

OPINION OF MR ADVOCATE GENERAL MANCINI
delivered on 2 December 1987 *

*Mr President,
Members of the Court,*

1. By a judgment delivered on 12 December 1985 the House of Lords has asked this Court to deliver a preliminary ruling on whether certain provisions of British patent law are compatible with the principles laid down by the EEC Treaty on the free movement of goods.

I shall first consider the relevant provisions. On 1 June 1978 the Patents Act 1977 came into force in the United Kingdom repealing the earlier Patents Act 1949. In conformity with the European Patent Convention, the new act increased the term of exclusive patent rights from 16 to 20 years. The original expiry dates of 'old existing patents' remained the same. For 'new existing patents', on the other hand, that is to say patents which on 1 June 1978 still had five or more years to run, an extension of four years was granted under transitional rules. However, from the start of that four-year period, the words 'licences of right' were automatically entered in the register and on the certificates corresponding to those patents.

The effect of that endorsement is as follows: under section 46 (3) (a) of the Patents Act 1977, from the time of such endorsement,

'any person shall ... be entitled as of right to a licence ... 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'. Moreover, under section 46 (3) (c), 'if in proceedings for infringement of the patent (otherwise than by the importation of any article) the defendant or defender undertakes to take a licence on such terms, no injunction or interdict shall be granted against him and the amount ... recoverable against him by way of damages shall not exceed double the amount which would have been payable by him as licensee if such a licence on those terms had been granted before the earliest infringement'.

In the course of the main proceedings Lord Diplock set out the scope and purpose of that provision, with particular regard to the powers it confers on the Comptroller. He stated that the Comptroller's decision merely had the same effects as would have been produced by a licensing agreement and 'merely makes lawful acts ... which if done without the consent of the patentee would be unlawful' (*Beecham Group PLC v Gist-Brocades NV* (1986) 1 WLR 51, at p. 61). However, that explanation does not take account of the words in brackets in section 46 (3) (c). As a result of that rider, a British infringer who imports from another State a product covered by a patent endorsed 'licences of right' is treated differently from an infringer who manufactures the same product within the United Kingdom and sells it there.

* Translated from the Italian.

In particular, provided the latter undertakes to apply for a licence of right he is at liberty to carry on his unlawful activity until the administrative measure is adopted; an infringer by importation on the other hand may find that imports are blocked even before they have begun and even if he has requested a licence. He will also have to pay damages whose amount, in contrast to those payable by a producer guilty of infringement, is not subject to any limit.

2. I will now turn to the facts of the case. On 15 September 1967, Allen and Hanburys Ltd, a pharmaceutical laboratory which is a subsidiary of Glaxo Operations UK Ltd, which in turn is owned by the multinational Glaxo Holdings PLC, obtained a patent under the Patents Act 1949 for 'salbutamol', a drug which is particularly effective in the treatment of asthma.

The drug is produced by Allen & Hanburys and in the United Kingdom it is always sold by that company under the proprietary name 'Ventolin'. In the rest of the Community—including Italy—the drug is protected by parallel patents held by various members of the group who are also responsible for marketing it. However, it should be noted that until a few years ago patents could not be granted for pharmaceutical inventions under Italian law. Accordingly the salbutamol to be found in Italian chemists' shops was not solely produced by Allen & Hanburys and sold by Glaxo; it was also manufactured and marketed by other undertakings, obviously without the consent of the British manufacturer.

Generics (UK) Ltd (hereinafter referred to as 'Generics') is a subsidiary of a company registered in Panama; it carries on business in the United Kingdom as a distributor of 'generic' drugs, that is to say drugs which are bought in bulk for resale either as branded drugs or, more commonly, under their chemical name. Since those distributors do not engage in research, the prices of such drugs are usually lower than the prices charged by the companies which hold the patents.

In November 1983, that is to say after the exclusive rights for salbutamol had been extended pursuant to the Patents Act 1977, Generics asked Allen and Hanburys for a licence of right in order to import from Italy the drug manufactured there without the consent of the inventor. That request was not granted and Generics made an application to the Comptroller on 2 August 1984. Shortly afterwards, however, before the Comptroller had taken a decision, Generics informed Allen & Hanburys of its intention to import the drug immediately. Allen & Hanburys brought proceedings for an injunction which was duly granted; Generics appealed against that judgment and the proceedings subsequently reached the House of Lords. As mentioned above, the House of Lords, pursuant to the third paragraph of Article 177 of the EEC Treaty, referred four questions to this Court which I may summarize as follows:

- '(1) Is the holder of a patent which, under the law of a Member State, is endorsed 'licences of right' prevented by Articles 30 and 36 of the EEC Treaty from obtaining from the competent national authorities an order prohibiting the importation from another Member State of goods which infringe the patent, where that law makes no provision for measures against a person

who infringes the same patent by acts other than importation?

- (2) Under the abovementioned Community provisions, are the national authorities which grant 'licences of right' under an obligation to include in such licences terms permitting importation from another Member State?
- (3) Is the answer to Questions 1 and 2 affected, and if so how, by the fact that the imported goods are pharmaceutical products and originate in a Member State whose legislation does not allow such products to be patented?
- (4) If the answers to Questions 1, 2 and 3 are to the effect that Articles 30 and 36 of the EEC Treaty do not allow such imports to be prohibited, may an injunction to that effect nevertheless be granted on the basis of the case-law of the Court of Justice and in particular of the principles it has enunciated on the subject of unfair competition and consumer protection?

3. The parties to the main proceedings, the United Kingdom, and the Commission of the European Communities have presented written observations and oral argument in the proceedings before this Court.

They have basically advanced two lines of argument. Allen and Hanburys and the United Kingdom argue that a patent endorsed 'licences of right' remains an industrial property right and as such may be protected pursuant to Article 36 of the Treaty. Although he does not have absolute control over his exclusive rights, the

inventor retains the power to act against a licensee who fails to comply with the terms of the licence. In the Community context it is clear from the Court's case-law that the holder of a patent cannot be denied the right to oppose the importation of patented products unless they have been marketed with his consent in the exporting country (judgment of 31 October 1974 in Case 15/74 *Centrafarm v Sterling Drug* [1974] ECR 1147; judgment of 22 June 1976 in Case 119/75 *Terrapin v Terranova* [1976] ECR 1039; judgment of 14 July 1981 in Case 187/80 *Merck v Stephar and Exler* [1981] ECR 2063).

That, according to Allen and Hanburys and the United Kingdom, is clearly not the position in this case. The fact that salbutamol could not be patented in Italy means that it would have served no useful purpose for Allen and Hanburys to consent to its marketing; Allen and Hanburys therefore had the right to oppose its importation into the United Kingdom. In the final analysis the power of the Comptroller and the national courts to suspend importation in such situations serves to strike the necessary balance between two interests of equal weight: the public interest dictating the grant of the licence of right and the protection that must still be afforded to a patent proprietor whose property rights have not yet been exhausted under Community law.

The Commission and Generics, on the other hand, consider that the holder of a patent endorsed 'licences of right' cannot prevent the exploitation of the invention by third parties but is merely entitled to receive a fair reward from the licensee. On that basis, and having regard to the judgment in *Merck* referred to above, the derogation from the principle of the free movement of goods provided for by Article 36 on grounds of the protection of industrial property cannot apply in this case. Moreover a measure prohibiting the importation of salbutamol

into the United Kingdom is clearly disproportionate to the need to safeguard the rights afforded by a patent bearing such an endorsement.

The conclusions that are to be drawn from each of the two views are obvious. The Commission and Generics consider that the ban on imports is not compatible with Community law. On the other hand it is regarded as lawful by Allen and Hanburys and the United Kingdom which, however, do not rely solely on the arguments referred to above (the legal impossibility of patenting the pharmaceutical product in Italy); they also invoke certain 'mandatory requirements' recognized by the Court in a long series of well-known cases. They argue that the prohibition is justified by the need to protect such interests as public health, fair trading and consumers' rights.

4. It is trite law that the provisions of the Treaty on the free movement of goods, in particular Article 30, preclude restrictions on imports and measures having equivalent effect, that is to say all national provisions capable of hindering directly or indirectly, actually or potentially, intra-Community trade. Equally, it scarcely needs saying that such restrictions and measures are lawful under Article 36 in so far as they are justified on certain grounds, including the protection of industrial and commercial property.

However, it is evident from the context and, in particular, from the second sentence of Article 36 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 policy, yet the

exercise of those rights may nevertheless, depending on the circumstances, be restricted by the prohibitions in the Treaty'. 'Inasmuch as it provides an exception to one of the fundamental principles of the common market, Article 36 in fact admits exceptions to the free movement of goods only to the extent to which such exceptions are justified for the purpose of safeguarding rights which constitute the specific subject-matter of that property' (judgment in *Terrapin v Terranova*, paragraph 5, my emphasis). Moreover, prohibitions or restrictions laid down by national provisions must not 'constitute a means of arbitrary discrimination or a disguised restriction' (Article 36, *in fine*).

That said, it seems to me that the main problem in this case is not to determine what effect a patent subject to the endorsement 'licences of right' actually has in Community law and whether the first part of Article 36 applies in such circumstances but to ascertain whether the rules at issue fall within the scope of the last sentence of Article 36, that is to say whether the ban on imports to which the grant of the licence is subject constitutes in itself arbitrary discrimination or a disguised restriction on trade.

It should be borne in mind that under the Patents Act 1977, during the four-year extension of the term of a new existing patent, any person who produced or imported the patented article could obtain a licence and that, in the words of Lord Diplock, such a licence 'merely makes lawful acts . . . which [otherwise] would be unlawful'. It has also been seen that no such equality exists in cases of patent infringements inasmuch as the competent authority does not have the power to enjoin an infringer who produces articles within

the country to suspend his unlawful operations whereas it may adopt restrictive measures having analogous effect with regard to an infringer by importation.

Asked by the Court to explain the reasons for that disparity, the United Kingdom stated that an infringer within the country can always obtain a licence as of right and thereby bring his infringement to an end. That outcome is thus 'inevitable'; since the delay in granting the licence is due not 'to any right of the patentee to prevent the grant' but 'to the failure of the parties to agree terms' it would be wrong to grant the patentee an injunction pending the grant of the licence.

In the case of an infringer by importation, the United Kingdom goes on, it may on the other hand be appropriate to prohibit importation as a term of the licence. But such a measure will be adopted only in exceptional circumstances, in particular 'where damages would not be an adequate remedy'. In that situation 'to deny a patentee relief by way of an interim injunction would be to allow importers a period of grace' which would give rise to the risk of unlicensed articles flooding on to the market which in turn would necessarily have irreversible consequences if it were later found that imports should have been prohibited. The United Kingdom therefore considers that it is unjustified to maintain that section 46 (3) (c) is protectionist in aim; as this case bears out, that provision seeks merely to defend the patentee against unfair competition.

It is a clever reply but it does not suffice to resolve the contradictions underlying the

provision. In any event by making the grant of the licence subject to a requirement that imports are to be suspended the nature of that grant as an individual right is ultimately negated (or to a large extent debased) and thus the licensee is denied the possibility of subsequently legalizing his own situation. We have already seen, however, that where the term of a patent has expired but has been extended by operation of law, 'any person [including an importer therefore] shall . . . be entitled as of right to a licence' and that one of the effects of such a grant is to regularize any prior infringements by the licensee.

But that is not all. The explanation furnished by the United Kingdom implies that the holder of a patent whose term has been extended continues to enjoy, as against an infringer by importation, all the rights enjoyed by the proprietor of a patent with full validity and whose rights are not exhausted. Such a result is not merely contrary to the letter and the spirit of section 46 but, from the point of view of Community law, it is manifestly a discriminatory measure. The justification for the patentee enjoying full rights is that the infringement in question consists in the importation of goods from another Member State.

It may also be noted that the measure in question comes nowhere near to meeting the conditions laid down in the *Terrapin v Terranova* judgment. The reasons are obvious. The United Kingdom states that a patentee must also be able to obtain an 'adequate remedy' in cases of infringement by importation. However, prohibition of imports would preclude any possibility for the importer to exploit the invention and thus pay to the patent proprietor the remuneration and damages to which he was entitled by law. It seems to me that it would

be difficult to conceive of any derogation which is less 'justified' or even less appropriate than this for protecting industrial property rights in the form of a patent whose term has been extended.

may be justified on the basis of: (a) the fact that it was impossible to patent the product in the exporting country; (b) mandatory requirements such as the protection of fair trading and the consumer.

All in all there are thus reasons enough for concluding that the power given to the Comptroller and the national courts to prohibit imports encounters an inescapable obstacle in the letter of Article 36 and the interpretation of that provision by the Court of Justice.

5. In the light of the foregoing it is an easy matter to resolve the problem raised by the second question. If, during the extension of the term of a new existing patent, 'any person' is entitled to exploit the invention in question as he sees fit, it is obvious that, leaving aside the question of infringement, the national authorities cannot make the grant of licences subject to terms that are likely to affect imports of goods from another Member State. Apart from denying importers alone the right to exploit the invention, such terms would ultimately act exclusively against products originating in the rest of the Community; they would thus in effect constitute a restriction on intra-Community trade and as such be contrary to the prohibition laid down in Article 30 of the Treaty. Once that conclusion is established, it is for the national authorities to determine precisely what means are most appropriate to ensure that the licences are granted in a manner compatible with Community law.

The third and fourth questions seek to establish whether, leaving aside the derogation on grounds of the protection of industrial property, the measure at issue

The answer can only be in the negative. With regard to (a), it is undeniable that at the time when salbutamol was invented it could not be patented in Italy. Notwithstanding that fact, there is no need to examine whether the Community principle concerning the exhaustion of exclusive rights applies in this case. On the contrary, the problem here concerns the position of a person who, on the basis of the law of his State, wishes to exploit an invention pursuant to a 'licence of right' which under that law may be granted *invito domino*, that is to say without the consent of the proprietor of the patent. In other words the fact that the salbutamol was produced in Italy without the permission of Allen and Hanburys is irrelevant to the position of someone who, like Generics, is entitled to obtain a licence to exploit that invention.

Finally, as regards the possibility of invoking any mandatory requirements, it is sufficient to point out that the Court has consistently held that such requirements must have been laid down for reasons which are in the public interest; they can be relied upon as derogations from Article 30 only in so far as the national rules apply without distinction to trade in domestic and imported products and are not protectionist in nature (judgment of 17 June 1981 in Case 113/80 *Commission v Ireland* [1981] ECR 1625, at paragraph 11; judgment of 6 November 1984 in Case 177/83 *Kohl v Ringelhan & Rennett* [1984] ECR 3651, at paragraph 14). As we have already seen, however, those conditions are not satisfied in this case.

6. On the basis of the foregoing considerations I propose that the Court should reply as follows to the questions referred to it by the House of Lords by judgment of 12 December 1985 in the proceedings brought by Allen and Hanburys Ltd against Generics (UK) Ltd:

- '(1) Articles 30 and 36 of the EEC Treaty are to be interpreted as meaning that the prohibitions laid down therein apply to the case where a national provision enables the proprietor of a patent endorsed 'licences of right' to obtain from the competent authorities of that State an interim injunction prohibiting the importation of goods produced without his consent but no analogous measure can be obtained against an infringer operating within that State.
- (2) The aforesaid Articles 30 and 36 prohibit the national authorities which are competent to grant a licence of right from including in that licence terms apt to hinder the importation of goods from other Member States. It is immaterial that the goods in question are pharmaceutical products which were not patentable in the exporting Member State.
- (3) Mandatory requirements relating to fair trading and consumer protection may justify derogations from the prohibition laid down by Article 30 of the EEC Treaty only in respect of national provisions which apply without distinction to trade in domestic products and imported products and do not have protectionist effects.'