deprived of his right to determine freely the conditions under which he markets his product. The substance of a patent right lies essentially in according the inventor an exclusive right of first placing the product on the market so as to allow him to obtain the reward for his creative effort. It is therefore necessary to allow the patent proprietor to prevent the importation and marketing of products manufactured under a compulsory licence in order to protect the substance of his exclusive rights under his patent.

OPINION OF MR ADVOCATE GENERAL MANCINI
delivered on 23 April 1985 *

Mr President,
Members of the Court,

1. The questions formulated by the Hoge Raad der Nederlanden [Supreme Court of the Netherlands] provide the Court with another opportunity to consider one of the most interesting and complex issues of Community law. Essentially the Court is asked to balance the requirements of the free movement of goods against the need to protect the industrial property rights and commercial guarantees provided for in the legal orders of the Member States. There is already a considerable amount of case-law on that subject. This case adds a new dimension to that case-law and care must be taken — and it will not be easy — to ensure that that new element is consistent with the existing principles.

The facts which gave rise to the case pending before the Hoge Raad concern the marketing in the Netherlands of a drug known as 'frusemide'. The manufacturing process of that drug was patented for the first time by the German undertaking Hoechst in the Federal Republic of Germany at the beginning of the sixties. At the same time Hoechst also took steps to protect its invention in the United Kingdom and the Netherlands and thus became the proprietor of three parallel patents. In 1972, under Hoechst's United Kingdom patent, a local undertaking, DDSA Pharmaceuticals

* Translated from the Italian.

Ltd (hereinafter referred to as DDSA), obtained by virtue of Section 41 of the Patents Act 1949, which was then in force, a compulsory licence for the manufacture, importation and sale of frusemide in the territory of the United Kingdom.

That provision provided as follows: 'Without prejudice to the foregoing provisions . . . , where a patent is in force in respect of; (a) a substance capable of being used as food or medicine . . . ; or (b) a process for producing such a substance . . . ; or (c) . . . , the comptroller shall on application made to him by any person interested, order the grant to the applicant of a licence under the patent on such terms as he thinks fit unless it appears to him that there are good reasons for refusing the application'.

The licence granted to DDSA was subject, *inter alia*, to a prohibition on the exportation of the drug. However, shortly before the expiry of the United Kingdom patent, towards the end of 1976, DDSA disregarded that prohibition and sold to Pharmon, a Netherlands pharmaceutical undertaking, a large consignment of frusemide tablets produced by it. Pharmon clearly intended to market in the Netherlands the drug which it had obtained in that way. However, it found itself facing legal proceedings instituted by Hoechst. As the proprietor of a Netherlands patent, which at the time had not yet expired, Hoechst obtained an injunction against Pharmon which confirmed the German undertaking's right to the exclusive exploitation of frusemide in the Netherlands.

Pharmon subsequently brought an action before the Arrondissementsrechtbank [District Court], Rotterdam, in order to establish that, in any event, the injunction did not cover the consignment of frusemide imported from the United Kingdom where, in its view, the drug had been put into circulation lawfully by DDSA, as Hoechst's licensee. The Arrondissementsrechtbank took the view that it was necessary to refer to the Court of Justice for an interpretation of certain Community rules and stayed the proceedings. However, Hoechst appealed against that judgment to the Gerechtshof [Regional Court of Appeal], The Hague. The Gerechtshof found that a contract of sale had in fact been concluded between Pharmon and DDSA; that the goods sold had been dispatched to the purchaser in the Netherlands; that in the light of those circumstances, those goods could not have been previously transferred in the United Kingdom; and that Hoechst had not received any royalties in respect of the sale to Pharmon. It therefore overturned the judgment of the Arrondissementsrechtbank.

Pharmon then lodged an appeal in cassation, claiming that the Gerechtshof was mistaken in finding that the consignment of tablets sold by DDSA had not been previously put into circulation. The Hoge Raad took the view that the facts of the case raised questions concerning the significance and scope of various rules of the Treaty. It therefore stayed the proceedings by a judgment of 13 January 1984 and requested the Court to make a preliminary ruling on the following questions:

(1) Is it incompatible with the rules on the free movement of goods within the Common Market for a proprietor of a patent to exercise his rights under the legislation of a Member State to oppose the putting into circulation in that State of a product protected by that patent, where that product is manufactured in another Member State and sold and supplied directly from there to a purchaser in the first-mentioned Member State by the holder of a compulsory licence under a parallel patent owned by the same patent proprietor in that other Member State?

(2) Does it make any difference to the answer to the first question whether a prohibition on exportation is attached to the above-mentioned compulsory licence by the authorities of the other Member State?

(3) Is it relevant to the answer to be given to the first question whether:

(a) the patent proprietor is in general entitled to royalties in respect of the products put into circulation by the licensee under his compulsory licence?

(b) the patent proprietor is entitled to royalties in respect of the specific consignment at issue in these proceedings?

(c) the patent proprietor is not only entitled to royalties but has also actually received (or wanted to receive) such royalties?

2. In the course of the procedure before the Court of Justice written observations were submitted by the parties in the main proceedings, the Governments of Denmark, the Federal Republic of Germany, France, Italy and the Netherlands, and by the United Kingdom and the Commission of the European Communities. Those observations provide two possible replies to question No 1. They also express the unanimous view that the inclusion of a prohibition on exportation in the conditions of a compulsory licence (question No 2) and the question whether or not the patent proprietor is entitled to royalties (question No 3) are not material to the solution of the problem raised in the first question.

The question at issue is the scope which must be attributed to the principle of 'the exhaustion of patent rights in the Community'. According to Pharmon, derogation from the rules on the free movement of goods on grounds of the protection of industrial and commercial property ceases to be justified not only when the product protected by the patent has been lawfully marketed in another Member State by the patent proprietor or with his consent, but also — which is the case in this instance — when it is put into circulation in the country of the holder of the exclusive rights by a person or undertaking who has obtained a compulsory licence to exploit the product in another Member State granted under the parallel patent.

On the other hand, according to Hoechst, the six Member States and the Commission, the compulsory licence cannot have the exhaustive effect of a patent right which is granted with the consent of the patent proprietor.

3. Let us consider the arguments which have been advanced in support of those views. Pharmon points out in the first place that the procedure for granting the compulsory licence under the Patents Act entitles the proprietor of the patent to intervene directly in the process of fixing the conditions to which the licence is subject, in particular in relation to the amount of royalties which the licensee must pay to him. As regards Community law, Pharmon then cites the *Hag* case. In that case too a third party exploited an industrial property right by virtue of an administrative measure (the sequestration of the entire capital of an undertaking) although the original proprietor had not given his consent. The Court considered that the rules relating to the free movement of goods overrode the patent proprietor's rights (judgment of 3 July 1974 in Case 192/73, *Van Zuylen* v *Hag AG* [1974] ECR 731). In Pharmon's view, the same principle should be applied in this case. It applies, *a fortiori*,

since in this instance the original proprietor has been divested not of all his rights, as in Hag, but only a part thereof, for which, he received 'reasonable' royalties.

But Pharmon goes further. In its judgment of 14 July 1981 (Case 187/80, *Merck* v *Stephar & Exler* [1981] ECR 2063), the Court held that 'it is for the proprietor of the patent to decide, in the light of all the circumstances, under what conditions he will market his product ... . (When he has done so, he) must ... accept the consequences of his choice, as regards the free movement of the product within the common market ... '. In other words the Court accepted the principle of *constructive consent.* It follows — according to Pharmon — that a person who submits an application in the United Kingdom for a patent under the Patents Act cannot object to the disadvantages which the application of that law may reserve for him, including the grant of compulsory licences to third parties.

As regards the opposing view, it must be stated immediately that there are certain differences between the way in which it is put forward by the Commission, on the one hand, and Hoechst and the six Member States, on the other. The Commission's position is moderate and more flexible, whilst the German undertaking and the Member States are more extreme and more rigid since they ask the Court to lay down a general rule and thereby make it impossible always and in every case for a compulsory licence to exhaust a patent right. In summarizing their arguments I will follow the line adopted by the Commission and will refer to the opinions expressed in the other observations only when they differ from the Commission's.

In the first place, the Commission analyses the logic behind the rules which in various national legal systems govern compulsory licences. It draws attention to their diversity and notes that in recent years such measures have been adopted infrequently. It does not deny that in certain situations compulsory licences may play an important rôle. Community law cannot therefore ignore them, and for that reason, under the 1975 Luxembourg Convention, provisions were adopted regulating them; those provisions were, however, not comprehensive. As regards the specific case of the United Kingdom, the Commission stresses the special nature of the provision laid down in the Patents Act 1949 (which is no longer in force). Section 41 concerned solely patents in respect of food or medicine and its purpose was to ensure that such products were sold at the lowest price possible. In addition, the provision guaranteed the patent proprietor fair compensation.

Having set the case in that context, the Commission divides its argument into two separate parts. In the first it considers the Hoge Raad's question with regard to the usual situation, in which the proprietor has *contracted* the licence to exploit the patent to a party operating in a different country. It concludes that in that situation 'the proprietor cannot rely on his exclusive rights in order to obstruct the free movement of goods by preventing his licensee from selling directly in the Member State in which the patent is registered' (p. 12, No 32).

Hoechst and certain of the Member States which have submitted observations do not accept that proposition. I, on the other hand, consider that it finds support in the Court's decisions and indeed that it is more far- reaching than the Commission thinks. The Commission's argument deals with contractual consent. However, a contract is only one of the forms in which a party can express his consent. It follows that, if the decisive factor which prevents the operation of the derogation from the rules on the freedom of movement is the patent

proprietor's consent, then in a case such as this nothing is gained by seeking to establish where and how the holder of the compulsory licence put into circulation for the first time the product manufactured by him. On the other hand, it is important to ascertain on what basis he did so. In other words it must be established whether, when the product was first put into circulation, he had obtained the express or implied consent of the holder of the exclusive rights or whether he acted against the latter's wishes. I will come back to that crucial aspect of this problem later.

In the second part of its argument, the Commission asks whether what applies to contractual licences (namely that the licensee is entitled to sell in the country in which the product is covered by an exclusive commercial protection) also applies to compulsory licences. The Commission's reply is that in principle it does not. In that respect it refers to the judgment in *Merck* which, in its view, Pharmon has misinterpreted. It is true that, according to the Court, 'it is for the proprietor of the patent to decide, in the light of all the circumstances, under what conditions he will market his product'. However, it is also true that the proprietor may be said to decide only where it is his own decision to grant the licence and not when that decision is imposed on him.

In any event another argument is decisive. There is much more than a merely formal distinction between a compulsory licence and a contractual licence. In the case of a compulsory licence the decision whether to grant a licence is not taken by the proprietor of the patent after he has assessed the situation of the market in which the product can be put into circulation, but by the State. Since the State takes account of national interest, it is clear that the effects of the licence granted by it cannot operate outside its territory. In other words, the condition imposed by Community law for the non-operation of the derogation from the free movement of goods — namely that the product must be marketed in another Member State by the proprietor of the patent or with his consent — is not satisfied.

In addition to those arguments, Hoechst and the Member States note that acts adopted by the public administration of a Member State are subject to the principle of territoriality. That principle means that Community law cannot confer on the holder of a compulsory licence rights which may also be relied on in the territory of other States. A compulsory licence is an exceptional measure which for the patent proprietor often resembles a penalty. If that is the case, the limits of its effectiveness are determined by the purpose — which usually coincides with the interests of the State — for which it was adopted. In Hoechst's view, to attribute extra-territorial effects to a compulsory licence would quite simply amount to exceeding the limits of the powers laid down in the EEC Treaty.

The Commission does not give an express opinion on that point. However, it cites the judgment of the Court of 20 January 1981 (Joined Cases 55 and 57/80, *Musik-Vertrieb membran* v *GEMA* [1981] ECR 147) and extracts from that judgment a proposition which appears to militate in favour of Pharmon's position. The cases concerned compulsory licences in the United Kingdom to reproduce and market in the United Kingdom musical works covered by copyright, in another State. The Court held that in a common market to which the principle of the free movement of goods

applies 'an author . . . is free to choose a place, in any of the Member States, in which to put his work into circulation . . . (and) may make that choice according to his best interest'. The Court concluded therefore that the Community rules on the movement of goods overrode national provisions concerning the exploitation of copyright which had not been harmonized.

Does it follow that the Commission's position lies between that of Pharmon and Hoechst and that the Commission is, at least to some extent, unable to make up its mind? I do not think so. As I have stated, its approach is objective and pragmatic. I think that it reasoned as follows: there are valid arguments on both sides. It is therefore necessary to consider those arguments up from the point of view of the law on the one hand and the Community interest on the other. It may be concluded that: (a) there are considerable differences between the national rules concerning compulsory licences; (b) the compatibility of the objectives of such rules with the freedom of movement is at least doubtful; (c) in any event it does not seem possible, at least in the present state of affairs, to declare such rules contrary to the provisions of the EEC Treaty; and that therefore '. . . it is preferable for the time being not to uphold the rights of a holder of a compulsory licence to sell directly products manufactured under (such a) licence in a territory in which a parallel patent exists' (p. 16 n. 44).

It is clear that in that passage the stress is laid on the expression 'for the time being'. The Commission is then convinced that a definitive solution to the problem of compulsory licences will be achieved only through the harmonization of the 10 systems. Until then, since those systems pursue purely national interests, it would be unfair to favour one or other Member State by allowing the free movment of goods produced under a compulsory licence granted by the State authorities; unfair — and the Commission warns — dangerous. If the Court were to accept Pharmon's view, the States which have not yet ratified the Convention on the Community Patent would have a fresh reason for putting off that step. In addition, certain States would make more frequent use of compulsory licences to make it possible for their less technically advanced industries to capture large shares of domestic and common markets by exploiting patents in respect of inventions made in other States.

The six Member States and Hoechst base their arguments on entirely different grounds. In their view it is vitally important to ensure that the economic value of patents and the financing of research into new technology, which at present are protected and promoted by national law, are not prejudiced or indeed negated by Community law. They therefore propose to reject clearly and without exception *any possible equivalence* between the effects which, at the Community level, flow from the patent proprietor's consent and the situation which arises as a result of the grant of a compulsory licence by the national authorities.

4. Article 36 of the EEC Treaty provides that 'the provisions of Article 30 to 34 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of . . . the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.

That provision was interpreted by the Court in its judgment of 31 October 1974 (Case 15/74, *Centrafarm* v *Sterling Drug* [1974] ECR 1147. The Court stated that, as a rule which provides an exception to the basic principle, '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 (industrial and commercial) property'. As regards parallel patents '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 . . . ', that justification no longer exists. The derogation from the free movement of goods is therefore not justified.

The Court thus incorporated into 'the body of Community law' the principle that rights and powers deriving from a patent are extinguished, and therefore may no longer be relied upon, when the protected product has been marketed — by the patent proprietor with his consent — in every country in the Community. The reasons which led the Court to adopt that rule (known as the 'exhaustion of the exclusive rights') were set out in the judgment in *Merck.* The Court stated that to allow an inventor or those claiming under him to rely on a 'patent held by him in one Member State in order to prevent the importation of the product *freely* marketed by him in another Member State . . . would bring about a partitioning of the national markets which would be contrary to the aims of the Treaty'.

That then is a first consideration which will help to resolve the problem in this case. An obstacle to the free movement of goods may be regarded as justified on the grounds of the protection of industrial and commercial property *only where the patent proprietor's consent is lacking.* As I suggested under point 3 above, it is of little importance to establish how and where the patented product was put into circulation. On the other hand, in connection with the movement of patented products it is essential to determine whether the patent proprietor has given his consent to the initial marketing of such products. However, the judgment in Merck provides other and, in my view, decisive support for the proposition that the licensee's consent is the key which opens the door of the common market to patented products.

The proprietor of a patent in a Member State, Merck & Co. Inc. sought to prevent various third parties from importing a product marketed in another State where its invention — and this was the crux of the dispute — was not patentable. The Commission and one of the parties in the main proceedings argued that Merck's conduct was unjustifiable because it decided to sell the product in the second State 'of (its) own free will'. On the other hand, Merck, supported by the French Government and the United Kingdom, claimed that the application of such a principle would have frustrated the purpose of the patent. Since the patent right was not recognized by the law of the country in which the product was marketed, the undertaking would not have enjoyed a monopoly when the product was first put into circulation.

The Court declared that 'in the light of that conflict of views, it must be stated that . . . the substance of a patent right lies . . . in according the inventor an exclusive right of first placing the product on the market. That right . . . enables the inventor, by allowing him a monopoly in

exploiting his product, to obtain the reward for his creative effort without, however *guaranteeing that he will obtain such a reward in all circumstances*'. He is not guaranteed a reward, for example, where he has decided 'in the light of all the circumstances under what conditions he will market his product, including the possibility of marketing it in a Member State where the law does not provide patent protection for the product in question'. In that situation the principle of the free movement of goods prevails and that principle is 'a fundamental principle forming part of the legal and economic circumstances which must be taken into account by the proprietor of the patent in determining the manner in which his exclusive right will be exercised'.

It would not have been possible to make a clearer decision in favour of the 'consensual' interpretation of the principle of exhaustion. Can the same reasoning be applied in this case? In my view it can, if only because that view is the sole solution which can ensure that the Court's judgment has the necessary flexibility. I am convinced that the problem raised by the Hoge Raad is not susceptible to rigid solutions such as those put forward by Pharmon, on the one hand, and Hoechst and the six Member States, on the other. In the present state of the Community rules on patents and in view of the differences between the laws governing licences in the Member States, such a rigid approach would present at least two risks: it might encourage the partitioning of national markets or, again, it might lead to uncontrolled exhaustion of industrial property rights from one State to another. As the Commission has already done so there is no need for me to point out the effects which such a state of affairs might have on Community integration in the field of patents or in connection with the economic and scientific exploitation of patents.

However, the solution which I recommend is not justified only by arguments of legal policy. Let us start from an incontrovertible fact: a compulsory licence usually entails the expropriation of the exclusive rights in the name and of and to meet a national interest. If that is the nature attributed to it, Pharmon is mistaken in claiming that in connection with compulsory licences the 'lack of consent' from the patent proprietor may be 'compensated for' or 'replaced' by the decision of the administration. However, the Commission is also mistaken in maintaining that a compulsory licence inevitably creates a conflict between the interests of the State and the patent proprietor — the former because it imposes the licence and the latter because the licence is imposed upon him — and, therefore, that such a measure can *never* involve an element of consent.

According to the Commission, consent is equivalent to a contract (see point 3 above). That is, however, a somewhat simplistic view. For example there is no contract, but there has been consent, where a compulsory licence is applied for by an undertaking legally and economically controlled by the patent proprietor. Moreover, that is not an abstract possibility since it is entirely conceivable that the patent proprietor may prefer to obtain through an intermediary a measure governed by the law of the State rather than subject itself to market forces by negotiating the grant of a licence with a third party.

I could cite other examples of more or less deliberate or conscious cooperation, where the interests of the State and those of the proprietor coincide. However, the example which I have given is sufficient for my purpose. Like the legal impossibility of obtaining a patent, a compulsory licence is a factor which deprives the patent proprietor

of the protection inherent in his right. It follows that a patent proprietor who, in full knowledge of the circumstances surrounding such a measure exposes himself *voluntarily* to the possibility of being deprived of his right, and who voluntarily allows the authorities to encroach upon his right, must accept the consequences of the choice which he has made. *Cuius commoda eius et incommoda* goes the Latin dictum. In substance that is also the principle which lies behind the judgment in *Merck*.

On the basis of those considerations it is therefore for the national court to determine in each individual case whether the grant of a compulsory licence constitutes for the patent proprietor a legal event, the scope and timing of which is uncertain and in respect of which the potential and subsequent putting into circulation of the patented product does not result directly from or is not indirectly related to his express or implied consent.

In the light of what I have said, the problems raised by the Hoge Raad in its judgment in Questions 2 and 3 lose any relevance.

5. On the basis of the foregoing considerations I propose that the Court should reply to Question No 1 submitted by the Hoge Raad by a judgment of 13 January 1984 as follows:

'In the present state of Community law, the rules of the EEC Treaty concerning the free movement of goods do not prohibit a patent proprietor from exercising his right, conferred on him by the law of each Member State, to oppose the importation and the marketing in that State of a product protected by the patent, with reference to products manufactured in another Member State, sold directly from that State and despatched to a purchaser in the first Member State by the holder of a compulsory licence granted under a parallel patent which the said proprietor of the original patent possesses in the other Member State. That is so provided that the holder of the patent has not expressly or implicitly manifested, before or after the putting into circulation of the product, his consent to the exploitation by third parties of the right which he holds.

In the light of that reply I propose that the Court should not rule on the remaining questions'.