JUDGMENT OF THE COURT
12 November 1996 *

In Case C-201/94,

REFERENCE to the Court under Article 177 of the EC Treaty by the High Court of Justice, Queen's Bench Division (United Kingdom), for a preliminary ruling in the proceedings pending before that court between

The Queen

and

The Medicines Control Agency,

***ex parte* Smith & Nephew Pharmaceuticals Ltd,**

and between

Primecrown Ltd

and

The Medicines Control Agency,

* Language of the case: English.

on the interpretation 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 (OJ, English Special Edition 1965-1966, p. 20), as amended in particular by Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36), and of the obligations associated with the authorization of proprietary medicinal products,

THE COURT,

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

Advocate General: P. Léger,
Registrar: D. Louterman-Hubeau, Principal Administrator,

after considering the written observations submitted on behalf of:

— Smith & Nephew Pharmaceuticals Limited, by Patrick Elias QC and Christopher Vajda, Barrister, instructed by Ashurst Morris Crisp, Solicitors,

— Primecrown Limited, by Michael J. Beloff QC and Andrew Nicol, Barrister, instructed by R. R. Sanghvi & Co., Solicitors,

— the United Kingdom Government, by John E. Collins, Assistant Treasury Solicitor, acting as Agent, and Richard Drabble, Barrister,

— the German Government, by Ernst Röder, Ministerialrat at the Federal Ministry of Economic Affairs, and Bernd Kloke, Regierungsrat at the same Ministry, acting as Agents,

— the French Government, by Catherine de Salins, Assistant Director at the Legal Affairs Directorate of the Ministry of Foreign Affairs, and Philippe Martinet, Secretary for Foreign Affairs at the same Directorate, acting as Agents,

— the Italian Government, represented by Ivo M. Braguglia, Avvocato dello Stato, acting as Agent,

— the Commission of the European Communities, represented by Richard Wainwright, Principal Legal Adviser, and Angela Bardenhewer, of its Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Smith & Nephew Pharmaceuticals Limited, represented by Patrick Elias and Christopher Vajda, Primecrown Limited, represented by Andrew Nicol and Martin Howe, Barrister, the United Kingdom Government, represented by John E. Collins and Richard Drabble, and the Commission, represented by Richard Wainwright, at the hearing on 12 December 1995,

after hearing the Opinion of the Advocate General at the sitting on 30 January 1996,

gives the following

Judgment

1 By order of 4 May 1994, received at the Court on 11 July 1994, the High Court of Justice, Queen's Bench Division (United Kingdom), referred to the Court for a preliminary ruling under Article 177 of the EC Treaty four questions on the interpretation 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 (OJ, English Special Edition 1965-1966, p. 20) as amended in particular by Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36), and the obligations associated with the authorization of proprietary medicinal products.

2 Those questions were raised in two sets of proceedings, the first between Smith & Nephew Pharmaceuticals Limited (hereinafter 'Smith & Nephew') on the one hand and the Medicines Control Agency (hereinafter 'the MCA') and Primecrown Limited (hereinafter 'Primecrown') on the other, and the second between Primecrown and the MCA, concerning the issue to Primecrown of a licence to import a proprietary medicinal product of Belgian origin bearing the same name, and manufactured under an agreement with the same licensor, as a product for which Smith & Nephew holds a marketing authorization in the United Kingdom.

3 The first recital in the preamble to Directive 65/65 states that 'the primary purpose of any rules concerning the production and distribution of proprietary medicinal products must be to safeguard public health'. According to the second recital 'this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community'.

4 Article 3 of Directive 65/65, as applicable at the material time, provided that no proprietary medicinal product could be placed on the market in a Member State unless a prior authorization had been issued by the competent authority of that Member State. Article 1(1) of Directive 65/65 defines a proprietary medicinal product as 'any ready-prepared medicinal product placed on the market under a special name and in a special pack'. Article 4 lists the information and documents which must accompany an application for a marketing authorization.

5 Article 5 of Directive 65/65 provides that a marketing authorization 'shall be refused if, after verification of the particulars and documents listed in Article 4, it proves that the proprietary medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative and quantitative composition is not as declared. Authorization shall likewise be refused if the particulars and documents submitted in support of the application do not comply with Article 4'.

6 On 1 January 1995 a new Community system of marketing authorizations came into force following the adoption 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) and 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). However, in view of the date on which the application for the marketing authorization at issue was submitted, those provisions are not applicable to the main proceedings.

7 In the United Kingdom, pursuant to the provisions transposing Directive 65/65 into national law, the MCA is the competent national authority for the issue of marketing authorizations.

8 The MCA has published leaflets on how to apply for marketing authorizations for parallel imports of medicinal products. Those leaflets bear the reference MAL 2 (PI) and are entitled 'Notes on Application for Product Licences (Parallel Importing) (Medicines for Human Use)'. MAL 2 (PI) defines a 'parallel import' of a proprietary medicinal product as fulfilling two requirements, namely that the product is covered by a marketing authorization in the United Kingdom and that an applicant wishes to import from another Member State a version of that product already covered by a marketing authorization issued by another Member State. In such a case there is a simplified form of application to the MCA, referred to as the 'PL (PI) procedure'. In accordance with that procedure, which is generally quicker

than the procedure provided for by Directive 65/65, the applicant is obliged to supply less information than that required for an application made under Directive 65/65. In order to qualify for the PL (PI) procedure the proprietary medicinal product concerned must satisfy several conditions, and in particular must have been made by or under licence to the manufacturer of the product covered by the United Kingdom marketing authorization or by a member of the same group of companies as the manufacturer of the product covered by the United Kingdom marketing authorization.

9 Smith & Nephew markets the proprietary medicinal product 'Ditropan' in the United Kingdom pursuant to an agreement concluded in 1982 with the United States company Marion Merrell Dow (hereinafter 'MMD'). Manufacture of the product in the United Kingdom is carried out on behalf of Smith & Nephew by Boots Pharmaceuticals Limited. Ditropan contains an active ingredient called oxybutynin hydrochloride, used for the treatment of some forms of urinary incontinence. According to the order for reference the application for a clinical trial licence for Ditropan and a subsequent application for a marketing authorization were made on the basis of data and other information supplied by MMD. That application was submitted by Smith & Nephew to the MCA in 1982. Since the MCA considered that information to be insufficient, particularly as regards the need to show that the product had no carcinogenic potential, Smith & Nephew was required to perform additional clinical studies and, according to the High Court of Justice, to change the formulation of the proprietary medicinal product from that which had been manufactured by MMD in the United States. As a result, a marketing authorization was not granted until January 1991.

10 On 8 October 1992 Primecrown submitted an application for an authorization under the PL (PI) procedure for the purpose of making parallel imports of a variant of Ditropan sold in France by Laboratoires Debat. The MCA rejected that application on the ground that there was no link between Smith & Nephew and Laboratoires Debat. On 22 February 1993 Primecrown made a further application to the MCA for an authorization under the PL (PI) procedure for the purpose of importing and selling, in the United Kingdom, Ditropan marketed in Belgium by Marion Merrell Dow Belgium (hereinafter 'MMD Belgium') pursuant to a Belgian marketing authorization.

11 By letter of 28 June 1993 MMD stated that it could not ensure that the excipients used in the Ditropan manufactured in Belgium were identical to those used in the Ditropan manufactured in the United Kingdom.

12 However, in a document signed on 8 July 1993 the pharmaceutical assessor appointed by the MCA concluded that the Belgian Ditropan was identical in formulation to Smith & Nephew's Ditropan.

13 On 24 August 1993 the MCA granted the authorization sought by Primecrown, erroneously taking the view that the requisite link existed between Smith & Nephew and MMD Belgium for the application of the PL (PI) procedure. The MCA considered that the case raised no public health problems at that time.

14 In a letter sent to the MCA on 7 September 1993, MMD stated that, although it knew of and controlled the specifications for Ditropan manufactured in Belgium, that was not true for the specification for Ditropan manufactured in the United Kingdom. MMD stated that Smith & Nephew was a separate legal entity from the MMD group of companies and that MMD merely provided it with the ingredient oxybutynin hydrochloride. It concluded that it could not confirm that the product specifications for Ditropan manufactured in Belgium were identical to those for Ditropan manufactured in the United Kingdom.

15 When it became aware that the requisite link for the purposes of the PL (PI) procedure did not exist between Smith & Nephew and MMD Belgium, the holder of the marketing authorization for Ditropan in Belgium, the MCA withdrew the marketing authorization granted to Primecrown.

16 On 26 January 1994 the High Court granted Smith & Nephew leave to bring proceedings for judicial review of the MCA's decision of 24 August 1993 authorizing Primecrown to import Belgian Ditropan into the United Kingdom. Primecrown applied to the High Court under section 107(2) of the Medicines Act 1968 for an order quashing the MCA's decision to withdraw authorization.

17 These are the circumstances in which the two applications were brought before the High Court of Justice. Taking the view that the outcome of the cases depended upon interpretation of Community law, the High Court referred the following four questions to the Court of Justice for a preliminary ruling:

'(1) Is an undertaking that holds a marketing authorization in respect of a branded medicinal product ("Product X"), such authorization having been granted in accordance with the procedures laid down by Directive 65/65, entitled to rely on Directive 65/65, and in particular Article 5 thereof, before a national court in order to challenge the validity of (and seek an order quashing) a marketing authorization to a competitor in respect of a proprietary medicinal product bearing the same name ("Product Y")?

(2) Is the licensing authority in Member State A entitled to grant a marketing authorization to Product Y which is sought to be imported from Member State B in circumstances where Product Y is not made by or under the control of the person holding the marketing authorization in Member State A or a member of the same group of companies?

(3) If the answer to Question 2 is in the positive,

(a) what preconditions must be fulfilled before Member State A is so entitled to grant a marketing authorization to Product Y; and in particular

(b) what data should Member State A have in its possession in respect of Product Y before the licensing authority grants a marketing authorization to Product Y?

(c) to what extent can the licensing authority rely on data supplied by the holder of the marketing authorization for Product X, in circumstances where the data exclusivity periods provided for by Article 4(8) of Directive 65/65 (as amended) have not expired?

(d) is the licensing authority entitled to grant a marketing authorization to Product Y which is sought to be imported in circumstances where the licensing authority has not compared the actual manufacturing processes of Product Y with those of Product X?

(4) Is the answer to Questions 2 to 3 above affected by the fact that the product licence holders of Product X and Product Y in Member State A and Member State B respectively are both licensees of the same commercial licensor who is situated outside the European Community?'

The second and third questions

18 By its second and third questions, which it is appropriate to consider first, the High Court seeks essentially to ascertain the conditions in which the competent authority of a Member State may grant a marketing authorization for a proprietary medicinal product which is sought to be imported from another Member State in which that product is covered by a marketing authorization, where the competent authority of the Member State of importation has already granted a marketing authorization for another proprietary medicinal product and where the two products have been manufactured by independent persons pursuant to an agreement concluded with the same licensor.

19 According to the first and second recitals in the preamble to Directive 65/65, the primary purpose of that directive is to ensure that, when a proprietary medicinal product is marketed, public health is safeguarded by means which cannot hinder the development of the pharmaceutical industry or trade in medicinal products within the Community. To that end, the directive requires that a series of documents as well as precise, detailed information be produced as a precondition to the granting of a marketing authorization, even where the proprietary medicinal product in question is covered by a marketing authorization granted by the competent authority of another Member State.

20 However, the objective of safeguarding public health pursued by Directive 65/65 justifies such stringent measures only in regard to proprietary medicinal products which are being put on the market for the first time.

21 Consequently, the provisions of Directive 65/65 concerning the procedure for issue of marketing authorizations cannot apply to a proprietary medicinal product covered by a marketing authorization in one Member State which is being imported into another Member State as a parallel import of a product already covered by a marketing authorization in that other Member State. In such a case, the imported proprietary medicinal product cannot be regarded as being placed on the market for the first time in the Member State of importation.

22 That was the effect of the Court's judgment in Case 104/75 *De Peijper* [1976] ECR 613, paragraphs 21 and 36, which stated that, if the public health authorities of the Member State of importation already have in their possession, as a result of importation on a previous occasion, all the pharmaceutical particulars relating to the medicinal product in question and considered to be absolutely necessary for the purpose of checking that the product is effective and not harmful, it is clearly unnecessary, in order to protect the health and life of humans, for those authorities to require a second trader who has imported a medicinal product which is in every respect the same or whose differences have no therapeutic effect, to produce these particulars again.

23 In *De Peijper* (paragraph 10) the Court considered the case of a proprietary medicinal product which was prepared in accordance with a uniform method of preparation and which had a well-defined qualitative and quantitive composition. The product was lawfully in circulation in several Member States since the authorizations required by the legislation of those States had been granted in relation to that product either to the manufacturer or to the person responsible for putting the product on the market. The product in question was in every respect the same as a product in respect of which the public health authorities of the Member State of importation already possessed documents relating to its method of preparation and its quantitive and qualitative composition, these documents having been previously produced to them by the manufacturer or his duly appointed importer in support of an application for an authorization to place it on the market.

24 Moreover, the proprietary medicinal products at issue in that judgment had been manufactured by the same group of companies and therefore had a common origin.

25 That case-law can be applied to a situation such as that at issue in the main proceedings, in which independent companies produce proprietary medicinal products, which have a common origin by virtue of the fact that they are manufactured pursuant to agreements concluded with the same licensor. Otherwise, such agreements could lead to partitioning of the national markets of the various Member States.

26 The competent authority in the Member State of importation must also verify that the two proprietary medicinal products, if not identical in all respects, have at least been manufactured according to the same formulation, using the same active ingredient, and that they also have the same therapeutic effects.

27 To that end, as the Court pointed out in *De Peijper*, paragraph 26, the competent authority has available to it legislative and administrative means capable of compelling the manufacturer, his duly appointed representative or the licensee for

the proprietary medicinal product in question to supply information in their possession which the authority considers to be necessary. Moreover, the competent authority may consult the file submitted in connection with the application for a marketing authorization for the proprietary medicinal product already authorized.

28 Finally, as the Court also held in *De Peijper*, paragraph 27, simple cooperation between the authorities of the Member States would enable them to obtain the necessary substantiating documents on a reciprocal basis.

29 If, on completion of its examination, the competent authority of the Member State of importation finds that all the abovementioned criteria are satisfied, the proprietary medicinal product to be imported must be regarded as having already been placed on the market in the Member State of importation and, consequently, must be entitled to benefit from the marketing authorization issued for the proprietary medicinal product already on the market, unless there are countervailing considerations relating to the effective protection of the life and health of humans.

30 If the competent national authority concludes that the proprietary medicinal product to be imported does not satisfy all the abovementioned criteria and cannot therefore be regarded as having already been placed on the market in the Member State of importation, it cannot issue the new marketing authorization required for the marketing of the product to be imported unless the conditions listed in Directive 65/65, as amended by Directive 87/21, are fulfilled. The discretion enjoyed by the competent authority of the Member State under the directive is very limited. It cannot, on any view, extend to the possibility of issuing a marketing authorization under Article 3 of Directive 65/65 when the information referred to in Article 4 of that directive has not been supplied in full and the tests referred to therein have not been performed. Such a marketing authorization may be issued only when it is shown that all the obligations set out in Article 4 have been complied with (see Case C-440/93 *R* v *Licensing Authority of the Department of Health, ex parte Scotia Pharmaceuticals* [1995] ECR I-2851).

31 It would therefore be contrary to Directive 65/65, as amended by Directive 87/21, for a competent national authority, in the context of an application for a marketing authorization falling within the scope of that directive, to use information supplied by an independent company, without its agreement, in support of an application for a marketing authorization concerning another proprietary medicinal product.

32 Consequently, when the competent authority of a Member State concludes that a proprietary medicinal product covered by a marketing authorization in another Member State and a proprietary medicinal product for which it has already issued a marketing authorization are manufactured by independent companies pursuant to agreements concluded with the same licensor and that those two products, although not identical in all respects, have at least been manufactured according to the same formulation, using the same active ingredient, and that they also have the same therapeutic effects, it must treat the imported product as being covered by the latter marketing authorization unless there are countervailing considerations relating to the effective protection of the life and health of humans. If the competent national authority concludes that the proprietary medicinal product to be imported does not satisfy those criteria, a new marketing authorization is required. That authorization can be issued only in accordance with the conditions laid down in Articles 3 and 4 of Directive 65/65, as amended by Directive 87/21.

The fourth question

33 The national court's fourth question asks whether the fact that, in this case, the manufacturing licences for the proprietary medicinal products were granted by the same legal person, established outside the European Community, affects the answer given above.

34 In the light of the answer to the second and third questions, it suffices to state that the fact that the grantor of the licences in respect of the two proprietary medicinal products in question is situated outside the European Community does not affect the answer given above.

The first question

35 By this question the national court asks in essence whether the holder of the original authorization issued under the normal procedure referred to in Directive 65/65 may rely on the directive, and in particular on Article 5 thereof, in proceedings before a national court in which it contests the validity of a marketing authorization granted by a competent public authority to one of its competitors for a proprietary medicinal product bearing the same name.

36 In Case 301/82 *Clin-Midy* v *Belgium* [1984] ECR 251, paragraph 4, the Court held that the provisions of Directive 65/65 laying down the conditions for the grant, suspension or revocation of a marketing authorization, in particular Article 21 thereof, are unconditional and sufficiently precise for them to be relied upon before a national court by the persons concerned in order to challenge any national provision laid down by law, regulation or administrative action which is incompatible with the directive.

37 Although Article 5 of Directive 65/65 was not specifically referred to in the judgment in *Clin-Midy*, it is unconditional and sufficiently precise for it to be relied upon before a national court in order to challenge a marketing authorization issued by a competent national authority.

38 However, the provisions of Directive 65/65, as amended by Directive 87/21, may be relied upon only in order to challenge the validity of an authorization issued on the basis of that directive.

39 Consequently, the answer to the national court should be that the holder of an original marketing authorization issued under the procedure referred to in Directive 65/65 may rely on the provisions of that directive, as amended, in particular

by Directive 87/21, and specifically on Article 5 thereof, in proceedings before a national court in order to challenge the validity of an authorization issued by the competent national authority on the basis of Directive 65/65, as amended, to one of its competitors for a proprietary medicinal product bearing the same name. The same applies where the authorization, although issued under another procedure laid down at national level, should have been issued on the basis of the directive.

Costs

40 The costs incurred by the United Kingdom, German, French and Italian Governments and by 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 High Court of Justice, Queen's Bench Division, by order of 4 May 1994, hereby rules:

(1) (a) When the competent authority of a Member State concludes that a proprietary medicinal product covered by a marketing authorization in

another Member State and a proprietary medicinal product for which it has already issued a marketing authorization are manufactured by independent companies pursuant to agreements concluded with the same licensor and that those two products, although not identical in all respects, have at least been manufactured according to the same formulation and using the same active ingredient and that they also have the same therapeutic effects, it must treat the imported proprietary medicinal product as being covered by the latter marketing authorization unless there are countervailing considerations relating to the effective protection of the life and health of humans.

(b) If the competent authority concludes that the proprietary medicinal product to be imported does not satisfy those criteria, a new marketing authorization is required. That authorization can be issued only in accordance with the conditions laid down in Articles 3 and 4 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, as amended in particular by Council Directive 87/21/EEC of 22 December 1986.

(2) The fact that the grantor of the licences in respect of the two proprietary medicinal products in question is situated outside the European Community does not affect the answer given above.

(3) The holder of an original marketing authorization issued under the procedure referred to in Directive 65/65 may rely on the provisions of that directive, as amended in particular by Directive 87/21, and specifically on Article 5 thereof, in proceedings before a national court in order to challenge the validity of an authorization issued by the competent national authority on the basis of Directive 65/65, as amended, to one of its competitors for a proprietary medicinal product bearing the same name. The same

applies where the authorization, although issued under another procedure laid down at national level, should have been issued on the basis of the directive.

Rodríguez Iglesias Moitinho de Almeida Murray

Sevón Kakouris Kapteyn

Edward Jann Ragnemalm

Delivered in open court in Luxembourg on 12 November 1996.

R. Grass G. C. Rodríguez Iglesias

Registrar President