OPINION OF ADVOCATE GENERAL JACOBS

delivered on 27 February 1997 *

1. The present case comes by way of a request for a preliminary ruling from the Hoge Raad der Nederlanden (Supreme Court of the Netherlands). It concerns the Community-wide problem of the interrelationship between the system of patent protection for pharmaceutical products and the requirement in Council Directive 65/65/EEC [1] that both an original patented pharmaceutical product and any copy made by a competitor following expiry of the patent must have a marketing authorization before they can be placed on the market.

2. The delay involved in the authorization procedure substantially shortens the useful period of the patentee's exclusive right to market his patented product since the period of patent protection, which runs from the date of filing the application for the patent, [2] continues running throughout the authorization procedure. (It appears that applications for marketing authorization cannot be made before patent protection is applied for because such prior disclosure would remove entitlement to the patent. [3]) Competitors seek to avoid suffering a similar delay by submitting their request for authorization to the relevant national authority before the patent has expired. In that way they seek to ensure that they obtain their own authorization in good time to enable them to market their competing product as soon as the patent expires. Such a practice has been held to be unlawful in the Netherlands on the ground that the provision of samples of a medicinal product by a competitor to the Netherlands registration authority during the validity of a national patent constitutes an infringement of that patent. The key question in the present case is whether such a national law is compatible with Article 30 of the EC Treaty.

3. The Court is also asked whether it is justifiable to grant a patentee, by way of a remedy for infringement of that law, an

* Original language: English.

1 — 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: OJ, English Special Edition 1965, p. 20. Article 3 of that Directive was amended by Article 1 of Council Directive 93/39/EEC of 14 June 1993, amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products, OJ 1993 L 214, p. 22, to take account of the fact that the system of national authorization to which Directive 65/65 referred has been replaced, in respect of certain products, by the system of Community-wide authorizations set up under Council Regulation (EEC) No 2309/93 of 22 July 1993, laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, OJ 1993 L 214, p. 1.

2 — See Article 47 of the Rijksoctrooiwet (Netherlands law on patents) 1910 ('the ROW 1910'), now Article 49(2) of the Rijksoctrooiwet 1995 ('the ROW 1995'), and Article 63 of the European Patent Convention. (The Munich Convention of 5 October 1973 on the grant of European Patents, which entered into force on 7 October 1977.)

3 — See Article 2 of the ROW 1910, Article 4 of the ROW 1995, and Article 54 of the European Patent Convention.

injunction prohibiting the competitor from selling its goods for a period running from the date upon which the relevant patent expired and equal to the likely period for which the competitor would normally have had to wait in order to obtain its marketing authorization.

4. The problem encountered by patentees as a result of the delays involved in obtaining marketing authorizations has now been addressed directly by Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products ('the Supplementary Protection Regulation', or simply 'the Regulation'). [4] That Regulation, which I consider more fully below, makes it possible for patentees to apply for an extension to the usual period of national patent protection in respect of an authorized product. The extension is calculated by reference to the period which elapsed between the date upon which the application for a basic patent was lodged and the date upon which the first authorization to place the product on the market in the Community was granted. [5] Application for such protection, however, is not possible if, as in the present case, the first authorization to place the product on the market was obtained before 1 January 1985. [6]

4 — OJ 1992 L 182, p. 1.

5 — Article 13.

6 — Article 19(1). (Different dates are provided in that Article in respect of Denmark, Germany, Belgium, and Italy.)

Facts and procedure

5. The patents in issue are two national patents granted in the Netherlands to Smith Kline & French Laboratories Limited ('SKF'). The first patent was granted on 18 March 1980 (patent No 162.073), pursuant to an application dated 9 March 1972 ('the first patent'). It expired on 9 March 1992. That patent was granted in respect of a process for the preparation of medicinal products which act by blocking histamine receptors.

6. The second patent was granted on 19 June 1991 (patent No 187.240), pursuant to an application dated 4 September 1973 and following publication of the application on 18 February 1991 ('the second patent'). It expired on 4 September 1993. The patented process concerned the preparation of a medicinal product having an antagonistic effect on the histamine receptor. The pharmaceutical preparation produced by that process has the generic name cimetidine and is marketed by SKF in the Netherlands under the brand name Tagamet. It appears that that product was in fact protected by both the first and second patents.

7. The date upon which SKF obtained marketing authorizations for the patented products is not stated. However, the referring court does state that the authorizations were obtained prior to 1 January 1985. The relevance of that date is, as explained above, that a supplementary protection period for patents cannot be applied for under the

Supplementary Protection Regulation [7] in respect of medicinal products authorized before that date.

8. Prior to the expiry of both patents, a competitor of SKF, Genfarma BV, filed applications with the Netherlands assessment board for medicinal products, known as the College ter Beoordeling van Geneesmiddelen ('the CBG'), for its own authorizations to market cimetidine in the form of 200 mg, 400 mg, and 800 mg tablets. Two applications were made on 22 October 1987 and a further application on 10 October 1989. Samples of those preparations were submitted to the CBG with those applications. The registrations were granted on 18 January 1990 in respect of the first two applications and on 17 December 1992 in respect of the third application. Genfarma BV thereafter transferred the registrations to Generics BV, the appellant in the proceedings before the referring court ('Generics'). [8] On 21 June 1993 those registrations were entered under Generics' name in the Register of Pharmaceutical Preparations.

9. SKF contends that the submission of samples to the CBG constituted an infringement of its patents, which were still in force at the date the samples were submitted. It relies on a judgment of the Hoge Raad concerning the interpretation of Article 30(3) of the Rijksoctrooiwet 1910 (the national law on patents, 'the ROW'). [9]

10. Article 30(3) of the ROW provides that:

'3. 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.'

11. According to the order for reference, in a judgment dated 18 December 1992 ('the 1992 judgment') [10] the Hoge Raad held that, where samples of a medicinal product manufactured in accordance with a patented process were, during the currency of the patent, provided to the CBG by a person other than the patentee so as to be able to place the product on the market immediately after the expiry of the patent, Article 30(3) was not applicable; accordingly, the patent was infringed.

7 — Cited in note 4.

8 — At the oral hearing SKF maintained that two of the three applications were in fact made by Generics, transferred to Genfarma and, following authorization, transferred back to Generics. Nothing, however, turns on that aspect of the facts.

9 — Now Article 53(3) of the ROW 1995.

10 — *Medicopharma* v *ICI* NJ 1993, 735.

12. Although, as Generics points out, that case concerned more than the mere submission of samples to the CBG, the judgment has been taken to mean that the submission of samples alone constituted an infringement of the patent and the first question referred is worded on the assumption that that is the position under Netherlands law.

13. The referring court explains that the 1992 judgment implies the following:

— that Article 30(3) of the ROW must be interpreted restrictively;

— that, by virtue of that provision, acts undertaken for the purposes of an examination of the patented object which give rise in principle to an infringement of the patent are permissible if and in so far as they are justified by the objective of the examination;

— that such will only be the case where the person carrying out the examination alleges, and if necessary proves, that his examination is exclusively and purely of a scientific nature or is solely aimed at achieving a goal which fulfils the purpose of the patent law, such as the advancement of technology.

14. Contending that Generics' registrations were obtained by means of infringement of one or both of its patents, SKF issued a writ against Generics on 6 August 1993. It claimed that Generics should be ordered:

— not to offer or supply cimetidine for consumption in any form whatever on the Netherlands market until 14 months after 4 September 1993 (that is to say, not before 5 November 1994), on pain of a penalty payment of HFL 50 per gramme of cimetidine product;

— not to transfer any registrations already obtained or yet to be obtained to a third party for a period of 14 months after 4 September 1993 (that is to say, not before 5 November 1994), on pain of a penalty payment of HFL 50 000 per day.

15. It appears that the period of 14 months was selected by SKF on the basis that if its patents had been respected, Generics would not have been able to apply for the registrations until the second patent had expired on 4 September 1993 and that, since it usually takes at least 14 months from application to registration, Generics would not have obtained the registrations until at least 14 months after that date.

16. On 13 October 1993, the President of the Rechtbank te 's-Gravenhage (District Court, The Hague) made an order in similar

terms to that requested by SKF. It prohibited Generics from making use of registrations obtained pursuant to applications filed prior to 4 September 1993 and from offering or supplying cimetidine for consumption in any form whatever on the Netherlands market before 5 November 1994, on pain, respectively, of penalty payments of HFL 25 000 per offer made and HFL 50 per gramme of cimetidine product supplied. It further prohibited Generics from transferring the aforementioned registrations to a third person or allowing such third person to make use thereof before 5 November 1994, on pain of a penalty payment of HFL 10 000 per day. Generics appealed against that order to the Gerechtshof te 's-Gravenhage (Regional Court of Appeal, The Hague) but the order was upheld. Generics then appealed (in cassation) to the Hoge Raad.

17. Generics argues that the Hoge Raad's 1992 judgment, concerning the interpretation of Article 30(3) of the ROW, is incompatible with Article 30 of the EC Treaty. In the present order for reference, the Hoge Raad states that that argument had not been raised in the proceedings giving rise to that judgment.

18. Generics further objects that, even if the order made by the Rechtbank were to be upheld in principle, an injunction for a period of 14 months is excessive. Whilst recognizing that 14 months is the usual time taken in practice to register an application for a marketing authorization, Generics points to the fact that Article 7 of Directive 65/65 requires national authorities to reach a decision upon a registration within 120 days of the application and provides that the only possibility of extension is an additional 90 days in exceptional cases. [11] That provision had been implemented in Netherlands law at the relevant time by Article 8(1) of the Besluit Registratie Geneesmiddelen (Decree on the registration of medicinal products). [12] Generics argues that the national authorities cannot derogate from the time-limit laid down in Article 8 of that Decree and that, in so far as they do not comply with that time-limit, the additional delay cannot form the basis of a sanction against third parties. At the oral hearing, Generics also suggested that compensation, or cancellation of the marketing authorizations, should have been considered as an alternative to an injunction.

19. Considering that the resolution of the dispute turns upon an interpretation of Community law, the Hoge Raad referred the following questions to this Court:

'(1) Is a rule of national law which confers on the proprietor of a patent in respect of certain medicinal products the right

11 — Article 7 of Directive 65/65, cited in note 1, provided originally that Member States should take all appropriate measures to ensure that the procedure for granting an authorization to place a proprietary medicinal product on the market was completed within 120 days of the date of submitting the application, but that, in exceptional cases, that time-limit could be extended for a further 90 days. Article 7 was amended by Article 1(6) of Directive 93/39, cited in note 1, so as to extend the time-limit to 210 days in all cases. Member States were obliged to implement that Article before 1 January 1995.

12 — Staatsblad 1977 537.

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 [13] 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?'

Article 30 (Question 1)

20. Article 30 of the Treaty prohibits, in trade between Member States, quantitative restrictions on imports and all measures having equivalent effect. By virtue of the first sentence of Article 36, Article 30 does not preclude prohibitions or restrictions which are justified on grounds of the protection of industrial and commercial property. By virtue of the second sentence, such prohibitions

13 — 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. That Directive, together with Council Directive 75/318 of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products, OJ 1975 L 147, p. 1, extended the harmonization process initiated by Directive 65/65.

or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. In order for Article 30 to apply to this case, the law in question must be capable of hindering directly or indirectly, actually or potentially, intra-Community trade. [14]

21. SKF maintains that intra-Community trade is not affected because the samples submitted to the CBG came from Canada. Indeed it emerged at the oral hearing that Generics does not dispute SKF's contention that the samples were imported into the Netherlands from Canada. However, the order for reference is silent as to the origin of the samples and it is upon the information contained in that document that the Court should base its judgment.

22. In any event, even if the samples in question were imported from Canada, an issue under Article 30 still arises because it does not necessarily follow that all the products to be marketed by Generics would come from the same source as the samples. Indeed, Generics explained at the hearing that it lawfully produces and markets cimetidine in Ireland, where SKF's patent has expired and where Generics obtained a marketing authorization in 1992. Since the effect of the law relating to the submission of samples is to delay the marketing of the products, that law accordingly has an effect on trade within the meaning of the *Dassonville* [15] formula in so far as it might affect the future marketing of products from other Member States, such as Ireland.

23. The United Kingdom argues that Article 30 has no application to the present case, regardless of the origin of the samples. It states that the Court has only applied Articles 30 and 36 to prevent the exercise of intellectual property rights in two types of case: where the product which is the subject of the action has been put on the market by the proprietor of the right or with his consent (the 'exhaustion of rights' doctrine); and where the measures permitted by national laws constitute a means of arbitrary discrimination or a disguised restriction on trade. It observes that, since the samples were placed on the market neither by the patentee nor with his consent, the prohibition on the use of samples cannot be objected to on the grounds that the patentee has exhausted his rights. It then reasons that, since the law in question also does not discriminate on grounds of nationality or residence or between imported and domestically produced goods, prima facie Article 30 has no application. It considers that national laws defining the extent of infringing use, particularly where harmonized as they are in

14 — Case 8/74 *Procureur du Roi* v *Dassonville* [1974] ECR 837.

15 — *Dassonville*, cited in note 14.

practice, [16] do not hinder nor are they likely to hinder trade between Member States where they are applied in relation to goods having no connection with the proprietor of the patent.

24. Even assuming that the Court has held that Articles 30 and 36 restrict the exercise of intellectual property rights only in the cases suggested by the United Kingdom, I do not agree that other cases fall outside the scope of Article 30. Where the Court has held that Articles 30 and 36 do not restrict the exercise of those rights, it has done so on the ground that the restrictions, although falling within Article 30, are justified under Article 36. That is true even in the cases which have come before the Court in relation to the preconditions to the grant of an intellectual property title, a matter which the Court has regarded as essentially a matter for national law — cases such as *Keurkoop* v *Nancy Kean Gifts*, [17] *Thetford* v *Fiamma*, [18] *CICRA* v *Renault* [19] and *Deutsche Renault* v *Audi*. [20] In those cases the products in question had not been marketed previously by the intellectual property owner or with his consent and the Court considered there to be no arbitrary discrimination or disguised restriction on trade. However, the Court held that the national laws in question fall outside the scope of Article 30, a view shared by Generics, the German and Greek Governments and the Commission. The issue is accordingly whether that law can be justified under Article 36.

25. The answer to the first question is thus that 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, falls within the scope of Article 30 of the Treaty.

Article 36 (Question 2)

26. Under Article 36 of the Treaty, as already mentioned, measures which fall within the scope of Article 30 may nevertheless be justified on grounds of the protection of industrial and commercial property, including, of course, intellectual property in the form of patents.

16 — The United Kingdom refers to the 'Declaration on the Adjustment of National Patent Law' annexed to the Luxembourg Agreement of 15 December 1989 relating to Community patents, OJ 1989 L 401, p. 1.

17 — Case 144/81 [1982] ECR 2853.

18 — Case 35/87 *Thetford and Another* v *Fiamma and Others* [1988] ECR 3585.

19 — Case 53/87 *CICRA and Another* v *Renault* [1988] ECR 6039.

20 — Case C-317/91 [1993] I-6227.

27. However, according to the Court's case-law, the exercise of patent rights, where it affects trade between Member States, must be 'justified for the purpose of safeguarding rights which constitute the specific subject-matter' of a patent. The 'specific subject-matter' of a patent includes the 'guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements' (the 'specific subject-matter' test). [21]

28. Generics argues that the Netherlands law is not a justified restriction on that test. It contends that the specific subject-matter of a patent is the exclusive right to first marketing, and the right to oppose infringements so as to obtain a fair reward, only during the validity of the patent. It accordingly reasons that, since in the present case no products were, or were to be, marketed until after expiry of the patent, it cannot be said that a prohibition on submission of samples to the registration authority during the validity of a patent was necessary to protect the exclusive right to first marketing or the reward.

29. That argument does not seem conclusive. Indeed the 'specific subject-matter' test could lead to the opposite result. The Netherlands law effectively extended, by a short period, the duration of the patentee's exclusive right to first marketing and so provided some compensation for the period lost while his product was undergoing the authorization procedure and before he could take advantage of his invention. Since the reasonableness of the length of patent protection is not contested, it could be argued that the Netherlands law is justified for the purpose of safeguarding the exclusive right to first marketing which falls within the 'specific subject-matter' of the patent.

30. It cannot be expected, in my view, that the 'specific subject-matter' test should provide a clear-cut answer. In fact that test, which was first formulated in *Centrafarm* v *Sterling Drug* [22] in 1974 to provide a rational basis for the notion of Community exhaustion, is not apt, and was not I think intended, to be used to solve detailed aspects of the scope of patent protection such as those

21 — Case 15/74 *Centrafarm* v *Sterling Drug* [1974] ECR 1147, paragraph 9 of the judgment. See also Case 187/80 *Merck* v *Stephar and Exler* [1981] ECR 2063, Case 19/84 *Pharmon* v *Hoechst* [1985] ECR 2281, Case 434/85 *Allen and Hanburys* v *Generics* [1988] ECR 1245, *Thetford* v *Fiamma*, cited in note 18, Case C-235/89 *Commission* v *Italy* [1992] I-777, Case C-30/90 *Commission* v *United Kingdom* [1992] ECR I-829, Case C-191/90 *Generics and Harris Pharmaceuticals* [1992] ECR I-5335 and Joined Cases C-267/95 and C-268/95 *Merck and Others* v *Primecrown and Others*, judgment of 5 December 1996.

22 — Cited in note 21.

arising in the present case. Indeed it is clear from the formulation itself that it has no vocation to be exhaustive, since the Court has prefaced its definitions of the 'specific subject-matter' of the patent with the words 'includes' [23] or 'in particular'. [24]

31. In the present cases, whether or not one takes the 'specific subject-matter' test as the starting-point, the decisive considerations seem to me to be the following, which focus on the justification for the restriction in concrete terms.

32. First, in so far as the submission of samples is treated as infringing the patent independently of its effect on the period of protection, the approach of the national provisions in issue seems both reasonable in itself and in line with other legal systems both within and outside the Community. That point is fully developed below.

33. Secondly, in so far as the national provisions have the effect of extending the patentee's protection and of preventing the competitor from initiating the authorization procedure for the generic product before the expiry of the 20-year term, that consequence again seems not unreasonable. Once again, the approach is in line with legal developments generally, both in the Community and elsewhere.

34. Thirdly, the present case bears no resemblance to those in which the Court has held that the rights of the patentee may be limited to the extent necessary to avoid those rights being used in such a way as to divide up the market. In particular there is no question in this case of the patentee having exhausted his rights or having consented in any way, directly or indirectly, to the conduct in question.

35. Fourthly, there is no discrimination. There is nothing to indicate that the law in question does not apply equally to samples produced on national territory and those produced in other Member States; nor that the origin of the products to be marketed in the future is in any way relevant to the application of the law; nor that only medicinal products manufactured in the Netherlands or belonging to proprietors of Netherlands nationality or residence can benefit from the application of the law. The law in question accordingly does not favour national production in any way.

23 — See *Allen and Hanburys* v *Generics*, cited in note 21, paragraph 11 of the judgment.

24 — See, for example, *Merck* v *Stephar*, cited in note 21, paragraph 4 of the judgment; *Commission* v *United Kingdom*, cited in note 21, paragraph 21.

36. In saying that there is no discrimination, I do not suggest that only discriminatory measures are unlawful. But the absence of discrimination, the absence of any abnormal protection of patent rights, and the absence of any dividing up of the market by the patentee or with his consent, appear cumulatively to remove any reason for Community law to intervene, and to suggest that the measures in issue are justified under the first sentence of Article 36. If however there were discrimination, the measures would of course in any event be unlawful under the second sentence of Article 36, as they would be if there were a disguised restriction on trade between Member States.

Other legal systems

37. It is helpful, as I have suggested, to have regard to the position in other legal systems. The Netherlands law appears to be consistent with the position in other Member States, in so far as that position can be ascertained. Pursuant to the Declaration on the Adjustment of National Patent Law annexed to the Community Patent Convention, [25] Member States undertook to adjust their law relating to national patents, in so far as they had not already done so, 'so as to bring it into conformity, as far as practicable, with corresponding provisions of the European Patent Convention, [26] the Agreement relating to Community Patents and the Patent Cooperation Treaty'. [27]

38. The original Community Patent Convention [28] was signed at Luxembourg in 1975 by the then nine Member States but never came into force. The amended Community Patent Convention [29], which is substantially the same, was signed at Luxembourg in 1989 but is similarly not yet in force because it has not been ratified by a sufficient number of Member States. Nevertheless the Court has been willing to take account of the Convention. [30]

39. Articles 25 to 27 of the Community Patent Convention contain a very wide definition of the scope of the patentee's protection. Article 25 provides that the proprietor of a Community patent has the right, *inter alia*, to prevent all third parties not having his consent from 'making, offering, putting on the market or using a product which is

25 — Cited in note 16.

26 — Cited in note 2.

27 — OJ 1989 L 401 p. 59.

28 — OJ 1976 L 17, p. 43.

29 — OJ 1989 L 401, p. 10.

30 — See *Commission* v *United Kingdom*, cited in note 21, paragraph 32 of the judgment; *Pharmon* v *Hoechst*, cited in note 21, paragraph 20; and Case 288/82 *Duijnstee* v *Goderbauer* [1983] ECR 3663, at paragraph 27.

the subject-matter of the patent, or importing or stocking the product for these purposes'. The exceptions to that right are very limited. The only ones which might be regarded as relevant for present purposes are 'acts done privately and for non-commercial purposes' and 'acts done for experimental purposes relating to the subject-matter of the patented invention'. [31] That second exception is in similar terms to the exception contained in Article 30(3) of the ROW (referred to at paragraph 10 above). Neither exception is sufficient, in my view, to cover the submission of samples for commercial purposes.

40. It might be added that the measure in issue is in no way inconsistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS'), to which the Community and the Member States are parties. Article 28 of that Agreement provides that a patentee has the right to prevent third parties not having his consent from 'making, using, offering for sale [or] selling' the product or importing the product for such purposes. Article 30 provides that the parties may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

31 — Article 27(a) and (b).

41. Furthermore, there has been some guidance from national courts as to the scope of the patentee's protection in circumstances similar to those of the present case. For example, the following acts have been held by national courts to constitute infringement of the patent when carried out during its validity: in Italy, in a case with little reasoning on the point, even the simple submission of a request for authorization of a pharmaceutical product; [32] in Germany (albeit before the introduction of an exception relating to experiments), trials of a pesticide in preparation for its marketing after expiry of the patent; [33] in Austria (although not in the context of pharmaceutical products), [34] the production of a sample in relation to future marketing; and in the United Kingdom, trials of a herbicide undertaken to demonstrate to a third party (whether a client or an authorization authority) the efficacy of the product, or in order to amass information to satisfy such third party. [35]

42. Moreover, in New Zealand (whose case-law is of persuasive value in the United Kingdom and Ireland) the Court of Appeal directly addressed the question in issue and held that the submission of samples did

32 — Judgment of the Tribunale di Torino of 8 June 1984, Giur. Piemontese, 1985, p. 105, a case which in fact concerned the Italian patent for cimetidine and in which SKF was a party. The judgment is silent as to whether or not samples were submitted.

33 — Judgment of the Bundesgerichtshof of 21 February 1989, BGHZ 107.46 ('Ethofumesat').

34 — OGH 17.11.1913, Patentblatt (PBI) 1914, 89.

35 — *Monsanto Co* v *Stauffer Chemical Co* [1985] RPC 515.

constitute an infringement of the patent. [36] That case in fact involved the same product as the present case, cimetidine, and SKF was the plaintiff. Cooke P. considered that the defendant had 'acted for the commercial advantage or springboard of being more ready to launch into the market when the patent expired'. Hardie Boys J concluded that the submission of samples was clearly a use of the patent and that 'it would be a distortion of the meaning of what is an ordinary English word to hold otherwise'. With regard to experimentation, he considered that 'doubtless experimentation will usually have an ultimate commercial objective; where it ends and infringement begins must often be a matter of degree. If the person concerned keeps his activities to himself, and does no more than further his own knowledge or skill, even though commercial advantage may be his final goal, he does not infringe. But if he goes beyond that, and uses the invention or makes it available to others, in a way that serves to advance him in the actual market place, then he infringes, for the market place is the sole preserve of the patentee'.

43. He also observed that overseas appellate authorities tended towards the view that the mere submission of samples constituted a breach of the patent, even if the precise point had not been decided. Moreover, in answer to the argument that it was not the court's duty to assist a patentee in extending his period of exclusivity, he commented that the delay involved in obtaining a marketing authorization was not a new, nor a local, problem, and that, even if it had not been raised in the cases mentioned, it had lain behind them. He concluded, however, that, whilst the courts had recognized the problem, they had insisted that any solution required legislative and not judicial intervention. Cooke P. observed that the New Zealand courts were operating in an international environment where consistency of approach was important.

44. It is true that in a German case it was held that the request for authorization of a certain type of broadcasting receiver did not constitute an infringement of the patent and that the national court did not appear to have been influenced by the fact that the request had been accompanied by a specimen of the receiver in question. [37]

45. It is also true that in *The Upjohn Company* v *T. Kerfoot & Co. Ltd* (the '*Upjohn*' case), [38] the English High Court held that the mere application for a marketing authorization in respect of a medicinal product, even when accompanied by test results, did not

36 — *Smith Kline and French Laboratories* v *Douglas Pharmaceuticals Ltd* [1991] FSR 522.

37 — Judgment of the Oberlandesgericht München of 23 January 1986 (6U 5660/84) cited in the judgment of the Bundesgerichtshof of 24 March 1987 BGHZ 100, 249. The Bundesgerichtshof confirmed the judgment of the Oberlandesgericht München for slightly different reasons.

38 — [1988] FSR 1 to 7.

constitute an infringement of the patent since it did not amount to 'use' of the patent within the meaning of Section 60(1) of the Patents Act 1977, even if interpreted in the light of the Community Patent Convention. [39]

46. However, the Court of Appeal of New Zealand, in the case cited earlier, [40] expressly distinguished the decision of the English High Court in the *Upjohn* case, stating that 'the furnishing of data is one thing, the supply of a sample another: it is a direct physical use of the subject matter of the patent itself'.

47. Again, in an Italian case, in an order dated 12 June 1995, the Tribunale di Milano held that experiments carried out during the validity of a patent by a competitor, in order to prepare the documents necessary for the application for a marketing authorization, and the submission of the application did not constitute a breach of the patent. [41] However, that decision, in contrast to the earlier Italian judgment to the opposite effect, cited above, was given in relation to a patent which could benefit from the entry into force of the Supplementary Protection Regulation: i. e. from the possibility of obtaining a certificate granting a supplementary period of protection in order to compensate for the time lost in obtaining a marketing authorization. Indeed the Tribunale di Milano reasoned that since the supplementary certificate was intended to compensate for the lost time, it was not reasonable to disadvantage third parties by preventing them from requesting marketing authorizations prior to expiry of the patent.

48. The position in Italy might be compared with that in the United States of America, where it had been held by the Court of Appeals for the Federal Circuit that the import of a patented compound in order to make dosage form capsules, upon which tests would be conducted in order to obtain data required for the approval of a regulatory body, constituted an infringement of the patent. [42] That decision was only reversed by legislation when the possibility of a supplementary period of protection was made available. According to the Supreme Court, the provision in The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the 'Hatch-Waxman Act'), which provided, in effect, that the submission of samples during the validity of a patent was no longer to be regarded as an infringement of that patent, was complementary to the provision in that same Act providing for the possibility of additional protection to compensate for the time lost in obtaining marketing authorizations. [43] I should perhaps add at this point that I do not consider it necessary for the Court to consider the justifiability of the

39 — Whitford J. mentioned that the aim of patentees was to extend their period of exclusivity (pp. 4 and 5).

40 — See paragraph 42 above.

41 — Giur. Ann. dir. ind., p. 1081.

42 — *Roche Products, Inc.* v *Bolar Pharmaceutical Co.*, 733 F2d 858 (Court of Appeals for the Federal Circuit, 1984).

43 — *Eli Lilly & Co.* v *Medtronic, Inc.*, (1990 US) 110 L Ed 2d 605.

Netherlands law in so far as it applies to patents which could have been the subject of a supplementary protection certificate.

49. In conclusion, the above survey shows that the judgment of the Hoge Raad of 18 December 1992 which is in issue in the present case is far from an arbitrary, unreasonable interpretation of the extent of patent protection.

Justification of supplementary protection

50. The Supplementary Protection Regulation, already referred to, [44] is also relevant to the justification of the measure in issue. Its adoption demonstrates the importance attached by the Community legislature to the erosion of the initial period of patent protection by the delays involved in obtaining a marketing authorization. Even if, as Generics submits, the judgment of the Hoge Raad of 18 December 1992 interpreting Article 30(3) of the ROW did not aim to give supplementary protection, I consider it reasonable for this Court to have regard to the practical effect of that law since the justification of a measure must be assessed in terms of its effects.

44 — See paragraph 4 above.

51. The Supplementary Protection Regulation now provides for the possibility of an extension to the national patent term, by an amount of time equal to the period which elapsed between the date upon which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years, provided, however, that the extension does not exceed five years. The recitals to the Regulation make it clear that the purpose of the Regulation is to compensate patentees for the time lost in obtaining a marketing authorization: the second, third, and sixth recitals state that:

'Whereas medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research;

Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and an authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research;

...

Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws ...'

52. Although the Regulation only allows the possibility of supplementary protection in respect of products which were still protected by a valid patent on the date upon which the Regulation entered into force and for which the first authorization to place the product on the market was obtained after 1 January 1985 (thus excluding the products in the present case), [45] I agree with the view of the Hoge Raad, expressed in the order for reference, that that does not mean that earlier products do not merit supplementary protection.

53. According to the Commission's Explanatory Memorandum, [46] the date of first authorization which was originally proposed (after 1 January 1984), which is not far off the date eventually adopted, was selected in order to permit European industry to catch up with its American competitors who had benefited from the possibility of a supplementary period of protection since 1984. The Commission also stated in that Memorandum that limiting the grant of supplementary certificates to patents which were still in force as at 1 July 1992 in addition to requiring that the authorization was granted after 1 January 1984, would mean that a product in respect of which a patent had been applied for in 1972 (i. e. 20 years earlier) could only benefit from a certificate if it had taken more than 12 years to obtain the corresponding marketing authorization. It explained that the period of 12 years was what had been calculated, for the purposes of the proposal for the Regulation, as the average time taken to obtain such an authorization. [47] Furthermore, it stated that, in devising the proposal, it had taken care to 'strike a balance between the interests of researchers and those of generic firms, notably in laying down the duration of the protection given by the certificate and the transitional arrangements'. [48]

54. However, that does not mean that the Commission considered prior national protection to be unacceptable. On the contrary, the Regulation was adopted for the very reason that the justifiability of various national measures was recognized. In paragraph 7 of its Explanatory Memorandum, the Commission argued that the fact that there were several parliamentary initiatives at national level, of which one was at a very advanced procedural stage, to provide for supplementary protection for patented medicinal products, made it necessary to harmonize the matter at Community level. As the sixth recital to the Regulation indicates, the aim was to avoid

45 — The first patent expired on 9 March 1992, before the Regulation came into force (six months after its publication on 2 July 1992 in the Official Journal), and the second patent, albeit in force at the date the Regulation entered into force, was the subject of a marketing authorization prior to 1 January 1985.

46 — COM (90) 101 final — SYN 255.

47 — Paragraph 61(b).

48 — Paragraph 25.

'disparities' between national laws which 'would be likely to create obstacles to the free movement of medicinal products within the Community'. Moreover, the Regulation impliedly recognizes the acceptability of prior national protection since it provides, in Article 20, that the Regulation does not apply to 'certificates granted in accordance with the national legislation of a Member State before the date on which this Regulation enters into force or to applications for a certificate filed in accordance with that legislation before the date of publication of this Regulation in the Official Journal ...'.

55. It is also noteworthy that an amendment to Article 63 of the European Patent Convention [49] was agreed by a conference of all the Contracting States in December 1991 in order to provide for the extension of the term of a European patent beyond 20 years, in relation to certain products (including pharmaceutical products) where official approval is required before a patented product can be marketed. However, the amendment has not yet come into force.

56. For all the above reasons, I consider that Article 30(3) of the ROW, as interpreted by the Hoge Raad in its judgment of 18 December 1992 and applied in the present case, is justified under Article 36 of the Treaty.

Grant of an injunction (Question 3)

57. With regard to the injunction, it is established that such a prohibition on the sale of the goods by a national court falls within the scope of Article 30. [50] I accordingly turn to the question of justification of that injunction under Article 36.

58. The law breached by Generics in the present case is national law, not Community law, and I have concluded that the national law which the injunction is protecting is justified under Community law. Nevertheless, the remedy granted under national law might not be justified under Article 36 if it went further than was necessary to protect the right in question, since the Court has held that 'national rules or practices do not fall within the exception specified in Article 36' if the interest in question can be 'as effectively protected by measures which do not

49 — Cited in note 2.

50 — See Case 58/80 *Dansk Supermarked* v *Imerco* [1981] ECR 181 and *Allen and Hanburys*, cited in note 21.

restrict intra-Community trade so much'. [51] Thus the Court may be called upon, within certain limits, to review the remedy to ensure that it is not disproportionate.

59. As to the choice of an injunction by way of remedy, the Court has already dealt with that issue to a certain extent in *Thetford* v *Fiamma*. [52] In that case, which concerned the import of articles infringing a national patent, Fiamma maintained that, in accordance with the principle of proportionality, the most that should be ordered was payment of a reasonable royalty since the specific subject-matter of the patent would be adequately protected by conferring on the proprietor the right to obtain reward for the marketing of the patented article, without going so far as to give him the right to obtain an injunction. However, the Court dismissed that argument by holding simply that the right of the proprietor of a patent to prevent the import of products manufactured without a licence is 'part of the substance of patent law' and that accordingly 'where national law normally provides for the issue of an injunction to prevent any infringement, that measure is justified under Article 36.'

60. Generics argues, however, that the present case is different because it concerns an injunction against the sale of products taking place after the expiry of the patent. It reasons that, since the patent has now expired, an injunction prohibiting the sale of products following expiry is not necessary to 'prevent', in the sense of 'forestall', an infringement of the patent.

61. Generics further argues that the choice of an injunction by way of a remedy is disproportionate because SKF could have applied for an injunction earlier, and because, as it argued at the oral hearing, the court could have considered awarding compensation, or cancelling the marketing authorizations, as an alternative to an injunction. [53]

62. The choice of the appropriate remedy is in my view essentially a matter for the national courts, and this Court should not intervene unless the national courts were to grant a remedy which was manifestly disproportionate. Merely to illustrate that point, I make the following observations. First, on the suggestion that damages might have been awarded rather than an injunction, I would observe that it might be very difficult to

51 — Case 104/75 *De Peijper* [1976] ECR 613, in the context of the health and life of humans.

52 — Cited in note 18.

53 — SKF maintains that it could not have been aware of Generics' applications before the marketing authorizations were actually granted. However, those authorizations were granted on 18 January 1990 and 17 December 1992, and the writ was not issued until August 1993.

calculate a fair level of damages. Moreover, an account of profits might not suffice because Generics would have benefited from an additional 14 months of presence upon the market in order to build up its reputation, thus increasing the degree of competition for the future. If that were so, it might make the type of injunction ordered in the present case the only fair remedy, and it is not unreasonable for the national court to wish to grant a remedy to SKF, even if SKF could have acted earlier. As to the possibility of cancelling the registrations, as opposed to an injunction prohibiting sales by way of injunction, I see little difference if the injunction was indeed based upon the average time taken to obtain a marketing authorization.

63. The above observations are made simply to indicate that the balancing act required in order to assess the most appropriate remedy in a particular case concerning an infringement of national law should, as a matter of general principle, be for the national court. This Court cannot become involved in such evaluations, save in cases in which it is clear from the order for reference that the remedy granted was manifestly disproportionate. That is not the case here.

Length of the injunction (Question 4)

64. With regard to the length of the injunction, Generics objects that the period of 14 months is unacceptable because it was based on the average time taken by the CBG in granting marketing authorizations, which considerably exceeded the period of 120 days stipulated in Directive 65/65. Generics argues that since the delay in granting authorization is unlawful in so far as it exceeds that period of 120 days, an injunction which prevents it from marketing beyond that period is also unlawful.

65. The United Kingdom points out that Directive 65/65 allows periods of suspension in certain cases [54] and that it is not clear whether the average of 14 months includes such periods, so that it is not entirely clear that 14 months is a breach of the Directive. However, the Hoge Raad phrases its question in terms of a period which 'exceeds the maximum period prescribed by Directives 65/65 and 75/319,' so the question is put on the basis that that period is in breach of the Directives.

54 — See Article 7, as amended by Article 1(6) of Directive 93/39 and supplemented by Article 4(c) of Directive 75/319.

66. In my view, however, even assuming that the delay of 14 months is not compatible with Community law, Directive 65/65 is of no assistance to Generics' case.

67. I have already concluded that both the right to prevent the submission of samples to the CBG during the currency of the patent, and the choice of an injunction, as opposed to, for example, damages, in order to remedy an infringement of that right are justified under Community law. It must follow that the length of an injunction which is calculated so as to place the patentee in the position in which he would have been had that right been respected is equally justified. Moreover that injunction puts Generics, as well as SKF, in approximately the situation in which it would have been if it had not infringed the patent. The result is therefore in accordance with equity. Indeed if the solution were otherwise, there might be an inducement for a competitor to infringe a patent, in the expectation that the resulting injunction would expire sooner than if it had to await the normal period for obtaining a marketing authorization.

68. It is true that Community law requires that a remedy be available to applicants for marketing authorizations where the authorities are in breach of Community law by exceeding the time-limits specified in Directive 65/65. However, Community law does not require that the remedy available in such circumstances should take a form which would have the effect of limiting the rights of the patentee. Generics may have a remedy, in other proceedings, against the authorities responsible for any delay in granting authorization, but cannot invoke any such delay in those proceedings as a basis for challenging the duration of the injunction.

69. It is therefore unnecessary to examine the question whether, by invoking the alleged breach of Directive 65/65 against SKF, Generics' argument on this point might have to rely on giving that Directive 'horizontal direct effect', that is, invoking its direct effect against a person other than the State, contrary to the Court's case-law. In my view there is no need to address that issue.

70. Finally, Generics seeks to base an argument on the fact that the product in question here, cimetidine, was protected by two patents owned by SKF. All three applications for marketing authorizations in respect of the competing products to be marketed by Generics were made before the second patent had been granted or even published and two of the three marketing authorizations (those in respect of 200 mg and 400 mg tablets) were even awarded before such grant or publication. [55] According to Generics, therefore, the lodging of the samples with the CBG only constituted a breach of the first patent, not the second. Generics thus argues that it is unjust to grant an injunction prohibiting it from selling all its products for a period running from the expiry of that second patent.

71. Whether, and the extent to which, the second patent was infringed is a question for the national courts to decide under national law. However, even if Generics is correct in its assertion that the second patent was not infringed, it still appears that if it had not infringed the first patent it would not have been able to lodge its applications for marketing authorizations prior to expiry of that patent (on 9 March 1992). By that time, the second patent had been granted (19 June 1991) and thus the authorizations could not lawfully have been applied for because it is accepted that the applications would have constituted a breach of the second patent if it had been in force at the time they were made. Thus, in calculating the injunction from the expiry of the second patent, all that the national court was doing was putting Generics back in roughly the position in which it would have been if it had not breached the national law prohibiting the submission of samples during the validity of the first patent. [56] As I concluded earlier, that is a justifiable aim.

72. I am therefore of the view that the injunction ordered by the Netherlands court is not objectionable under Community law.

55 — See the dates set out at paragraphs 5 to 8 above.

56 — Possibly even better, since the actual time taken to approve the authorizations was longer: the applications were made on 22 October 1987 and 10 October 1989 and the authorizations were not granted until 18 January 1990 and 17 December 1992: thus the delays were approximately 27 months and 38 months respectively.

Conclusion

73. Accordingly, I am of the opinion that the questions referred to the Court by the Hoge Raad should be answered as follows:

(1) 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 falls within the scope of Article 30 of the EC Treaty; however, where no supplementary protection certificate could have been applied for, that measure is justified under Article 36 of the Treaty on the ground of the protection of industrial and commercial property.

(2) The judicial prohibition imposed in the present case restraining, for a specified period following expiry of the patent, the marketing of products whose marketing authorization was obtained in breach of the patent falls within the scope of Article 30 of the Treaty but is justified under Article 36 of the Treaty on the ground of the protection of industrial and commercial property. That is so notwithstanding that that period exceeds the period specified in Directives 65/65 and 75/319 for the authorization of medicinal products.