OPINION OF ADVOCATE GENERAL LÉGER
delivered on 30 January 1996 *

1. The High Court, Queen's Bench Division, is asking the Court of Justice to interpret 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, [1] as amended in particular by Council Directive 87/21/EEC of 22 December 1986. [2] In substance, it is asking the Court to rule on the Community law requirements concerning the issue of marketing authorizations for medicinal products [3] in the context of parallel imports.

The relevant legislation and the facts

The Community legislation

2. Because of their particular nature, medicinal products receive special attention from the Community legislature, as is evident from the complex, but coherent, body of harmonizing directives — of which Directive 65/65 remains the basic directive — that has been adopted. The primary purpose is twofold: to ensure protection of public health [4] while also progressively bringing about the free movement of medicinal products. [5] Those twin aims still apply, although recently the Community legislature has concentrated on other aspects of medicinal products policy which are not directly connected to the protection of public health. That is, in particular, the case with Directive 87/21 which safeguards the rights of innovative firms.

3. Nevertheless, there are still a number of restraints on the free movement of medicinal products within the Community due to the need for a national authorization in order to put a medicinal product on the market and to the lack of price uniformity in relation to medical products.

4. A new Community system of marketing authorizations came into force on 1 January 1995. That system is a further step towards

* Original language: French.

1 — OJ, English Special Edition 1965-1966, p. 20.

2 — OJ 1987 L 15, p. 36.

3 — It should be pointed out that since the entry into force of Council Directive 89/341/EEC of 3 May 1989 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC (OJ 1989 L 142, p. 11), the term 'medicinal product' has replaced the term 'proprietary medicinal product' in all Community legislation concerning medicinal products for human use.

4 — First recital in the preamble to Directive 65/65.

5 — Second, third, and fourth recitals in the preamble to Directive 65/65.

the realization of a single market in medicinal products.

5. It establishes two new procedures:

— a decentralized procedure set up by a Council directive of 14 June 1993 [6] providing for the mutual recognition of marketing authorizations;

— a centralized procedure adopted on 22 July 1993 by a Council regulation, [7] a procedure providing for a Community marketing authorization issued by the European Agency for the Evaluation of Medicinal Products; a marketing authorization issued by that Agency is valid throughout the Community.

6. However, owing to the date on which the application for the marketing authorization at issue was made, Articles 3, 4 and 5 of Council Directive 65/65 and Articles 30 and 36 of the EC Treaty still apply to the present case.

7. The authorities competent for the issuing of marketing authorizations for medicinal products for human use are essentially the national authorities. Article 3 of Directive 65/65 provides that no proprietary medicinal product may be placed on the market in a Member State unless an authorization has been issued by the competent authority of that State in accordance with that directive. The marketing authorization thus issued is valid only on the national territory of the Member State which granted it. A new marketing authorization is necessary and must be obtained in each Member State in which the medicinal product is marketed.

8. In order to avoid differences in evaluation by the competent national authorities and in order to achieve the objective of the free movement of medicinal products, two fundamental directives were adopted on 20 May 1975. They are Directive 75/318/EEC ('the Standards and Protocols Directive') [8] and Directive 75/319/EEC [9] which, by requiring the competent national authorities to examine applications for marketing authorizations in accordance with the protocols set out in the annex to the Standards and Protocols Directive, harmonize the methods for supervising medicinal products placed on the market and establish several elements of mutual recognition in the Community's pharmaceutical legislation. [10]

6 — Directive 93/39/EEC amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22).

7 — Regulation (EEC) No 2309/93 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).

8 — Council Directive on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (OJ 1975 L 147, p. 1).

9 — Council Directive on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1975 L 147, p. 13).

10 — Article 9 et seq. of Directive 75/319 provide for a multi-State procedure and Article 12 et seq. provide for a consultation procedure.

9. The objective clearly pursued is therefore that of giving effect at Community level to marketing authorizations issued nationally. [11]

10. Article 4 of Directive 65/65, heavily amended and harmonized by those 1975 directives, defines the procedure and the documents required in order to obtain a marketing authorization. In particular, point 8 of the second paragraph of Article 4 requires communication of the results of tests conducted in order to establish the quality, safety and efficacy of the proprietary medicinal product.

11. However, Directive 87/21 provides for an 'abridged' procedure for medicinal products which are 'essentially similar' to a product already authorized in the country concerned by the application, which does not require an applicant for a marketing authorization to submit pharmacological, toxicological or clinical tests.

12. The abridged procedure concerns marketing authorizations for generic medicinal products. That follows from the Commission's Explanatory Memorandum. [12] A generic medicinal product is a copy of an innovative medicinal product whose formula can be reproduced by other manufacturers, the copy being sold under the same description at a price generally lower than the innovative product. In such a case, since the entry into force of Directive 87/21, an applicant for a marketing authorization for a generic medicinal product may refer to the results in the file relating to the original innovative proprietary medicinal product, either with the consent of the holder of the marketing authorization for the innovative product, or otherwise if a period of six to ten years has elapsed since the first marketing of the original proprietary product in the Community (data exclusivity period).

13. Article 5 of Directive 65/65 provides that the authorization must be refused if the medicinal product does not satisfy the three criteria on the basis of which decisions to issue marketing authorizations are taken, namely safety, quality and therapeutic efficacy, and if the documents and particulars submitted in support of the application do not comply with Article 4.

14. The Community legislature therefore wishes to impose compliance with common,

11 — Fourth recital in the preamble to the Standards and Protocols Directive; third recital in the preamble to Directive 75/319: 'Whereas, in order to progress towards free movement of proprietary medicinal products, the issue of authorizations to place one and the same proprietary medicinal product on the market in two or more Member States should be facilitated'.

12 — Explanatory Memorandum [COM(84) 437 final of 25 September 1984] concerning the proposal for a Council directive amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, point 14 et seq.; my analysis of Directive 87/21 in my Opinion delivered on 9 February 1995 in Case C-440/93 *Scotia Pharmaceuticals* [1995] ECR I-2851.

uniform rules on all national authorities having competence to issue marketing authorizations. Where a marketing authorization is issued in accordance with a harmonized procedure, there will no longer be anything to prevent the medicinal product authorized by the competent national authority of one of the Member States from circulating freely within the Community. [13]

15. So, the first barrier to the free movement of medicinal products, namely the requirement for a national marketing authorization, is to be overcome by harmonizing the supervisory methods and the documents and particulars to be submitted in support of an application for a marketing authorization.

16. On the other hand, it is more difficult to harmonize the price of the medicinal products in the Community. The reasons for the price differences are generally explained by the existence of fixed prices or price controls in some Member States and by disparities in the rules relating to the maximum amounts of refunds granted to patients under the various national sickness insurance schemes. [14]

17. That is why the phenomenon of 'parallel imports' has assumed considerable importance in this type of trade. The phenomenon occurs when traders outside the manufacturer's official distribution network purchase products on the market from wholesalers or retailers in the country of production or in other intermediary countries where prices are low, and export them to countries where prices are high. The parallel importer's aim is to exploit those price differences, which are sometimes very large, in order to obtain a profit, while keeping his price below the manufacturer's official sale price.

18. To keep my explanation of this case clear, I will call the product which has been the subject of a parallel import 'product Y', the reference product in the Member State into which it is imported 'product X', and I will refer to the Member State of importation as Member State A and the State of exportation as Member State B.

19. Pursuant to Article 3 of Directive 65/65, in the absence of a centralized Community procedure for marketing authorizations and for the reciprocal recognition of national consents, the authorization necessary for marketing medicinal product Y in the territory of Member State A is a matter falling within the competence of the national authorities of Member State A. Under those circumstances, it is legitimate from the point of view of public health for State A to be able to check that product Y is similar to product X. According to its ordinary meaning, 'similar' refers to things which are

13 — Fourth recital in the preamble to the Standards and Protocols Directive: 'the adoption of the same standards and protocols by all the Member States will enable the competent authorities to arrive at their decision on the basis of uniform tests and by reference to uniform criteria and will therefore help to avoid differences in evaluation'.

14 — To that effect, see point 2 of the Opinion of Advocate General Jacobs delivered on 14 December 1995 in Joined Cases C-427/93 and C-436/93 *Bristol-Myers Squibb and Others* v *Paranova* [1996] ECR I-3457; Mattera, A: *Le marché unique européen*, ed. Jupiter, p. 473.

comparable to one another, that is to say, that they may be regarded as being alike. I would therefore say that medicinal products are similar if their characteristics and methods of manufacture do not display any significant differences. Article 4a of Directive 65/65 [15] lists the characteristics of a medicinal product. [16]

20. In the event of an application being made for a marketing authorization for medicinal product Y authorized in Member State B, Member State A (the importing State) could therefore proceed to require from the applicant certain data held by the manufacturer or manufacturers of medicinal products X and Y.

21. However, in the case of a parallel import, the importer has no link with the manufacturer. Consequently, it is difficult for him to supply the manufacturer's documents by way of proof of the safety, efficacy and quality of the product and the fact that product Y is identical to the product X, for which Member State A has granted a marketing authorization.

22. That is why, in the absence of harmonized rules governing the parallel import of medicinal products, the Court of Justice laid down, in its judgment in Case 104/75 *De Peijper,* [17] principles which the Commission reproduced in an interpretative communication of 6 May 1982. [18]

23. The facts of the *De Peijper* case were as follows. In 1973 Centrafarm BV bought from an English wholesaler several batches of valium; Centrafarm then imported that product into the Netherlands as valium coming from the British factory belonging to the Hoffmann-La Roche Group. Before marketing it in the Netherlands, Centrafarm repackaged that product in standard packages bearing that firm's trademark and serial number. Apparently, that repackaging did not alter the quality, safety or therapeutic effect of the product.

24. A similar product was sold officially in the Netherlands under the name 'Valium' by La Roche's exclusive importer but at a much higher price.

25. As regards the facts, the Court pointed out that, according to the documents before

15 — Amended by Council Directive 83/570/EEC of 26 October 1983 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1983 L 332, p. 1).

16 — They are its name, its qualitative and quantitative composition, its pharmacological properties, its clinical particulars (therapeutic indications, contra-indications ...) ...

17 — [1976] ECR 613.

18 — OJ 1982 C 115, p. 5.

it, the pharmaceutical product imported by Centrafarm had been prepared in accordance with a uniform method of preparation and a well-defined qualitative and quantitative composition, that it had been placed in circulation in several Member States, that notice of the issue of the authorizations from the various Member States concerned had been given by official publication, and finally that the product in question was '... *in every respect similar to a product in respect of which the public health authorities of the Member State into which the first product has been imported* already possess the documents relating to the method of preparation and also to the quantitative and qualitative composition, since these documents were produced to them previously by the manufacturer or his duly appointed importer in support of a [previous] application for authorization to place them on the market.' [19] *In other words, product Y imported from Great Britain was already authorized by the Netherlands in the form of product X.*

26. On the basis of their national legislation the Netherlands authorities wished to prevent Centrafarm from marketing the valium imported from Great Britain, which was similar to the valium already authorized in the Netherlands, came from the same manufacturer and was imported from Great Britain by an authorized importer. They justified their objections on the grounds that it was impossible for the parallel importer (i) to provide the authorities with the full file relating to the quality, efficacy and safety of the medicinal product — a file which the importer authorized by the manufacturer had, however, already submitted to the same authorities in order to obtain the marketing authorization for that product — and (ii) to obtain from the manufacturer the supervisory records relating to each batch.

27. The Court held that '... national rules or practices which make possible for a manufacturer of the pharmaceutical product in question and his duly appointed representatives, simply by refusing to produce the documents relating to the medicinal operation in general or to a specific batch of that preparation, to enjoy a monopoly of the importing and marketing of the product, must be regarded as being unnecessarily restrictive and cannot therefore come within the exceptions specified in Article 36 of the Treaty, unless it is clearly proved that any other rules or practices would obviously be beyond the means which can reasonably be expected of an administration operating in a normal manner.

It is only if the information or documents to be produced by the manufacturer or his duly appointed importer show that there are several variants of the medicinal preparation and that the differences between these variants have a therapeutic effect that there would be any justification for treating the variants as different medicinal preparations, for the purpose of authorizing them to be placed on the market and as regards producing the relevant documents ...'. [20]

28. Since the proposal for a directive concerning parallel imports of proprietary

19 — Judgment in Case 104/75 *De Peijper*, cited above, paragraph 10, my emphasis.

20 — Judgment in Case 104/75, paragraphs 2 and 3 of the operative part.

medicinal products [21] had not yet been submitted to the Council, [22] that judgment gave rise to a Commission communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted. [23] In that communication the Commission accepts that importing Member States may check that a proprietary medicinal product that has been imported in parallel is in fact covered by the marketing authorization already granted. For that purpose the competent authorities may require the parallel importer to supply certain information readily accessible to him, for example the name and permanent address of the person responsible for placing the product on the market in the Member State concerned, and any other information useful for the marketing of the proprietary medicinal product in question, such as its composition, therapeutic indications, side effects and specimens. It also states that where the competent authorities have at their disposal all the information submitted by an authorized importer or by the manufacturer, submitted when a previous application for a marketing authorization for the same product was made, they are entitled to require the manufacturer, or his duly appointed importer, to state whether several variants of the same medicinal product have been manufactured and whether those variants show that there are differences having a notable therapeutic effect which would justify treating those variants as different medicinal products.

29. That communication is in no way binding and only the Federal Republic of Germany, the Kingdom of the Netherlands, the United Kingdom and the Kingdom of Denmark instituted a simplified registration procedure, based on the principles of that communication, for medicinal products imported in parallel.

The national legislation at issue

30. Concomitant with the ordinary legal rules governing the grant of marketing authorizations for medicinal products for human use, the United Kingdom legislation establishes a special procedure which relates only to marketing authorizations for medicinal products which have been imported in parallel. Those rules are directly based on the Commission's communication.

31. The Medicines Act 1968 contains general provisions concerning the licensing authority (the Medicines Control Agency, hereinafter 'the MCA') and lays down the procedure to be followed regarding the grant of a marketing authorization ('product licence') for a proprietary medicinal product for human use. Section 19(1) provides that the competent authority shall take into account the safety, efficacy and the quality of the medicinal product concerned when granting a marketing authorization. In order to determine the quality of the product, that authority examines its characteristics and the method of its manufacture.

21 — OJ 1980 C 143, p. 8.

22 — For the reasons for withdrawing the proposal in question, see paragraphs 4 and 5 of the Commission communication on parallel imports of proprietary medicinal products, cited above.

23 — Ibid.

32. Applications for marketing authorizations for parallel imports of medicinal products are examined according to a specific procedure, which is generally quicker and requires less supporting information, as laid down in a document published by the MCA. That document bears the reference MAL 2 (PI). [24]

33. The MAL 2 (PI) document lays down the conditions which must be satisfied for an application to be taken into consideration under the authorization procedures for a product which has been imported in parallel and states that if any of the conditions are not satisfied the application will be rejected.

34. Product Y at issue must satisfy the following conditions:

It must be

'(a) a product which is to be imported from a Member State of the European Community;

(b) a proprietary medicinal product (as defined in Article 1 of EC Directive 65/65) for human use which is not a vaccine, toxin, serum or based on human blood, a blood constituent, or a radioactive isotope, or homeopathic product, as specified in Article 34 of EC Directive 75/319/EEC;

(c) covered by a currently valid marketing authorization granted, in accordance with Article 3 of EC Directive 65/65, by the regulatory authority of an EC Member State;

(d) either have no differences, having therapeutic effect, from a product covered by a UK product licence (PL) or be identical to a product covered by a UK product licence of right (PLR) (except for solid dose preparations where differences in colour, marking and size unlikely to have any therapeutic effect may also be acceptable);

(e) made by, or under licence to:

(i) the manufacturer who made the product covered by the UK product licence; or

(ii) a member of the same group of companies as the manufacturer who made the products covered by the UK product licence.' [25]

24 — Entitled 'Notes on application for Product Licences (Parallel Importing) (Medicines for human use)'.

25 — Order for reference, paragraph 5.

35. The compatibility of those provisions with Community law was raised in legal proceedings between Smith & Nephew Pharmaceuticals Ltd (hereinafter 'S & N') and Primecrown Ltd (hereinafter 'Primecrown').

Facts

36. S & N is a pharmaceutical undertaking whose research is concentrated on two main areas of medicine: the treatment of major burns and incontinence.

37. In May 1982 S & N concluded an agreement with Marion Laboratories Inc. (hereinafter 'Marion'), an American company, for the marketing in the United Kingdom and certain other territories of Ditropan, which has been marketed in the United States since 1975. Ditropan is a medicinal product which contains an active ingredient oxbutynin hydrochloride used for the treatment of some forms of urinary incontinence.

38. In October 1982 S & N submitted an application for a clinical trial licence for Ditropan in the United Kingdom, which was followed by an application for a marketing authorization. Those applications were made on the basis of the data and other information supplied to S & N by Marion. Since the MCA considered that information to be insufficient to convince it of the safety and therapeutic efficacy of Ditropan [26] it did not grant a marketing authorization.

39. According to the case documents, S & N amended the formulation of the drug from that produced in the United States by Marion Merrell Dow ('MMD'), the owner of the trademark Ditropan.

'The product had already been on the market since 1975 in the United States, i.e. some considerable time before S & N made its application. *S & N also however had to change the formulation of the drug from that which had been manufactured by MMD in the US.*' [27]

40. It was only in January 1991 that a marketing authorization for Ditropan was granted to S & N by the MCA. S & N markets the product in the United Kingdom and has it manufactured by Boots Pharmaceuticals Ltd. I will call that 'product X'.

41. On 8 October 1992 Primecrown submitted an application for a parallel importing product licence to permit it to sell in the

26 — Certain specific concerns had to be addressed. For example, the lack of cancer-causing potential of the product had to be demonstrated, notwithstanding that S & N had supplied American data on that question.

27 — Order for reference, paragraph 9, my emphasis.

United Kingdom a product called Ditropan which had been authorized for sale in France since 1984. However, the MCA informed it that its application would be rejected if the French product had not been manufactured by S & N or by a member of the same group of companies as S & N, the manufacturer of the product X covered by the United Kingdom licence, or else under licence from S & N or a member of the same group of companies as S & N, whereupon Primecrown withdrew its application.

42. On 22 February 1993 Primecrown made a further application for a product licence (parallel importing), this time to sell in the United Kingdom Ditropan put on the market in Belgium pursuant to a 1986 Belgian marketing authorization. I shall call this product 'product Y'.

43. The pharmaceutical assessor chosen by the MCA concluded that the Belgian Ditropan had the same composition as the Ditropan of S & N [28] and erroneously found that there was a link between S & N and MMD Belgium, the holder of the Belgian authorization. On the basis of that information, on 24 August 1993 the MCA granted Primecrown a licence for the Belgian Ditropan and informed S & N of that fact.

44. Subsequently, the MCA established that there was no link between S & N and MMD Belgium, and on 29 September 1993 it annulled the licence erroneously granted and notified S & N of that new decision.

45. Those are the circumstances in which two cases concerning the marketing of the Belgian Ditropan were brought before the High Court of Justice in London.

46. In the first case, Primecrown brought an action for an order quashing the MCA's decision of 29 September 1993 to revoke the licence granted to it and applied for interim relief. Holding that S & N was not 'a person to whom the decision relates', the judge hearing the application did not allow S & N to intervene at the hearing of the application for interim relief.

47. In the second case, S & N made an application to have set aside the MCA's decision of 24 August 1993 to grant to Primecrown a product licence for the United Kingdom in respect of product Y.

48. S & N disputes the lawfulness of the grant of a product licence to Primecrown. It relies on two submissions: first, product Y is not manufactured by, or under licence from, S & N, the manufacturer of the product X covered by the United Kingdom licence; secondly, the MCA misused its file which had enabled it to obtain the product licence for product X in January 1991.

28 — Ibid., paragraph 12.

49. Primecrown submits that the MCA wrongly suspended the decision to grant it a product licence for medicinal product Y. It claims that the requirement for there to be a link to the same manufacturer or a member of the same group of companies as the manufacturer who obtained the product licence in Member State A, laid down by the United Kingdom rules, [29] is incompatible with the Community rules.

50. Being unsure as to the compatibility of the requirements laid down by paragraph (e) of the MAL 2 (PI) document with Community law, the High Court, Queen's Bench Division, ordered that the applications submitted by S & N and by Primecrown should be stayed until the Court of Justice has given a preliminary ruling pursuant to Article 177 of the EC Treaty.

The questions referred

51. The Court is requested to give a preliminary ruling on the following questions:

'(1) Is an undertaking which 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

29 — Paragraph (e) of the MAL 2 (PI) document.

(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?'

52. As regards the first question, the national court is asking in substance whether, in the circumstances of the present case, S & N may invoke the direct effect of Article 5 of Directive 65/65 in order to challenge the marketing authorization issued on 24 August 1993 to Primecrown by the MCA. The national court's other questions essentially concern the requirements of Community law concerning the grant or withdrawal of a marketing authorization for a medicinal product which has been imported in parallel.

The first question

53. The question is whether Article 5 of Directive 65/65 has direct effect.

54. It is established since the judgment in *Enka* v *Inspecteur der Invoerrechten en Accijnzen* [30] that '... where the Community authorities have, by directive, imposed on Member States the obligation to pursue a particular course of conduct, the effectiveness of such an act would be weakened if individuals were prevented from relying on it before their national courts and if the latter were prevented from taking it into consideration as an element of Community law.' [31] That is especially so 'when the individual invokes a provision of a directive before a national court in order that the latter shall rule whether the competent national authorities, in exercising the choice which is left to them as to the form and the methods for

30 — Judgment in Case 38/77 [1977] ECR 2203.

31 — Ibid., paragraph 9.

implementing the directive, have kept within the limits of their discretion as set out in the directive'. [32]

55. The conditions which the Court of Justice applies in order to assess whether a provision of a directive is endowed with direct effect are that the provision relied on must be unconditional and sufficiently precise. [33]

56. Let us therefore examine whether the provisions of Directive 65/65 concerning the right of the holder of a marketing authorization for product X to challenge the validity of a marketing authorization granted to a third-party parallel importer of a product Y which is similar to product X are unconditional and sufficiently precise.

57. S & N claims that the competent authority was not entitled to use the file which it had produced to the MCA with a view to obtaining its marketing authorization for medicinal product X in order to establish whether product Y imported by Primecrown was similar to its own product and thereby grant a marketing authorization for product Y. Since point 8 of the second paragraph of Article 4 of Directive 65/65 has granted its specific rights over those documents, it is reasonable for it to be able to defend those rights before the courts.

58. It should be remembered that Article 5 of the directive provides that:

'The authorization provided for in Article 3 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 or 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.'

59. Point 8(a)(i) of the second paragraph of Article 4, as amended by Directive 87/21, provides that an applicant for a marketing authorization shall not be required to provide the results of certain tests only if 'the proprietary medicinal product is essentially similar to a product authorized in the country concerned by the application and ... *the person responsible for the marketing of the original proprietary medicinal product has consented* to the pharmacological, toxicological or clinical references contained in the file on the original proprietary medicinal product being used for the purpose of examining the application in question'.

32 — Ibid., paragraph 10.

33 — Judgment in Case 8/81 *Becker* v *Finanzamt Muenster-Innenstadt* [1982] ECR 53, paragraph 25.

60. The Commission considers that S & N could rely directly on Article 5 of Directive 65/65 only if the MCA dealt with Primecrown's application in accordance with the abridged procedure. Except in that case, its right as an innovative firm is not recognized. Since the case is not one of an application examined under the harmonized abridged procedure but one concerning the simplified procedure for parallel imports, S & N's application must be unsuccessful.

61. I do not consider that it is necessary to follow the Commission's line of reasoning. The right of an innovative firm has been specially recognized and protected by the Community legislature. The Court enshrined that right in its recent judgment in Case C-440/93 *Scotia Pharmaceuticals*. [34] Such Community rules would be deprived of their practical effect if the occurrence of parallel importation — for which the rules are not harmonized — led a competent authority to issue a marketing authorization in disregard of the right of an innovative firm. Moreover, it is clear that under Directive 87/21 only certain information in the file of the innovative firm may — *subject to certain conditions* — be used by a subsequent applicant. If parallel importation meant that the subsequent applicant was exempted from the need to observe those rules, the rights of the innovative firm would be even more seriously impaired, since, in that case, it is the whole of its file which is used and not merely certain documents.

62. However, in order for S & N to be entitled to rely on the direct effect of Article 5, three conditions must be satisfied: [35]

(1) S & N must be an innovative firm;

(2) The MCA must have used its file without its consent in order to authorize the marketing of medicinal product Y;

(3) Medicinal product Y must be a generic product.

63. *As regards the first condition*, it is necessary to establish whether S & N is an innovative firm. In other words, it is necessary to assess whether the two Ditropan products, X and Y, are merely identical or similar versions of the Ditropan manufactured in the United States by MMD, or whether the product X manufactured by S & N is innovative in relation to the product Y manufactured by the Belgian firm. Only the national court is competent to appraise those facts.

34 — Cited above.

35 — See my Opinion in the *Scotia Pharmaceuticals* case, cited above, point 24 et seq.

64. It is certainly not for the Court of Justice to assess whether or not an undertaking is innovative. However, I consider that a Community definition of that term must be given, since it has specific legal consequences, in particular in regard to Directive 87/21. Consequently, it is not a matter for appraisal by the national courts alone without review by the Court of Justice, since such review is necessary to prevent a risk of differing interpretations of that Community concept.

65. As far as I am aware, no Community definition has been given, not even at the hearing at which the question was expressly raised. In its Explanatory Memorandum concerning the proposal for Directive 87/21, [36] the Commission referred to the concept in this way.

'This practice seriously penalizes the innovatory firm which has had to meet the high cost of clinical trials and animal experiments, while its product can be copied at lower cost and sometimes within a very short period. Protection of a medicinal innovation by means of a patent is not in fact always possible or effective, as, for example, in the case of a natural substance or of a substance which is already known but on which additional research has been carried out with a view to *a new therapeutic use*.'

'The proposed amendment of Article 4(8) of Directive 65/65/EEC is intended to re-establish the normal principle for exemption, i.e. that according to which the innovative firm consents to the second applicant referring to the tests described in the dossier of the original medicine.'

'Where the innovatory producer does not give its consent or if the bibliographical evidence cannot be adduced, it appeared advisable to insert a clause not permitting the second applicant to submit an application in simplified form in respect of a copy of a medicine until ten years have elapsed following the authorization of the original medicinal product in the country concerned by the application. This ten-year period will enable the partial recovery of the *research investment*, which might not be protected otherwise, for example by a patent.' [37]

66. It may accordingly be said that an innovative medicinal product is not necessarily covered by a patent. But the Community legislature intends to grant a right of protection to innovative products which cannot be protected by a patent.

36 — Cited in footnote 12 above.

37 — Paragraphs 14 and 15, my emphasis.

67. My view is confirmed by a reading of the second recital in the preamble to Directive 87/21 which provides that:

'... experience has shown that it is advisable to stipulate more precisely the cases in which the results of pharmacological and toxicological tests or clinical trials do not have to be provided with a view to obtaining authorization for a *proprietary medicinal product which is essentially similar* to an authorized product, while *ensuring that innovative firms are not placed at a disadvantage*', [38]

and of point 8 of the second paragraph of Article 4 of Directive 65/65, as amended by Directive 87/21, which provides that:

'However, and *without prejudice to the law relating to the protection of industrial and commercial property* ...'. [39]

68. So, the Community legislature does make it clear that the right which it wishes to grant the innovative firm in Directive 87/21 must not be confused with the specific rights recognized by way of protection of commercial and industrial property. Directive 87/21 aims to safeguard the rights of the innovative firm over and above the commercial and industrial rights which it otherwise holds (that is to say patent and trademark rights).

69. On the basis of those few indications, I propose that the Court should define an innovative product for the purposes of Directive 87/21 as a product whose composition, therapeutic indication, manufacture or method of administration is characterized by significant innovation.

70. This may be so in the case of:

— a medicinal product whose new method of administration constitutes a significant innovation;

— a medicinal product which, having entirely new indications, is therefore of therapeutic significance;

— a medicinal product whose manufacture is based on processes which display a significant technical advance.

38 — My emphasis.

39 — My emphasis.

71. In order for S & N to be characterized as an innovative undertaking in the manufacture of the Ditropan authorized for sale in 1991, its research would have to have resulted in the discovery of a new medicinal product according to the criteria which I have defined above. However, it is not for the Court of Justice to take the place of the national court on this point, particularly as the order for reference is contradictory in some respects.

72. According to the documents before the Court, there are:

— licence agreements between the American company, MMD, and S & N, and between MMD and the Belgian company,

— an identical therapeutic indication between those products marketed in Belgium, in the United Kingdom and in the United States,

— no complaints about the trademark of product X being identical to both product Y and the Ditropan manufactured in the United States, which might give rise to confusion in the minds of consumers.

73. As regards medicinal products X and Y, we therefore have two similar versions of the same product, which seems to be confirmed by the MCA's expert. [40] Since the Belgian marketing authorization for product Y was obtained in 1986, therefore before the United Kingdom marketing authorization for product X, medicinal product Y could not be a copy of medicinal product X.

74. On the other hand, at the hearing the representative of the United Kingdom indicated that he regarded S & N as the innovative firm in the development of product X.

75. That seems to be confirmed, firstly, by a letter from a Mr Boyd of the MMD, who states:

'Although the Ditropan product specifications in Belgium are known and controlled by Marion Merrell Dow this is not true for the Ditropan product specifications in the UK where the product is licensed to Smith & Nephew Ltd. Smith & Nephew is a separate legal entity from the MMD group of companies. Marion Merrell Dow merely provides the oxybutynin chloride drug substance to Smith & Nephew. As such *it is not possible to confirm that the product specifications of Ditropan manufactured in Belgium*

40 — See the order for reference, paragraph 12.

are identical to those of the product manufactured in the UK by Smith & Nephew.' [41]

76. *Secondly*, that also seems to be confirmed by the order for reference which states: 'S & N also however had to change the formulation of the drug ...'. [42]

77. In view of the contradictions I have pointed out, I submit that the Court should refer to the court seized of the main proceedings the matter of determining, having regard to the results of the experts' reports produced by (or at the request of) the parties to the main proceedings, whether the United Kingdom Ditropan product is innovative.

78. Assuming that S & N is an innovative firm, *a second condition* must be satisfied in order for its reliance on the direct effect of Article 5 of Directive 65/65 to be successful. The MCA must have used its file in granting a marketing authorization to Primecrown.

79. That point is hardly in dispute. At the hearing the representative of the United Kingdom accepted it in explaining that the requirement for a legal link between the manufacturer of product X and of product Y thereby enables an infringement of the rights of the innovatory firm to be avoided; the file which the innovative firm previously placed at its disposition is used by the MCA to grant a marketing authorization to the parallel importer only if that link exists.

80. *Thirdly*, the medicinal product for which Primecrown is applying a marketing authorization must be a generic medicinal product, namely a copy of the medicinal product manufactured by S & N.

81. S & N claims that the two products are different, relying on the letter from Mr Boyd. [43] Primecrown disputes this, claiming that not only is S & N not innovative but, moreover, the two products X and Y are identical and both stem from research carried out by MMD USA. Medicinal product Y is not therefore a generic of an innovative medicinal product X.

82. However, since a proper reply to that question cannot usefully be given without an evaluation of the facts contained in the experts' documents, the Court can only remit that question to the court hearing the substantive proceedings for an answer.

41 — Order for reference, paragraph 15, my emphasis.

42 — Ibid., paragraph 9.

43 — Point 75 of this Opinion.

83. In conclusion, I consider that the Court should state that S & N is entitled to rely on Article 5 of Directive 65/65 before a national court in order to challenge the validity of a marketing authorization granted to a competitor for a proprietary medicinal product bearing the same name ('product Y') only if:

— that authorization was granted on the basis of data contained in its file submitted to the MCA in order to obtain the marketing authorization for medicinal product X in January 1991;

— product X manufactured by or under the control of S & N is innovative;

— medicinal product Y is a copy of medicinal product X manufactured by S & N.

84. It is for the court hearing the substantive proceedings to assess whether or not those conditions are satisfied, having regard to the results of the experts' report prepared by (or at the request of) the parties to the main proceedings.

85. If those conditions are not satisfied, S & N could derive no right from Directive 65/65 to contest the authorization issued to Primecrown.

86. To accept the contrary would undermine the aim of that Community legislation which is also to bring about the free movement of goods between Member States. For any trader is bound to oppose a competitor's entry onto the market.

87. Moreover, to allow S & N to rely on the directive for that purpose would amount to conferring horizontal direct effect on that directive. The Court has always set its face against this: 'The effect of extending that case-law to the sphere of relations between individuals would be to recognize a power in the Community to enact obligations for individuals with immediate effect, whereas it has competence to do so only where it is empowered to adopt regulations'. [44]

The second question

88. Where the existence of a link to the same company or to the same group of companies as the company which manufactures medicinal product X led to the grant of the marketing authorization in Member State A, is it necessary for the grant of a marketing authorization for medicinal product Y? In other words, may a marketing authorization for medicinal product Y be refused (or withdrawn) when that condition is not satisfied?

44 — Judgment in Case C-91/92 *Faccini Dori* v *Recreb* [1994] ECR I-3325, paragraph 24.

89. The procedures for issuing marketing authorizations in the case of imports have not been harmonized. [45] It must therefore be examined whether that measure is compatible with Article 36 of the Treaty.

The Court has consistently held that:

'... Article 36 of the Treaty remains applicable as regards the manufacture and marketing of proprietary medicinal products as long as harmonization of national rules has not been fully achieved in that field (see the judgments in Case 215/87 *Schumacher* [1989] ECR 617, paragraph 15; Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 48; Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747, paragraph 26; Case C-62/90 *Commission* v *Germany* [1992] ECR I-2575, paragraph 10; and Case C-317/92 *Commission* v *Germany* [1994] ECR I-2039, paragraph 14)'. [46]

90. Under Article 36 of the Treaty, legislation or a national practice which has, or is likely to have, a restrictive effect on imports of pharmaceutical products is compatible with the Treaty only in so far as it is necessary for the effective protection of the health and life of humans or industrial and commercial property. However, Article 36 also provides that 'such ... restrictions shall not ... constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.

91. The representative of the United Kingdom justifies that condition by referring to the *ratio legis* of Directive 87/21. It is, it says, intended to safeguard the rights of the innovative firm.

92. When examining the first question I set out the circumstances in which the interests of the innovative firm might legitimately be protected. [47] Furthermore, the primary purpose of the Community rules on medicinal products is always the protection of public health and the completion of the single market. Consequently, in protecting legitimate economic interests, the Member States must ensure that the measures adopted restrict Community trade as little as possible. [48]

93. Because of its general, absolute and automatic nature, the national provision at issue prevents similar medicinal products already authorized in the country of importation and of exportation from being imported *even when the interests of the innovative firm are not affected.* Since measures less restrictive of Community trade and just as effective could

45 — See point 22 of this Opinion.

46 — Judgment in Case C-320/93 *Ortscheit* [1994] ECR I-5243, paragraph 14.

47 — In particular, point 62 of this Opinion.

48 — To that effect, see the judgment in Case 247/81 *Commission* v *Germany* [1984] ECR 1111, paragraphs 11 to 13.

most certainly be adopted, it must be held that such a provision cannot benefit from the derogation provided for in Article 36 of the Treaty.

The third question

94. In its third question, the national court asks about the information concerning product Y imported in parallel from Member State B which Member State A must require [Question 3(a) and (b)].

95. Since marketing authorizations for medicinal products which have been imported in parallel have not been made the subject of harmonized rules, [49] the Member States alone have the power — provided that the fundamental principles laid down by the Treaty are observed and having due regard to the aims pursued by the Community legislature in its rules concerning marketing authorizations for medicinal products for human use — to lay down the rules which are to apply in that regard. [50]

96. The Court has consistently observed that: 'The spirit of cooperation which must prevail in preliminary ruling proceedings requires the national court to have regard to the function entrusted to the Court of Justice, which is to contribute to the administration of justice in the Member States and not to give opinions on general or hypothetical questions (judgments in Case 149/82 *Robards* v *Insurance Officer* [1983] ECR 171 and in Case C-83/91 *Meilicke* v *ADV/ORGA* [1992] ECR I-4871, paragraph 25)'; [51] *a fortiori* the Court may not go into a national legislature's domain by positively laying down conditions for the issue of a marketing authorization. I do not therefore propose answering these points.

97. In its third question the national court also asks whether, faced with an application for a marketing authorization for product Y which has been imported in parallel, the competent authority of Member State A may:

— take into account information supplied by the holder of the marketing authorization for product X, where the period laid down by Article 4.8 of Directive 65/65 (as amended) has not expired;

— grant a marketing authorization for product Y (which is to be imported) when the licensing authority has not compared the actual manufacturing processes of product Y with those of product X.

98. In view of the aims pursued by the Community legislature with regard to medicinal products for human use [52] I consider that the competent authority of Member State A may take into consideration the

49 — Point 22 of this Opinion.

50 — Judgment in Case C-320/93 *Ortscheit*, cited above, paragraphs 16 to 18.

51 — Judgment in Case C-412/93 *Leclerc-Siplec* v *TF1 Publicité and M6 Publicité* [1995] ECR I-179, paragraph 12.

52 — Point 2 et seq. of this Opinion.

information supplied by the holder of the marketing authorization for product X, unless the interests specifically protected by Directive 87/21 are affected. [53]

99. As regards the problem of comparing the actual manufacturing processes, it should be recalled that the primary aim of the Community rules on marketing authorizations for medicinal products for human use is to ensure the protection of public health.

100. In relation to a marketing authorization dealt with under the abridged procedure provided for by Directive 87/21, the Court has recently held that: 'The abridged procedure in no way relaxes the requirements of safety and efficacy which must be met by medicinal products ...'. [54]

101. I submit that the Court's position should be no different where the procedure in question is one involving the parallel import of medicinal products, and I do so for the following reasons.

102. One of the documents which must accompany any application for a marketing authorization for medicinal products is a 'brief description of the method of preparation'. [55] The Standards and Protocols Directive harmonizes the minimum requirements which that description must contain. [56]

Directive 75/319 provides that the duties of the qualified experts are to check the proper performance of that obligation [57] subject to the control of the competent authorities. [58]

103. The control of the method of manufacture of a medicinal product is an important and mandatory step in the procedure for examining applications for marketing authorizations. It is a mandatory requirement whatever kind of procedure is followed (normal or abridged).

104. I have also indicated that innovation may consist in a product manufactured according to processes which represent a significant technical advance. [59]

105. Let us imagine a case where a product Y displays that characteristic and a product X authorized in Member State A does not do so. On grounds related to the protection of health and life of humans, Member State A would be entitled to refuse approval of medicinal product Y manufactured under a new process which it had not yet recognized, and such a decision would be in conformity with the case-law of the Court of Justice.

106. The Court has held that: 'Member States are entitled, at the present stage of harmonization and in the absence of a procedure for Community authorization or

53 — As regards that issue, see point 61 et seq. of this Opinion.

54 — Judgment in *Scotia Pharmaceuticals*, cited above, paragraph 17.

55 — Article 4, point 4, of Directive 65/65.

56 — Point B of Part 1 of the Annex to Directive 75/318.

57 — Article 2 of Directive 75/319.

58 — Ibid., Article 4.

59 — Point 70 of this Opinion.

mutual recognition of national authorizations, to prohibit entirely the marketing in their territory of medicinal products which have not been authorized by the competent national authorities'. [60] The Court justified that ruling on the grounds that: '... it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they intend to ensure [for health and life of humans]'. [61]

107. Moreover, it should be noted that in its judgment in the *De Peijper* case, cited above, the Court took account of that factor when verifying the similarity of products X and Y. [62]

108. Consequently, it should be held that a comparison of the method of manufacturing medicinal product X with the method of manufacturing medicinal product Y is necessary.

The fourth question

109. The national court asks whether the fact that the holders of the marketing authorizations for product X and product Y in Member State A and Member State B respectively are both licensees of the same licensor who is situated outside the European Community affects the answer to Questions 2 and 3.

110. Where medicinal products X and Y have been lawfully placed on the market in a Member State, in accordance with the rules laid down by Directive 65/65, the fact that the licensor is situated outside the European Community does not affect the answers to be given to the second and third questions.

Conclusion

111. I therefore propose that the Court should reply as follows to the questions submitted to it by the High Court of Justice, Queen's Bench Division, for a preliminary ruling:

(1) In circumstances such as those in the main proceedings, an undertaking that holds a marketing authorization in respect of a branded medicinal product

60 — Judgment in Case C-320/93 *Ortscheit*, cited above, paragraph 18.

61 — Ibid., paragraph 16.

62 — Cited above, paragraph 10, first subparagraph.

('product X'), such authorization having been granted in accordance with the procedures laid down by 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, by the licensing authority in the Member State of importation ('Member State A'), is entitled to rely on Directive 65/65, and in particular Article 5 thereof, before a national court in order to challenge the validity of a marketing authorization granted by the competent authority in Member State A to a competitor in respect of a proprietary medicinal product ('product Y') only if that authorization was granted on the basis of the file which enabled it to obtain the marketing authorization for product X and if product X is innovative and product Y is a copy of product X. In any event, it is for the national court to assess whether those conditions are satisfied.

(2) Article 36 of the EC Treaty does not preclude the licensing authority in Member State A from issuing a marketing authorization in respect of product Y which is sought to be imported from Member State B, where product Y is not made by, or under the control of, the person holding the marketing authorization in Member State A or by, or under the control of, a member of the same group of companies which holds such an authorization.

(3) Faced with an application for a marketing authorization for a product Y which has been imported in parallel, the licensing authority of Member State A:

— may take into consideration the information supplied by the holder of the marketing authorization for product X, unless the interests specifically protected by Council Directive 87/21/EEC of 22 December 1986, amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, are affected,

— must compare the actual manufacturing processes of product Y with those of product X.

(4) where products X and Y have been lawfully placed on the market in a Member State in accordance with the rules laid down by Directive 65/65, the fact that the licensor is situated outside the European Community does not affect the answers to Questions 2 and 3.