JUDGMENT OF THE COURT
9 July 1997 *

In Case C-316/95,

REFERENCE to the Court under Article 177 of the EC Treaty by the Hoge Raad der Nederlanden for a preliminary ruling in the proceedings pending before that court between

Generics BV

and

Smith Kline & French Laboratories Ltd

on the interpretation of Articles 30 and 36 of the EC Treaty,

THE COURT,

composed of: G. C. Rodríguez Iglesias, President, J. C. Moitinho de Almeida, J. L. Murray and L. Sevón (Presidents of Chambers), P. J. G. Kapteyn, C. Gulmann (Rapporteur), D. A. O. Edward, G. Hirsch, P. Jann, H. Ragnemalm and M. Wathelet, Judges,

* Language of the case: Dutch.

Advocate General: F. G. Jacobs,
Registrar: D. Louterman-Hubeau, Principal Administrator,

after considering the written observations submitted on behalf of:

— Generics BV, by G. van der Wal, of the Hague Bar,

— Smith Kline & French Laboratories Ltd, by C. J. J. C. van Nispen and D. B. Schutjens, of the Hague Bar, and E. H. Pijnacker Hordijk, of the Amsterdam Bar,

— the German Government, by A. Dittrich, Regierungsdirektor in the Federal Ministry of Justice, and B. Kloke, Oberregierungsrat in the Federal Ministry of the Economy, acting as Agents,

— the Greek Government, by K. Grigoriou, Legal Agent to the State Legal Council, and L. Pneumatikou, Specialist Adviser in the Special Community Legal Affairs Department of the Ministry of Foreign Affairs, acting as Agents,

— the United Kingdom Government, by L. Nicoll, of the Treasury Solicitor's Department, acting as Agent, and

— the Commission of the European Communities, by H. van Lier, Principal Legal Adviser, and B. J. Drijber, of its Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Generics BV, represented by G. van der Wal; of Smith Kline & French Laboratories Ltd, represented by C. J. J. C. van Nispen and E. H. Pijnacker Hordijk; of the Greek Government, represented by K. Grigoriou and V. Kontolaimos, Deputy Legal Adviser to the State Legal Council, acting as Agent; of the United Kingdom Government, represented by L. Nicoll and M. Silverleaf QC; and of the Commission, represented by B. J. Drijber, at the hearing on 7 January 1997,

after hearing the Opinion of the Advocate General at the sitting on 27 February 1997,

gives the following

Judgment

1 By judgment of 29 September 1995, received at the Court on 5 October 1995, the Hoge Raad der Nederlanden (Supreme Court of the Netherlands) referred to the Court for a preliminary ruling under Article 177 of the EC Treaty four questions on the interpretation of Articles 30 and 36 of the EC Treaty.

2 Those questions were raised in proceedings between Generics BV ('Generics') and Smith Kline & French Laboratories Ltd ('SKF') concerning infringement of a pharmaceutical patent right.

3 On 19 June 1991, following an application submitted on 4 September 1973, SKF was granted a Netherlands patent in respect of a manufacturing process for a pharmaceutical preparation having the generic name 'cimetidine', which it marketed in the Netherlands under the brand name 'Tagamet'. That patent expired on 4 September 1993.

4 On 22 October 1987 and 10 October 1989, Genfarma BV ('Genfarma') filed three applications with the College ter Beoordeling van Geneesmiddelen (assessment board for medicinal products, 'the CBG') to register 200-mg, 400-mg, and 800-mg cimetidine tablets. Samples of those preparations were submitted to the CBG with the applications. Genfarma was granted registration on 18 January 1990 in respect of the first two applications and on 17 December 1992 in respect of the third.

5 Genfarma subsequently transferred those registrations to Generics and, on 21 June 1993, they were entered under Generics' name in the register of pharmaceutical preparations.

6 On 6 August 1993, SKF applied to the President of the Arrondissementsrechtbank (District Court), The Hague, for an injunction restraining Generics, until 5 November 1994, from offering or supplying cimetidine on the Netherlands market or transferring to third parties the registrations relating to that product.

7 SKF considered that the submission of the samples of cimetidine preparation to the CBG constituted an infringement of its patent as protected by the Rijksoctrooiwet 1910 (Netherlands Law on Patents, 'the ROW'), as it then applied. In particular, SKF referred to the judgment delivered by the Hoge Raad on 18 December 1992 in *Medicopharma* v *ICI*, in which it was held that submission to the CBG of samples of a medicinal product manufactured in accordance with a patented process, by a person other than the patentee, with a view to placing the product on the market after the expiry of the patent, was not covered by the exemption in Article 30(3) of the ROW. That paragraph provides: 'The exclusive right does not extend to acts undertaken solely for the purposes of an examination of the patented object, which must be taken to include a product directly obtained by means of the application of the patented process.'

8 Taking the view, therefore, that Generics could not have applied for the registrations until after the expiry of the patent on 4 September 1993 and that, given the average actual duration of the registration procedure in the Netherlands, it would not have obtained them for another 14 months, SKF asked for the injunction against Generics to extend until 5 November 1994.

9 That injunction was granted, although the conditions imposed on Generics were limited to a prohibition on offering or supplying cimetidine before 5 November 1994 on the basis of registrations obtained under applications filed before 4 September 1993 and a prohibition on transferring such registrations before 5 November 1994. That decision was upheld by the Gerechtshof (Regional Court of Appeal), The Hague, in a judgment which Generics has sought to have quashed and referred back for the matter to be reconsidered.

10 It appears from the order for reference that one of the main grounds on which Generics challenges the Gerechtshof's judgment is in relation to the finding that neither the prohibition on providing the CBG with samples of medicinal products covered by a patent to the CBG during the validity of the patent nor a moratorium imposed with a view to preventing Generics from profiting unfairly from a wrongful act committed against SKF constitutes a barrier to intra-Community trade incompatible with Articles 30 and 36 of the Treaty.

11 Generics further maintains that the moratorium imposed on it is in any event incompatible with Council Directive 65/65/EEC of 26 January 1965 (OJ, English Special Edition 1965, p. 20) and Council Directive 75/319/EEC of 20 May 1975 (OJ 1975 L 147, p. 13), both on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. That moratorium was, it asserts, fixed on the basis of the average duration of the registration procedure in the Netherlands, and not of the maximum duration authorized by those directives.

12 Article 7 of Directive 65/65 requires national authorities to reach a decision within 120 days of the application and provides that that period may be extended by

90 days in exceptional cases. Article 4(c) of Directive 75/319 provides that where the competent authorities avail themselves of the option of requiring the applicant to supplement certain particulars accompanying the application, the time-limits laid down in Article 7 of Directive 65/65 are to be suspended until such time as the supplementary information required has been provided. Likewise, those time-limits are to be suspended for the time allowed to the applicant, where appropriate, for giving oral or written explanation.

13 The Hoge Raad decided to stay the proceedings and refer the following questions to the Court:

'(1) Is a rule of national law which confers on the proprietor of a patent in respect of certain medicinal products the right to oppose, during the currency of that patent, the submission by another person of samples of the patented medicinal products (or of medicinal products produced in accordance with the patented process) to the authority responsible for the registration of medicinal products, to be regarded as a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 30 of the EC Treaty?

(2) If so, is that measure covered by the exception laid down in Article 36 of the EC Treaty in respect of restrictions which are justified on the ground of the protection of industrial property?

(3) Where, during the currency of a patent, an infringement of that patent is committed under national law and there is a danger that the person committing that infringement or a third person may still profit from the infringement following the expiry of the patent, or that the proprietor of the patent may still suffer some disadvantage as a result of the infringement following the expiry of the patent, does a judicial prohibition imposed in order to prevent that potential harm which restrains, for a specified period after the expiry of the patent, the placing on the market of products which were protected by the patent during its currency, constitute a measure which is prohibited by Article 30 of the EC Treaty and which is not covered by the exception contained in Article 36 of the EC Treaty?

(4) Where the infringement referred to in (3) above consists in the submission of samples with a view to the registration of a medicinal product, as referred to in (1) above, and in consequence thereof a judicial prohibition of the kind referred to in (3) above is imposed for a period which exceeds the maximum period prescribed by Directives 65/65/EEC and 75/319/EEC for the registration of medicinal products, does the fact that the duration of the prohibition exceeds that maximum render the prohibition incompatible to that extent with Community law and, if so, does that mean that the person on whom the prohibition is imposed can invoke that incompatibility, by virtue of Community law, as against the former proprietor of the patent?'

The first question

14 By its first question, the national court seeks, in substance, to ascertain whether application of a rule of national law giving the proprietor of a patent in respect of a manufacturing process for a medicinal product the right to oppose the submission by another person of samples of medicinal products manufactured in accordance with that process to the authority competent for issuing authorizations to place medicinal products on the market ('marketing authorizations') constitutes a measure having equivalent effect to a quantitative restriction within the meaning of Article 30 of the EC Treaty.

15 It has consistently been held that any measure capable of hindering, directly or indirectly, actually or potentially, intra-Community trade constitutes a measure having an effect equivalent to a quantitative restriction (Case 8/74 *Procureur du Roi* v *Dassonville* [1974] ECR 837, paragraph 5, and Case C-412/93 *Leclerc-Siplec* v *TF1 Publicité and M6 Publicité* [1995] ECR I-179, paragraph 18).

16 In so far as it prohibits competitors from submitting samples of a medicinal product manufactured by a patented process for the purpose of an application for marketing authorization before the expiry of the relevant patent, a provision such as that in issue in the main proceedings has the effect, *inter alia*, of preventing any

competitor from obtaining such authorization for that type of product before the end of the period of waiting that follows the filing of an application for that purpose after the expiry of the patent. Thus, it will not in any event be possible for a medicinal product, manufactured by the same process and lawfully in circulation in Member State A while the relevant patent is still in force in Member State B, to be marketed in Member State B as soon as that patent expires. Were it not for the provision in issue, samples of such a product could lawfully be submitted for the purpose of an application for a marketing authorization before the expiry of the patent, so that there would be no obstacle to the issuing of such authorization while the patent was still valid or, consequently, to the importation of the generic medicinal product from Member State A to Member State B immediately after the expiry of the patent.

17 The answer must therefore be that application of a rule of national law which gives the proprietor of a patent in respect of a manufacturing process for a medicinal product the right to oppose the submission by another person of samples of medicinal products manufactured in accordance with that process to the authority competent for issuing marketing authorizations constitutes a measure having equivalent effect to a quantitative restriction within the meaning of Article 30 of the Treaty.

The second question

18 The second question is, in substance, whether application of a rule of national law which gives the proprietor of a patent in respect of a manufacturing process for a medicinal product the right to oppose the submission by another person of samples of medicinal products, manufactured in accordance with that process by a person other than the patentee, to the authority competent for issuing marketing authorizations, is justified under Article 36 of the Treaty.

19 The Court has held that, in providing an exception, on grounds of the protection of industrial and commercial property, to one of the fundamental principles of the

common market, Article 36 of the Treaty admits such derogation only in so far as it is justified for the purpose of safeguarding rights constituting the specific subject-matter of that property, and that, as regards patents, includes, in particular, allowing the holder a monopoly of first exploitation of his product (see, to that effect, Case 187/80 *Merck* v *Stephar and Exler* [1981] ECR 2063, paragraph 10).

20 In the present case, the right of the proprietor of a patent in respect of a manufacturing process for a medicinal product to oppose the use by another person of samples of medicinal products manufactured in accordance with that process for the purpose of obtaining a marketing authorization falls within the specific subject-matter of the patent right in so far as such samples have been used without the direct or indirect consent of the patentee. In that connection, moreover, it may be noted that both Article 25 of the Community Patent Convention (OJ 1989 L 401, p. 10) and Article 28 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS', OJ 1994 L 336, p. 214) confer the right to prevent third parties not having the consent of the proprietor of the patent from, *inter alia*, using the product obtained directly by the process which is the subject-matter of the patent. In the present case, to preclude application of a national rule providing for the right indicated above would in fact allow an encroachment on the monopoly of first exploitation of the product as referred to in the preceding paragraph.

21 Furthermore, measures having an effect equivalent to quantitative restrictions justified on grounds relating to the protection of industrial and commercial property are permitted by Article 36 on the express condition that they do not constitute either a means of arbitrary discrimination or a disguised restriction on trade between Member States (see, *inter alia*, Case C-191/90 *Generics and Harris Pharmaceuticals* v *Smith Kline and French* [1992] ECR I-5335, paragraph 21).

22 There is, however, nothing in the documents before the Court to suggest that the ROW is discriminatory in nature or that it seeks to favour domestic products over those from other Member States.

23 The answer must therefore be that application of a rule of national law which gives the proprietor of a patent in respect of a manufacturing process for a medicinal product the right to oppose the submission by another person of samples of medicinal products, manufactured in accordance with that process by a person other than the patentee, to the authority competent for issuing marketing authorizations, is justified under Article 36 of the Treaty.

The third question

24 In substance, the national court's third question is whether, when a person other than the patentee has infringed the patent laws of a Member State by submitting samples of a medicinal product manufactured in accordance with a patented process to the authority competent for issuing marketing authorizations and has thus obtained the authorization sought, an order of a national court prohibiting the infringer from marketing such a product for a specified period following expiry of the patent in order to prevent him from deriving any unfair profit from his infringement constitutes a measure having equivalent effect within the meaning of Article 30 of the Treaty capable of being justified under Article 36.

25 Such a measure, inasmuch as it prohibits the marketing in one Member State of a product lawfully sold in another Member State, constitutes a measure having equivalent effect within the meaning of Article 30 of the Treaty.

26 As regards the application of Article 36, Generics submits that, as a way of providing reparation, a prohibition on the sale of products after expiry of the patent is contrary to the principle of proportionality, given the alternative remedies of damages or cancellation of the marketing authorizations.

27 As to that, if Generics had respected SKF's patent right, it could not have submitted the cimetidine samples until that patent had expired. SKF would thus have been able to continue to market its product without competition from the generic product marketed by Generics throughout the period required to obtain the marketing authorization.

28 The moratorium imposed by the court on the infringer of the patent right, in so far as it seeks to place the proprietor of the patent in the position in which it would, in principle, have been had its rights been respected, cannot in itself be held to be a disproportionate form of reparation.

29 The answer must therefore be that, when a person other than the patentee has infringed the patent laws of a Member State by submitting samples of a medicinal product manufactured in accordance with a patented process to the authority competent for issuing marketing authorizations and has thus obtained the authorization sought, an order of a national court prohibiting the infringer from marketing such a product for a specified period following the expiry of the patent in order to prevent him from deriving any unfair profit from his infringement constitutes a measure having equivalent effect within the meaning of Article 30 of the Treaty capable of being justified under Article 36 of the Treaty.

The fourth question

30 In substance, the national court's fourth question is whether, where the submission of samples of a medicinal product to the competent authority with a view to obtaining a marketing authorization has given rise to a patent infringement, Community law, and in particular Article 36 of the Treaty, precludes a national court from prohibiting the infringer from marketing that product for 14 months after the expiry of the patent in question, when that period, although exceeding the maximum period authorized by Article 7 of Directive 65/65 read in conjunction with Article 4(c) of Directive 75/319 for the procedure for granting a marketing

authorization, corresponds to the actual average duration of such a procedure in the Member State concerned.

31 Since the duration of the prohibition imposed by the national court corresponds, as stated in the order for reference, to the actual average duration of the registration procedure in the Member State concerned, its effect is, as has already been made clear in paragraph 28 above, to place the proprietor of the patent in the position in which it would in principle have been if its rights had been respected.

32 It is not disputed that, in the present case, the 14-month period exceeds the maximum period authorized by the abovementioned directives. That circumstance cannot, however, be relied on by an infringer as against the proprietor of the patent in order to obtain a shorter prohibition period. The contrary view would amount, in the present circumstances, to accepting the risk of favouring the infringer over the victim of the infringement.

33 A solution such as that adopted by the national court does not, therefore, appear to give rise, in circumstances such as those of the present case, to any disproportionate consequences for the infringer of the patent right.

34 The answer must therefore be that, where the submission of samples of a medicinal product to the competent authority with a view to obtaining a marketing authorization has given rise to a patent infringement, Community law, and in particular Article 36 of the Treaty, does not preclude a national court from prohibiting the infringer from marketing that product for 14 months after the expiry of the patent in question, when that period, although exceeding the maximum period authorized by Article 7 of Directive 65/65 read in conjunction with Article 4(c) of Directive 75/319 for the procedure for granting a marketing authorization, corresponds to the actual average duration of such a procedure in the Member State concerned.

Costs

35 The costs incurred by the German, Greek and United Kingdom Governments and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT,

in answer to the questions referred to it by the Hoge Raad der Nederlanden, by judgment of 29 September 1995, hereby rules:

1. **Application of a rule of national law which gives the proprietor of a patent in respect of a manufacturing process for a medicinal product the right to oppose the submission by another person of samples of medicinal products manufactured in accordance with that process to the authority competent for issuing marketing authorizations constitutes a measure having equivalent effect to a quantitative restriction within the meaning of Article 30 of the EC Treaty.**

2. **Application of a rule of national law which gives the proprietor of a patent in respect of a manufacturing process for a medicinal product the right to oppose the submission by another person of samples of medicinal products, manufactured in accordance with that process by a person other than the patentee, to the authority competent for issuing marketing authorizations, is justified under Article 36 of the EC Treaty.**

3. When a person other than the patentee has infringed the patent laws of a Member State by submitting samples of a medicinal product manufactured in accordance with a patented process to the authority competent for issuing marketing authorizations and has thus obtained the authorization sought, an order of a national court prohibiting the infringer from marketing such a product for a specified period following the expiry of the patent in order to prevent him from deriving any unfair profit from his infringement constitutes a measure having equivalent effect within the meaning of Article 30 of the EC Treaty capable of being justified under Article 36 of that Treaty.

4. Where the submission of samples of a medicinal product to the competent authority with a view to obtaining a marketing authorization has given rise to a patent infringement, Community law, and in particular Article 36 of the Treaty, does not preclude a national court from prohibiting the infringer from marketing that product for 14 months after the expiry of the patent in question, when that period, although exceeding the maximum period authorized by Article 7 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, read in conjunction with Article 4(c) of 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, for the procedure for granting a marketing authorization, corresponds to the actual average duration of such a procedure in the Member State concerned.

Rodríguez Iglesias Moitinho de Almeida Murray

Sevón Kapteyn Gulmann

Edward Hirsch Jann

Ragnemalm Wathelet

Delivered in open court in Luxembourg on 9 July 1997.

R. Grass

Registrar

G. C. Rodríguez Iglesias

President