REPORT FOR THE HEARING
in Case C-191/90 *

I — Facts and procedure

A — *Legislative background*

1. National law

Patented inventions in the United Kingdom are governed by the Patents Act 1977 (hereinafter 'Patents Act'), which came into force on 1 June 1978.

(a) In conformity with the provisions of the European Patent Convention, the period of validity of United Kingdom patents was extended from 16 to 20 years by the Patents Act.

The transitional provisions of Schedule 1 of the Patents Act provide that patents whose remaining period of validity on 1 June 1978 was greater than 5 years were to be endorsed 'licences of right' during the last four years of their period of validity, now extended to 20 years.

(b) According to section 46(3)(a) of the Patents Act:

'Where such an entry is made in respect of a patent —

(a) any person shall, at any time after the entry is made, be entitled as of right to a licence under the patent on such terms as may be settled by agreement or, in default of agreement, by the Comptroller on the application of the proprietor of the patent or the person requiring the licence'.

(c) According to the case-law of the House of Lords (*Allen and Hanburys Ltd* v *Generics (UK) Ltd and Gist Brocades NV and Others and the Comptroller General of Patents* [1986] RPC p. 242), the Comptroller General of Patents (hereinafter 'Comptroller') may, in exercise of the discretionary power he is accorded to settle terms for licences of right, take into account sections 48(3)(b)(ii), 48(3)(c)(i) and (ii), and 50(1) and (2) of the Patents Act relating to compulsory provisions.

(d) Section 48(3) of the Act provides that the Comptroller may grant compulsory licences under a patent any time after the expiration

* Language of the case: English.

of three years from the date of the grant of a patent on the following grounds:

'(a) where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable;

(b) where the patented invention is a product, that a demand for the product in the United Kingdom —

(i) is not being met on reasonable terms, or

(ii) is being met to a substantial extent by importation;

(c) where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked —

(i) where the invention is a product, by the importation of the product,

(ii) where the invention is a process, by the importation of a product obtained directly by means of the process or to which the process has been applied'.

Section 50 of the Patents Act provides that:

'(1) The powers of the Comptroller on an application under section 48 above in respect of a patent shall be exercised with a view to securing the following general purposes: —

(a) that inventions which can be worked on a commercial scale in the United Kingdom and which should in the public interest be so worked shall be worked there without undue delay and to the fullest extent that is reasonably practicable;

(b) that the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the nature of the invention;

c) that the interests of any person for the time being working or developing an invention in the United Kingdom under the protection of a patent shall not be unfairly prejudiced.

(2) Subject to subsection (1) above, the Comptroller shall, in determining whether to make an order or entry in pursuance of such an application, take account of the following matters, that is to say —

(a) the nature of the invention, the time which has elapsed since the publication in the journal of a notice of the grant of the patent and the measures already taken by the proprietor of the patent or any licensee to make full use of the invention;

(b) the ability of any person to whom a licence would be granted under the order concerned to work the invention to the public advantage; and

(c) the risks to be undertaken by that person in providing capital and working the invention if the application for an order is granted,

but shall not be required to take account of matters subsequent to the making of the application'.

(e) On the basis of those provisions, the practice of the competent authorities in settling, in default of agreement between the parties, the terms of licences of right is to prohibit the licensee from importing from non-member countries the product covered by the patents where the proprietor of the patent manufactures the product within the United Kingdom and, conversely, to authorize the licensee to import the product from non-member countries where the product is manufactured by the proprietor of the patent in the territory of another Member State.

2. Community law

Apart from Articles 30 and 36 of the EEC-Treaty, the provisions of Articles 47 and 209 of the Act concerning the conditions of accession of the Kingdom of Spain and the Portuguese Republic and the adjustments to the Treaties should be considered.

Articles 47 and 209 are exceptions to the general rule abolishing, from 1 January 1986, quantitative restrictions on imports and exports and any measure having equivalent effect between the Community and the two new Member states. They provide as follows:

'1. (...) the holder, or his beneficiary, of a patent for a chemical or pharmaceutical product ... filed in a Member State at a time when a product patent could not be obtained in [Spain] [1] (or) [Portugal] [2] for that product may rely upon the rights granted by that patent in order to prevent the import and marketing of that product in the present Member State or States where that product enjoys patent protection even if that product was put on the market in [Spain] [1] (or) [Portugal] [2] for the first time by him or with his consent.

2. This right may be invoked for the products referred to in paragraph 1 until the end of the third year after [Spain] [1] (or) [Portugal] [2] has made these products patentable'.

B — *Background to the dispute*

(a) Smith Kline and French Laboratories Limited (hereinafter 'SKF') manufactures a pharmaceutical product named 'Cimetidine'. This product, marketed under the brand name 'Tagamet', is used in the treatment of gastric and duodenal ulcers.

SKF manufactures Cimetidine in the form of raw material in Ireland and makes up the finished product in the United Kingdom.

1 — Article 47 Act of Accession
2 — Article 209 Act of Accession

(b) SKF is the proprietor in the United Kingdom of two patents dated 9 March 1972 covering this product.

By virtue of the abovementioned provisions of the Patents Act, the validity of these patents, which would normally have expired on 9 March 1988, has been extended to 9 March 1992. The patents have consequently been endorsed 'licences of right'.

In Ireland, SKF is the proprietor of two patents which have now expired. SKF has commenced legal proceedings with a view to extending one of its patents.

In the other Member States SKF is the proprietor of patents which are still valid.

(c) Generics (UK) Limited (hereinafter 'Generics') and Harris Pharmaceuticals Limited ('Harris') applied for licences of right to manufacture, import and sell Cimetidine. By a decision of 13 March 1988 the Comptroller settled terms of the licence of right since the parties could not agree on conditions for the granting of licences.

The Comptroller fixed the rate of royalty at 28% of SKF's selling price of Cimetidine as it then was. Furthermore, he authorized Generics and Harris to import Cimetidine from non-member countries whether in the form of raw material or of finished product.

On 2 March 1989 SKF appealed to the Patents Court, which varied the decision. The Patents Court increased the rate of royalty to 45% of the selling price and included a term in the conditions for the licence of right prohibiting the licence holders from importing Cimetidine, as a finished product, from non-member countries and from Spain and Portugal. The Patents Court, on the other hand, refused to include a term prohibiting importation of Cimetidine in the form of raw material from non-member countries.

(d) The Court of Appeal refused the appeals by Generics and Harris against the amount of the royalties set by the Patents Court.

(e) Generics and Harris and SKF also raised before the Court of Appeal the matter of the importation of the products covered by the patents from non-member countries and from Spain and Portugal.

Generics and Harris disputed the term prohibiting them from importing the finished product from those countries.

SKF contested the authorization to import raw materials granted to the two undertakings.

(f) By order of 13 February 1990, received at the Court Registry on 19 June 1990, the Court of Appeal stayed the proceedings and referred the following questions to the Court

of Justice of the EEC for a preliminary ruling:

'1. Is it compatible with Articles 30 and 36 of the EEC Treaty for a competent authority charged with settling the terms of a licence under a patent compulsorily endorsed "licences of right" to rely upon the provisions of sub-sections 48(3)(a) and 50(1)(c) of The Patents Act 1977 in determining whether or not to include as a term of such a licence the right to import patented products from outside the EEC? Is it contrary to Articles 30 and 36 for it normally to apply sub-sections 48(3)(a) and 50(1)(c) as requiring it to refuse a licence to import from another country when the patentee works the patent by manufacture in the United Kingdom but to grant a licence to import from a third country where the patentee works the patent by importation of products manufactured in other Member States of the EEC?

2 (a) Is the answer to the previous question affected by the fact that sub-sections 48(3)(a) and 50(1)(c) of the Patents Act 1977 apply to the grant of compulsory patent licences and provide that a compulsory licence may be granted in respect of a patent if the same is not being worked in the United Kingdom?

(b) Is the answer to the previous question affected if, in exercising its discretion as to whether or not to permit importation from a third country, the competent authority places reliance upon sub-sections 48(3)(a) and 50(1)(c) of the Patents Act 1977 in ascertaining what factors are relevant to take into account?

3 Having regard to the provisions of the Treaties of Accession of Spain and Portugal to the EEC and the judgment of the Court of Justice in Case 434/85 (*Allen and Hanburys Limited* v *Generics (UK) Limited* [1988] ECR 1245) is it contrary to Articles 30 and 36 of the EEC Treaty for the competent authority in settling the terms of a licence of right in respect of a patent for a pharmaceutical product to include a term restricting importation of that product from Spain or Portugal?'

In accordance with Article 20 of the Protocol on the Statute of the Court of Justice of the European Economic Community, written observations were submitted by:

— the Government of the United Kingdom of Great Britain and Northern Ireland, represented initially by Rosemary M. Caudwell, of the Treasury Solicitor's Department, subsequently by S. Cochrane, of the Treasury Solicitor's Department, acting as Agent;

— the Kingdom of Spain, initially represented by Carlos Bastarreche Sagües, Director General for Community Legal and Institutional Co-ordination, subsequently by Alberto José Navarro González, Director General for Community Legal and Institutional Coordination, and by Antonio Hierro Hernández-Mora, Abogado del Estado, acting as Agents;

— Harris, represented by Kenneth Parker and Henry Carr, barristers of Roiter and Zucker;

— SKF, represented by Robin Jacob, QC, and Guy Burkill, barrister of Simmons and Simmons;

— Generics, represented by Stephen Kon, solicitor of S. J. Berwin and Co., assisted by Sheila Radford, solicitor of S. J. Berwin and Co.;

— the Commission of the European Communities, represented by Richard Wainwright, Legal Adviser, acting as Agent.

Upon hearing the report of the Judge-Rapporteur and the views of the Advocate General, the Court decided to open the oral procedure without any preparatory inquiry.

II — Summary of the written observations submitted to the Court

A — *National law applicable to the dispute in the main proceedings*

The United Kingdom, SKF, Harris and Generics refer to the abovementioned judgment of the House of Lords (*Allen and Hanburys Ltd* v *Generics (UK) Ltd and Gist Brocades NV and Others and the Comptroller General of Patents* [1986], given by Lord Justice Nicholls, which adjudged the Comptroller to be able to rely on the provisions of the Patents Act in relation to compulsory licences to settle the terms of licences of right.

The United Kingdom nevertheless emphasizes that licences of right must be distinguished from compulsory licences.

These two categories of licences differ both in their nature and in the consequences which flow from them in law.

Licences of right are governed by section 46 of the Patents Act, whose provisions are voluntary. The patentee, may at any time during the life of the patent, apply to the Comptroller for endorsement as 'licence of right'.

It is only in the specific case of patents whose period of validity has been extended in accordance with the transitional provisions of the Patents Act that that section applies compulsorily.

The consequences which follow from entry on the register of 'licence of right' are identical in both cases. Any person is entitled to a licence under the patent on terms to be agreed by the parties or, in the absence of agreement, terms fixed by the Comptroller. In return, the patent holder is required to pay only half the renewal fees.

Thus the Comptroller only intervenes in a small number of cases to settle the terms of the licence.

With regard to compulsory licences, governed by sections 48 to 54 of the Patents Act, these are granted by the Comptroller where he considers that the application submitted to him is on one of the grounds listed in section 48.

SKF points out more specifically that the objectives envisaged by sections 48 and 50 of the Patents Act, which aim to promote industry within the United Kingdom, had already been implemented by legislation prior to the Patents Act. The rule of practice followed by the competent authorities was the following: where a patentee was working his invention in the United Kingdom, any compulsory licence would preclude importation. On the other hand, where a patentee was working the invention abroad and importing himself, then importation by a licensee would be permitted.

This rule was applied in the same way in the context of the Patents Act 1977. In accordance with the judgment of the Court of Justice in Case 434/85 (*Allen and Hanburys* v *Generics* [1988] ECR 1245), all licences of right which have subsequently been settled in the United Kingdom permit both manufacture within the United Kingdom and also importation of products made in other EEC-Member States.

Generics points out that the Commission has brought infringement proceedings in respect of section 48 of the Patents Act (*Commission* v *United Kingdom* Case C-30/90). That case concerns the question of compulsory licences and the discriminatory effect of section 48 in relation to imports from other Member States. It is not however directly related to the present case, which concerns only the issue of importation from outside the Community by a licensee.

Harris refers the Court to the Opinion of Advocate General Mancini in Case 434/85, above, where licences of right under the Patents Act are discussed.

Harris believes that it was a perfectly proper exercise of legislative authority to require, in sections 48(3) and 50 of the Patents Act, that the person to whom the United Kingdom monopoly was granted by virtue of the patent take due account of United Kingdom interests. In the name of those interests the Comptroller may, when settling the terms of a compulsory licence, prohibit importation from outside the Community.

By virtue of the abovementioned decision of the House of Lords, these considerations also apply to licences of right. The Comptroller may, accordingly, where he settles

terms for such licences, have regard to the underlying policy which is the furtherance of the special United Kingdom interests.

Harris also refers to the provisions which apply to the grant of authorization to place on the market medical products and the legal proceedings brought by SKF against it when Harris submitted an application for authorization for Cimetidine.

According to the *Commission*, the relevance of sections 48(3) and 50 of the Patents Act to the present case derives from the practice of the Comptroller not to licence imports from non-member countries if the product is already being manufactured adequately in the United Kingdom.

B — *The first question*

SKF maintains that Patents Court's approach of taking into account the existence of manufacturing within the United Kingdom as the sole determining factor for the purposes of imposing restrictions on imports by the licensee is wrong. It constitutes wrongful discrimination against undertakings based in other Member States.

In the first place, such discrimination is contrary to Article 30 of the Treaty.

The terms of a licence of right must be considered from two contrasting standpoints, that of the licensee on whom restrictions are imposed, and that of the patentee whose business and exploitation of the patent may be affected by the acts of the licensee.

In Case 434/85, above, the only relevant standpoint was that of the licensee as the case involved discrimination between several categories of licensee. In the present case, which concerns discrimination between several categories of patentee, the standpoint of the patentee should be considered.

In this respect, the inclusion in the licence of a term permitting imports from non-member countries where the patentee manufactures the product in another Member State is a measure having equivalent effect to a quantitative restriction on imports.

Products imported from a non-member country by the licensee will be in competition with those of the patentee, reducing the patentee's sales. Trade between Member States will then be affected since the patentee will be forced to reduce imports from the Member State where he manufactures the product. In the present case, Cimetidine imported from Hungary and Yugoslavia, where patent protection is difficult to obtain, will gradually replace imports by SKF from Ireland.

In the second place, such discrimination may not be justified by Article 36 of the Treaty.

With regard to the first sentence of Article 36, it is hard to see, from the point of view of the patentee, that a clause which diminishes the rights of the patentee by permitting the licensee to import, from non-member countries amounts to the protection of industrial and commercial property. The specific subject matter of a patent endorsed 'licences of right' still includes the right to object to the grant of licences permitting imports from non-member countries. The first sentence of Article 36 is therefore inapplicable.

Moreover, the requirements of the second sentence of Article 36 are not satisfied. Discrimination between patentees manufacturing in the United Kingdom and patentees who choose to work their inventions in other Member states is arbitrary because it is not based on any proper ground. The former only have to face competition from manufacturers in other Member States of the Community, the latter face competition from imports from anywhere in the world. Such discrimination is undesirable. It favours purely national working of patents and does not allow manufacturers and consumers to benefit from economies of scale which flow from the centralization of manufacturing operations at a one plant.

The approach adopted by the Patents Court amounts also to a disguised restriction on trade between Member States. It promotes, for the abovementioned reasons, United Kingdom manufacture by patentees, and discourages working of patents by way of imports from other Member States.

The patentee is disadvantaged in the sense that he cannot treat the Community as a single market, and choose his manufacturing base according to purely economic criteria. The application of section 48(3)(b) and 50(1)(c), whose object is to favour national production and, it would appear, most often United Kingdom companies, constitutes arbitrary discrimination (judgment in Case 434/85 *Allen and Hanburys*, above) and a measure having an effect equivalent to a quantitative restriction (judgment in Case 249/81 *Commission* v *Ireland* [1982] ECR 4005).

SKF infers from the above considerations that where, by virtue of the discretion conferred upon it, the appropriate authority responsible for settling the terms of a licence of right refuses to permit importation from non-member countries where the patentee manufactures in the United Kingdom, then it should also refuse to permit such imports in the case where the patentee manufactures in another Member State of the Community.

That analysis does not apply, however, where the patentee is himself working the invention in a non-member country. In such a case, an inclusion in the licence of a term permitting import from non-member countries has no effect on trade between Member States.

Finally, it should be noted that, from the point of view of the licensee, a term in a compulsory licence restricting import from non-member countries has itself no effect on trade between Member States and therefore does not contravene Article 30 of the Treaty

(judgment in Case 51/75 *EMI* v *CBS* [1976] ECR 811, paragraphs 8 to 21).

SKF proposes, therefore, that the first question should be answered as follows:

'Articles 30 and 36 of the EEC Treaty must be interpreted as precluding the competent authority from exercising its discretion to settle a term in a licence of right which permits imports from non-member countries, in a case where the patentee works the patent by importation of product manufactured in other Member States of the EEC, where it would not in comparable circumstances settle such a term in the case where the patentee works the patent by manufacture in the United Kingdom'.

The *Commission* proposes to reformulate the first question as follows:

'Are Articles 30 and 36 of the Treaty to be interpreted as allowing the competent authorities of a Member state to refuse a "licence of right" to import from non-member countries when a product is manufactured in that Member State, but to grant a licence to import from non-member countries when that product is manufactured in another Member State'.

The judgment of the Court in *Allen and Hanburys*, above, although concerning different facts, requires that a negative reply be given to this question. That judgment declared discrimination as between products manufactured in one Member State and products imported from another Member State to be contrary to Community law. Moreover, the Commission has brought infringement proceedings against discriminatory provisions contained in United Kingdom legislation on compulsory licences, and in particular sections 48(3)(a) and 50(1)(c) of the Patents Act (Case C-30/90 *Commission* v *United Kingdom*). Those proceedings, according to the Commission, deal with substantially the same point as the present case.

In so far as the practice of the competent authorities for settling the terms of licences of right acts as an incentive to manufacture in the United Kingdom and discourages the patent owner from treating the common market as a single market and from deciding where to manufacture within that market on the basis of purely economic considerations, it affects intra-Community trade and constitutes arbitrary discrimination. It is therefore incompatible with Articles 30 and 36 of the Treaty.

This does not mean that the Comptroller is obliged to allow imports from non-member countries. He need merely, when settling the terms of a licence of right in relation to those imports, treat manufacture in the United Kingdom and manufacture in another Community country on the same footing.

In relation to the first part of the question, *Harris* claims that in settling terms of licences of right the competent authority may, in pursuance of the interests of the United Kingdom envisaged by sections 48 and 50 of the Patents Act, prohibit importation of products covered by the patent from countries outside the Community. This

construction does not run counter to the judgment in *Allen and Hanburys*, above, which only involves prohibitions on the importation of products covered by a patent from Member States.

As regards the conditions under which the competent authority exercises that power, which are the subject of the second part of the question, Harris maintains that that authority is not acting in disregard of any Community law provision when refusing to impose on the licensee a term prohibiting the importation of a product covered by the patent from non-member countries where the patentee does not manufacture the product in the United Kingdom.

Harris puts forward the following argument in support of that view:

1. There are no apparent grounds for contending that the Comptroller's refusal to prohibit the licensee from importing patented products from outside the Community would impede Community trade. In the present case, in the absence of any such prohibition, the patentee is free to manufacture and sell in the Community and the licensee is free to manufacture in the United Kingdom and import raw material from suppliers located both inside and outside the Community. The royalty set by the Patents Court constitutes fair compensation for the patentee, whose legitimate interests are thereby protected.

2. On the contrary, the imposition of the obligation on the Comptroller to prohibit the licensee from importing from non-member countries would have serious detrimental consequences for trade, in particular for Community trade, and would cause serious competitive distortions.

In the present case, the patents owned by SKF in various Member States other than the United Kingdom (including Ireland if the legal proceedings to extend the life of the patent are successful) would prevent Harris from manufacturing or importing the product in raw-material form in those States. If a ban were imposed on importation into the United Kingdom from outside the Community in the context of the terms of the licence of right settled by the Comptroller, Harris could bring the drug on to the Community market only by manufacturing it in the United Kingdom.

In that case, Harris would be placed at an overwhelming competitive disadvantage in relation to SKF, which enjoys very substantial benefits from its manufacturing location in Ireland.

Harris would thus be either shut out of the Community market or placed at a disadvantage by comparison with the patentee. Trade between Member States would then be reduced and the consumer would be the ultimate victim of these various restrictions and distortions.

3. Furthermore, to compel the Comptroller to impose such a prohibition at the stage of settling terms of the licence of right would constrain him to take account of non-United Kingdom interests when the underlying policy of the abovementioned provisions of the

Patents Act is to facilitate the commercial working of patents in the United Kingdom.

A new and very different policy to that envisaged by the United Kingdom legislature, which has set up a coherent regime governing property rights which are United Kingdom in origin, would thus be arbitrarily introduced.

Generics submits observations in the same vein as those of Harris.

Its arguments are as follows:

1. The competent authority may indeed rely upon sections 48(3)(a) and 50(1)(c) of the Patents Act in determining whether to permit a licensee of right to import the patented products from outside the Community.

(a) First of all, Generics seeks to show that the present case concerns different points to those in the Commission's infringement proceedings (Case C-30/90) in relation to section 48 of the Patents Act, which incite the patentee or his beneficiaries to manufacture in the United Kingdom or risk an obligatory licence being granted to a third party.

The present case, unlike the infringement proceedings referred to above, does not concern the conditions under which the Comptroller is to determine whether or not to grant a licence of right. It only concerns those factors which the Comptroller can legitimately take into account in settling the terms of licences of right.

Furthermore, the present case has no impact on where a patented product is manufactured in the Community. It only concerns whether or not the Comptroller has a discretion to refuse importation from outside the Community where a patented product is not being manufactured in the United Kingdom.

The Comptroller may not, on the other hand exercise his discretion in the present case to:

require domestic manufacture of the patented product in preference to manufacture in another Member State;

discriminate between Member States in determining whether or not to allow importation of the patented product from another Member State.

(b) In the second place, the provisions in question, in so far as they apply to licences of right, are not in contravention of Articles 30 and 36 of the Treaty as regards importation of the patented product.

The judgment in *EMI Records Ltd* v *CBS United Kingdom Ltd* (above, paragraph 10) establishes that Article 30 does not offer protection as regards imports from non-member countries since such imports do not affect

trade between Member States. It should be pointed out, on this point, that the judgment in *Allen and Hanburys*, above, only concerns restrictions in intra-Community trade.

Furthermore, in the absence of a common Community system of patent protection, the continued existence of legislation conferring different levels of patent protection is not in itself an infringement of Article 30 of the Treaty (see especially the judgments in Cases 144/81 *Keurkoop BV* v *Nancy Kean Gifts BV* [1982] ECR 2853, paragraph 18, and 35/87 *Thetford Corp.* v *Fiamma SpA* [1989] ECR 3585).

Community law affects the terms on which imports may be made from non-member countries only in so far as the Community has adopted particular measures relating to such imports as part of its common commercial policy under Article 113 of the Treaty. If the Community has not adopted such measures then Member States are free to set the terms on which such imports can be made, subject to compliance with Community requirements concerning the importation of pharmaceuticals as set out in the Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1975 L 147, p. 13).

In the present case it has never been suggested that the policy pursued by the Comptroller in application of section 48 of the Patents Act runs contrary in any way to Article 113 of the Treaty or to Council Regulation (EEC) 288/82 of 5 February 1982 on common rules for imports (OJ 1982 L 35, p. 1).

2. Articles 30 and 36 of the Treaty do not prevent the competent authorities from discriminating, on the basis of the Patents Act, between cases where the patented product is manufactured domestically and cases where the patented product is manufactured in another Member state.

(a) Contrary to SKF's argument, the Comptroller may not legitimately take into account the interests of manufacturers in other Member States when settling terms of a licence of right. The Comptroller would be going beyond purely national policy which he is charged with implementing. He has no jurisdiction to implement the policy objectives of other Member States. Finally and above all, the Comptroller would be required to impose the objectives laid down by the United Kingdom legislature, in particular the protection of national industry, on other Member States without knowing whether those States wish to pursue that policy.

(b) This practice does not constitute discrimination between national products and imports from other Member States.

It must be pointed out that the present case is only concerned with the application of national policy with regard to imports from non-member countries.

Furthermore, the argument, based on Case C-30/90, that there is discrimination where the patentee is incited to manufacture domestically cannot be accepted.

The arguments adduced in Case C-30/90 cannot be applied to the present case for the abovementioned reasons.

In any event, the differences in national rules on matters such as patents amount to 'objective differences' which justify the United Kingdom in differentiating between manufacture there under a United Kingdom patent and manufacture elsewhere in the Community under a patent in the Member State concerned.

The essential flaw in SKF's argument is that it assumes, on the one hand, that the licensee is in the same position as a patentee as regards working the parallel patents in other Member States and, on the other, that the protection offered by the patent legislation in other Member States is comparable to that in the United Kingdom.

As Lord Justice Nicholls stated in the judgment of the Court of Appeal in the present case, the differences in legislation between Member States prevent the licensee from competing with the patentee in the Community market.

In the present case, the application of separate rules of Irish law will not allow the licensee to manufacture the product in Ireland if SKF's application for a patent extension is granted, having regard to the patents which SKF owns. If the licensee is unable to import the product from outside the Community, it will then be forced to manufacture the product in the United Kingdom on terms which are less favourable than those which apply to the patentee.

When the Comptroller authorizes the licensee to import the product from non-member countries where the patentee does not work the patent in the United Kingdom, he is merely taking into account the objective differences between conditions for the importer and the domestic manufacturer arising from the differences between national legislation.

Furthermore, Article 89 implicitly recognizes that there is a clear divergence between the Member States as regards the grant of compulsory licenses which requires adjustment over a period of time.

The United Kingdom refers to the judgment of the Court in *Allen and Hanburys Limited*, above, concerning patents endorsed as subject to licences of right, but points out that it cannot be applied in the present case, which concerns trade between a Member State and a non-member country.

(a) According to the case-law of the Court, the exercise of an intellectual property right to restrict importation from non-member countries is not subject to the same limitations as apply in respect of the free movement of goods between Member States and does not constitute a measure having equivalent effect within the meaning of Article 30 of the Treaty (judgments in Case 51/75 *EMI Records* v *CBS United Kingdom* [1972] and Case 270/80 *Polydor Limited* v

Harlequin Record Shops Limited [1982] ECR 329).

It follows that the competent authorities, when settling terms of licences of right, may prohibit imports from a non-member country without being in breach of Community law.

(b) However, the argument put forward by SKF whereby the competent authority is bound to treat manufacture of the patented product in another Member State as a product manufactured in the United Kingdom is unfounded. This argument, which relies on Article 30 of the Treaty, rests on the premise that refusal to prohibit importation restricts intra-Community trade, but such a restriction has not been established. It should be noted at this point that, upon the grant of the licence, the licensee is free to import in such quantity as it wishes into the United Kingdom from other Member States.

The United Kingdom Government submits that Community law has no application to the present case. It adds that, if SKF were to succeed in its action, the effect would be to extend its Irish patent rights into the United Kingdom.

The Spanish Government does not see fit to submit observations on the first question and refers to the observations which it submitted as intervener in Case C-30/90.

C — *The second question*

SKF submits that neither of the matters set out in this question should affect the answer to the first question. The effect of section 48(3)(a) and 50(1)(c) of the Patents Act 1977 in this case is to create arbitrary discrimination as between manufacturers in the United Kingdom and those in other Community Member States.

A patentee who does not manufacture the product in the United Kingdom is penalized. The loss or dilution of his monopoly rights by the grant of a licence of right authorizing imports from non-member countries cannot adequately be compensated by the right to receive a fair return on his patent.

Furthermore, the obligation to work the patent in the United Kingdom is not necessary, as the United Kingdom market's needs can be satisfied by imports from other Member States.

The Commission wonders whether the factors in this question should be separated from the first question. In any event, it believes that these factors do not affect the answer to the first question.

Harris has not examined the first question separately from the second question.

Generics submits that the application of sections 48 and 50 of the Patents Act to compulsory licences will be dealt with in Case C-30/90. The factors referred to in that question, therefore, do not affect the answer to the first question.

Generics proposes the following answer to Question 2(b):

'It makes no difference whether, in the exercise of his discretion whether or not to allow importation from a third country, the Comptroller is regarded as being required by the Patents Act 1977 to adopt the abovementioned policy, or whether in adopting such a policy he is regarded as merely having reference to the factors set out in section 48(3)(a)'.

In either case, the Comptroller's decision, in the absence of legislation pursuant to Article 113 of the Treaty, is a matter for national legislation which, in the present state of Community law, has not yet been harmonized.

The United Kingdom Government also proposes that the Court reply that the factors concerning compulsory licences in the question do not affect the answer to the first question concerning licences of right.

The Spanish Government has not submitted observations on this question.

D — *The third question*

The Spanish Government submits that it is contrary to Articles 30 and 36 of the Treaty for the competent authority, in settling the terms of a licence of right in respect of a patent for a pharmaceutical product, to include a term restricting importation of that product from Spain or Portugal.

Article 47 of the Act of Accession does not provide any basis for such a condition.

That article, which restricts the general principle of the free movement of goods enshrined in Article 30 of the EEC Treaty and Article 42 of the Treaty of Accession, was worded in such a way as to limit as far as possible the effects at variance with that principle. It must, therefore, be interpreted narrowly.

The right to give effect to the restriction provided for by that article is vested solely in the patentee or his beneficiary. Furthermore, the exercise of that right is merely optional.

If the competent authority were to impose a restriction on importation by virtue of these provisions, it would commit a twofold infringement. In the first place, it would thereby arrogate to itself rights which belong

solely to the holder of the patent or his beneficiary and, in the second place, it would change a right in the domain of the inventor into an obligation imposed on the holder of a licence of right.

This would ignore the underlying reason for Article 47 of the Act of Accession, which is to offset the injury which might be caused to certain holders of a patents for pharmaceutical products registered in the Member States of the Community of Ten as a result of their inability to obtain comparable protection for those products in Spain before 7 October 1992. The formula was devised to enable the holder of the patent to invoke his right to prevent parallel exports from Spain for a limited period (until 7 October 1995).

Comparison of Article 47 with the national rules on licences of right tends to support this construction.

Article 47, whose aim is to offer compensation for the damage caused by the inability to obtain in Spain a monopoly on the exploitation of a pharmaceutical product under a patent, may not be applied in the context of national rules on licences of right which do not safeguard any monopoly of manufacture or marketing.

A term included in a licence of right restricting the importation of pharmaceutical products from Spain and Portugal cannot, therefore, be justified by the derogations provided for in the Act of Accession, and is contrary to Article 30 and 36 of the EEC Treaty.

The Commission, the United Kingdom Government, Generics and Harris submit observations which, in substance, agree on the question raised.

Those observations are based on Articles 47 and 209 of the Act of Accession.

(a) The aim of those provisions is to put in place a derogation from the application of the 'exhaustion of rights' doctrine. According to that doctrine, once the products covered by the patent are put on the market in a Member State either by the owner of the patent or with his consent, the holder of the patent has exhausted his rights in relation to those products and the patent may not be relied upon to prevent the product from circulating in the Community (judgment in Case 15/74 *Centrafarm* v *Sterling Drug & Winthrop* [1974] ECR 1147).

The doctrine applies even where the product was not patentable in the Member State where it was first marketed (judgment in Case 187/80 *Merck* v *Stephar* [1981] ECR 2063).

The abovementioned articles of the Act of Accession are exceptions to the principle laid down in the latter decision. The articles in question provide that the doctrine of exhaustion of rights shall not apply, during a specified period, to British pharmaceutical prod-

ucts which are marketed in Spain and Portugal and which are not patentable there.

(b) Patents endorsed as 'licences of right' are 'weak' patents. Their specific subject matter is the right of their holder to obtain a fair return. As the Court held in *Allen and Hanburys*, above, a patentee cannot rely on a provision of national legislation which entitles him to oppose importation by the licensee from another Member State.

(c) There is no 'right of first marketing' for these patents which could be regarded as having been exhausted.

The doctrine of exhaustion of rights does not therefore apply to these patents.

Consequently, the abovementioned provisions of the Act of Accession derogating from this doctrine also do not apply.

Moreover, this is the interpretation which Lord Justice Nicholls accepted in the decision of the Court of Appeal.

(d) There is therefore no difference between the licensee's imports from Spain and Portugal and imports from other Member States.

SKF submits, on the other hand, that Spain and Portugal must be treated as non-member countries when settling the terms of licences of right for the importation of pharmaceutical products.

Articles 47 and 209 of the Act of Accession oust the doctrine of exhaustion of rights since a patentee can enforce his patent against the importation of his own goods. According to SKF, these articles go further than that doctrine because the words 'even if' mean that he can also enforce his patent against other goods made or imported by third parties, including licensees.

The transitional provisions allow the patentee to regard the products in question as products emanating from non-member countries.

In the absence of explicit wording, patents subject to licences of right should not be excluded from the application of the provisions in question. It should be recalled, furthermore, that where a patent is subject to a licence of right, the patent holder is not to be deemed to have exhausted his rights (judgment in Case 19/84 *Pharmon* v *Hoechst* [1985] ECR 2281). Under those circumstances, if a patentee can enforce the patent against importation of his own products, *a fortiori*, he can enforce it against goods made and imported by third parties without his authorization.

Neither the principles laid down by the judgement in *Allen and Hanburys*, above, concerning the application of Article 30, nor the provisions of Article 36 apply in this case since the restriction on the importation of products from Spain and Portugal are based on the derogating provisions of the Act of Accession.

F. Grevisse
Judge-Rapporteur