JUDGMENT OF THE COURT (Fifth Chamber)
21 March 1991 *

In Case C-60/89,

REFERENCE to the Court under Article 177 of the EEC Treaty by the Seventh Criminal Chamber of the Cour d'Appel, Aix-en-Provence, France, for a preliminary ruling in the criminal proceedings pending before that court against

Jean Monteil, Saint-Etienne, France,

Daniel Samanni, Auxerre, France,

on the interpretation of the concept of medicinal product and its definition in Community law,

THE COURT (Fifth Chamber),

composed of: J. C. Moitinho de Almeida, President of the Chamber, G. C. Rodríguez Iglesias, Sir Gordon Slynn, F. Grévisse and M. Zuleeg, Judges,

Advocate General: G. Tesauro,
Registrar: H. A. Rühl, Principal Administrator,

after considering the written observations submitted on behalf of

Daniel Samanni and Jean Monteil, by Jean-Claude Fourgoux, of the Paris Bar,

the Italian Government, by Pier Giorgio Ferri, Avvocato dello Stato, acting as Agent,

* Language of the case: French.

the Commission of the European Communities, by Blanca Rodríguez Galindo, a member of the Commission's Legal Department, and Hervé Lehman, a French official seconded to the Commission, acting as Agents,

having regard to the Report for the Hearing,

after hearing oral argument presented by Messrs Samanni and Monteil, by the Syndicat des Pharmaciens des Bouches-du-Rhône (Pharmacists' Association of the *département* of Bouches-du-Rhône), the civil party claiming damages, represented by Bruno Celice, Avocat with the right of audience before the French Cour de Cassation and Conseil d'Etat, the French Government, represented by Hélène Duchène, Secretary for Foreign Affairs at the Ministry of Foreign Affairs, acting as Agent, and the Commission, at the sitting on 24 October 1990,

after hearing the Opinion of the Advocate General at the sitting on 16 January 1991,

gives the following

Judgment

1 By judgment of 7 November 1988, which was received at the Court Registry on 1 March 1989, the Cour d'Appel, Aix-en-Provence, referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty a question on the interpretation of the concept of medicinal product and its definition in Community law.

2 The question was raised in criminal proceedings for the illegal practice of the profession of pharmacy and complicity therein brought respectively against Daniel Samanni, for selling in the 'Casino' shop of which he was the manager eosin of a strength of 2% and modified alcohol of a strength of 70%, and against Jean Monteil, as purchasing manager of the 'Casino' group, for supplying the first of those two products.

3 Considering that those products must be regarded as medicinal products, the right to sell which is reserved to dispensing pharmacists by Article L.512 of the French Code de la Santé, the Syndicat des Pharmaciens des Bouches-du-Rhône joined the proceedings as a civil party claiming damages from the defendants.

4 On 14 June 1988, Messrs Samanni and Monteil were each fined FF 8 000 by the Tribunal Correctionnel (Criminal Court), Marseilles, and ordered to pay FF 1 in damages and FF 2 000 pursuant to Article 475.1 of the Code of Criminal Procedure; they appealed against that judgment to the Cour d'Appel, Aix-en-Provence, contending that neither eosin of a strength of 2% nor alcohol of a strength of 70% could be regarded as a medicinal product under Article L.511 of the Code de la Santé Publique or Article 1 of Directive 65/65 of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (Official Journal, English Special Edition 1965-1966, p. 20).

5 The national court then referred the following question to the Court of Justice for a preliminary ruling:

'Are eosin of a strength of 2% and modified alcohol of a strength of 70% medicinal products the right to sell which is reserved to pharmacists, as defined by European Community law?'

6 Reference is made to the Report for the Hearing for a fuller account of the facts of the case, the course of the procedure and the written observations submitted to the Court, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court.

7 The question submitted by the national court raises two issues. The first is whether products like eosin of a strength of 2% and modified alcohol of a strength of 70% fall within the Community definition of medicinal products given in Directive 65/65. The second seeks to determine to what extent Community law allows the domestic legislation of a Member State to reserve to pharmacists the right to sell medicinal products.

The classification of eosin of a strength of 2% and modified alcohol of a strength of 70%

8 It follows from the documents before the Court and the oral argument presented to it that the classification of the two products in question must be examined in the

light both of Directive 65/65 and of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (Official Journal 1976 L 262, p. 169).

9 Directive 65/65, which has been amended on several occasions, defines a proprietary medicinal product as 'any ready-prepared medicinal product placed on the market under a special name and in a special pack'.

10 Pursuant to the first subparagraph of Article 1(2) of Directive 65/65, a medicinal product is 'any substance or combination of substances presented for treating or preventing disease in human beings or animals', and according to the second subparagraph 'any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals' is likewise regarded as a medicinal product.

11 The directive thus gives two definitions of medicinal products: a definition of medicinal products 'by virtue of their presentation' and a definition of medicinal products 'by virtue of their function'. A product is a medicinal product if it falls within either of those definitions.

12 It should be added that those two definitions cannot be regarded as strictly distinct from each other. As is stated in paragraph 22 of the judgment in Case 227/82 *Van Bennekom* [1983] ECR 3883, a substance which is endowed with 'properties for treating or preventing disease in human beings or animals' within the meaning of the first Community definition but is not 'presented' as such falls within the scope of the second Community definition of a medicinal product.

13 Article 1(1) of Directive 76/768 defines a cosmetic product as 'any substance or preparation intended for placing in contact with the various external parts of the

human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours'.

14 As is stated in the fifth recital in the preamble to Directive 76/768, which indicates that that directive relates only to cosmetic products and not to pharmaceutical specialities and medicinal products, the rules which it contains relate only to cosmetic products and not to medicinal products.

15 Thus, whilst it is not impossible that, in dubious cases, the definition of a cosmetic product might be considered in conjunction with that of a medicinal product before a product is classified as a medicinal product by virtue of its function, the fact remains that a product which displays the character of a medicinal product or a proprietary medicinal product does not come within the scope of Directive 76/768 and is subject only to Directive 65/65 and the provisions amending it.

16 That conclusion is, moreover, the only one that fulfils the aim of protecting public health pursued by both directives, since the legal rules applicable to proprietary medicinal products are more rigorous than those applicable to cosmetic products, in view of the particular dangers which the former may present to public health and cosmetic products generally do not.

17 In those circumstances, even if it comes within the definition contained in Article 1(1) of Directive 76/768, a product must nevertheless be treated as a 'medicinal product' and be made subject to the corresponding rules if it is presented as possessing properties for the treatment or prevention of illness or disease or if it is intended to be administered with a view to restoring, correcting or modifying physiological functions.

18 It is therefore necessary to consider whether products such as eosin of a strength of 2% and modified alcohol of a strength of 70% fall within the definition of medicinal products.

19 In view of the foregoing observations, certain matters relied on by Messrs Samanni and Monteil to show that the two products in question are within the scope of the directive on cosmetic products cannot be regarded as significant.

20 That applies in particular to the fact that eosin of a strength of 2% and modified alcohol of a strength of 70% are 'applied superficially' to the skin, since medicinal products may also be so applied, and to the indication of precautions for use such as 'Do not swallow' and the fact that those products are not 'intended to be ingested, inhaled, injected or implanted in the human body', since although Directive 76/768 excludes from its scope products that are used in that way it certainly does not bring products within its scope simply because they are used in a different way.

21 However, it is undisputed — and is also stated by Messrs Samanni and Monteil and by the Commission — that eosin of a strength of 2% and modified alcohol of a strength of 70% have antiseptic and antibacterial properties.

22 As the Commission points out, where eosin of a strength of 2% and modified alcohol of a strength of 70% are presented as antiseptic and antibacterial products for the treatment or prevention of infection and lesions of the skin, they come within the definition of medicinal products by virtue of their presentation, within the meaning of Directive 65/65.

23 It must nevertheless be added that according to the judgment in *Van Bennekom*, supra, the concept of 'presentation' of a product must be broadly construed and a product is 'presented for treating or preventing disease' within the meaning of Directive 65/65 not only when it is expressly 'indicated' or 'recommended' as such, possibly by means of labels, leaflets or oral representation, but also whenever

any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, having regard to its presentation, have the properties in question.

24 According to the same judgment, the external form given to the product in question may serve as strong evidence, but is not the sole or conclusive evidence; it must be stated that the 'form' must be taken to mean not only the form of the product itself but also that of its packaging, which may, for reasons of marketing policy, tend to make it resemble a medicinal product, and account must also be taken of the attitude of an averagely well-informed consumer, in whom the form given to a product may inspire particular confidence similar to that normally inspired in him by proprietary medicinal products, having regard to the safeguards normally associated with the manufacture and marketing of the latter type of product.

25 As regards the question whether or not eosin of a strength of 2% and modified alcohol of a strength of 70% must be classified as medicinal products by virtue of their function, the fact that they are antiseptic and antibacterial products is not in itself conclusive. Even if the inquiry is restricted to those products which may help to prevent or treat illness, the range of antiseptic and antibacterial products is still very extensive. It includes both ordinary soaps, which no-one classifies as medicinal products, and powerful antiseptics used in surgery which cannot be classified as anything other than medicinal products.

26 It should be observed that, according to the Member States, eosin of a strength of 2% and modified alcohol of a strength of 70% are known and used to varying extents, are used under diverse conditions and are supplemented by different adjuvants.

27 Although the essential purpose of Directive 65/65 may, as is indicated in the fourth recital in its preamble, be to remove obstacles to trade in proprietary medicinal products within the Community and although for that purpose Article 1 gives a definition of proprietary medicinal products and of medicinal products, it nevertheless constitutes, as is pointed out in the judgment in *Van Bennekom*, supra, merely a first stage in the approximation of national legislation on the production and distribution of pharmaceutical products.

28 At the present stage of development of Community law, it is difficult to avoid the continued existence, for the time being and, doubtless, so long as harmonization of the measures necessary to ensure the protection of health is not more complete, of differences in the classification of products as between Member States.

29 Consequently, it is for the national authorities to determine, subject to review by the courts, whether or not eosin of a strength of 2% and modified alcohol of a strength of 70% constitute medicinal products by virtue of their function within the meaning of the second subparagraph of Article 1(2) of Directive 65/65. In that regard, account must be taken of the adjuvants also entering into the composition of the product, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.

30 It must therefore be stated in reply to the first part of the question submitted by the national court that:

(a) eosin of a strength of 2% and modified alcohol of a strength of 70% are medicinal products within the meaning of the first subparagraph of Article 1(2) 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 when they are presented for treating or preventing disease;

(b) in classifying those products in the light of the second definition of medicinal product given in the second subparagraph of Article 1(2) of Council Directive 65/65/EEC, account must be taken of the adjuvants also entering into the composition of the product, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.

The pharmacists' monopoly

31 It is apparent from the order for reference and from the other documents before the Court that the national court makes a connection between the classification of a product as a medicinal product and its sale exclusively through pharmacies.

32 It is necessary first to recall the aim pursued by the Community rules on medicinal products.

33 The sole purpose of Directive 65/65 and the various directives amending it is to give a Community definition of medicinal products and proprietary medicinal products, with the exception of the proprietary medicinal products mentioned in Article 34 of the second Council directive, Directive 75/319/EEC of 20 May 1975 (Official Journal 1975 L 147, p. 13), in order to determine the scope of the harmonized procedure for marketing authorizations introduced by it with a view to facilitating the free movement of such products.

34 That finding is supported by the preamble to Council Directive 85/432/EEC of 16 September 1985 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy (Official Journal 1985 L 253, p. 34). It states that 'the geographical distribution of pharmacies and the monopoly of the supply of medicinal products continue to be matters for the Member States'.

35 It follows that as Community law stands at present, no harmonization of the rules on the marketing of medicinal products in each Member State having been carried out (judgment in Joined Cases 87/85 and 88/85 *Legia* v *Minister for Health* [1986] ECR 1707), the Member States continue to be empowered to lay down rules on the distribution, in the strict sense of the term, of pharmaceutical products, subject to compliance with the Treaty, in particular the provisions on the free movement of goods.

36 Similarly, the Member States may, subject to the same reservation, impose restrictions on the sale or marketing of products not covered by Directive 65/65, whether they be other medicinal products or substances, pharmaceutical compo-

sitions or other products similar to them (judgments in *Van Bennekom*, supra, and in Case 35/85 *Tissier* [1986] ECR 1207).

37 As the Court has already held, legislation which restricts or prohibits certain forms of advertising and certain means of sales promotion may, although it does not directly affect imports, be such as to restrict their volume because it affects marketing opportunities for the imported products. The possibility cannot be ruled out that to compel a producer either to adopt advertising or sales promotion schemes which differ from one Member State to another or to discontinue a scheme which he considers to be particularly effective may constitute an obstacle to imports even if the legislation in question applies to domestic products and imported products without distinction. That finding applies *a fortiori* when the rules in question deprive the trader concerned of the possibility of using not a means of advertising but a method of marketing whereby he realizes almost all his sales, for example mail order (judgments in Case 286/8 *Oosthoek's Uitgeversmaatschappij* [1982] ECR 4575 and Case 382/87 *Buet* v *Ministère Publique* [1989] ECR 1235).

38 It follows that a monopoly granted to dispensing pharmacists in respect of the marketing of medicinal or other products is capable, in so far as it restricts sales to certain channels, of affecting the possibilities of marketing imported products and may accordingly constitute a measure having an effect equivalent to a quantitative restriction on imports within the meaning of Article 30 of the Treaty.

39 However, a monopoly for pharmacists may be justified by one of the general interests mentioned in Article 36 of the Treaty, which include the protection of health and life of humans. Moreover, since in principle it applies without distinction to domestic and imported products, that monopoly may also be justified on grounds of consumer protection, which, as the Court has held, is one of the imperative requirements which may justify a measure liable to hinder intra-Community trade (judgment in Case 25/88 *Wurmser* [1989] ECR 1105, at paragraph 10).

40 In the absence of harmonization of the rules on the distribution both of medicinal products and of 'para-pharmaceutical' products, it is for the Member States to choose the level to which they wish to ensure the protection of public health.

41 In the case of medicinal products within the meaning of Directive 65/65, account must be taken of the very particular nature of the product and the market involved, which explains the fact that in all the Member States there are, albeit with differences of detail, rules restricting their marketing and, in particular, some form of monopoly on the retail sale of such products is granted to pharmacists by reason of the safeguards which pharmacists must provide and the information which they must be in a position to furnish to the consumer.

42 It must nevertheless be observed that, in the abovementioned part of the preamble to Directive 85/432, the Council refers to and thus acknowledges the existence of a pharmacists' monopoly in the Member States, but does not, in view of the fact that it is not a Community concept, give any definition of it.

43 It follows that although in principle the Member States may reserve to pharmacists the right to make retail sales of products that fall within the Community definition of medicinal products and although, in those circumstances, their monopoly over those products may be presumed to constitute an appropriate way of protecting public health, evidence to the contrary may be produced with respect to certain products whose use would not involve any serious danger to public health and whose inclusion within the pharmacists' monopoly would seem manifestly disproportionate, that is to say contrary to the principles laid down by the Court for the interpretation of Articles 30 to 36 of the Treaty.

44 If pharmacists are granted a monopoly of other products, such as 'para-pharmaceutical' products, which may be of widely varying kinds, the need for such a monopoly in order to protect public health or the health of consumers must, regardless of how the products concerned are classified under national law, be established in each individual case, and those two aims must not be attainable by measures less restrictive of intra-Community trade.

45 It is for the national court to decide, having regard to those criteria, whether the action before it is well founded.

46 It must therefore be stated in reply to the second part of the question submitted by the national court that:

under Community law as it now stands, the determination of the rules governing the distribution of pharmaceutical products remains a matter for the Member States, provided that the provisions of the Treaty, and in particular those relating to the free movement of goods, are respected;

a monopoly of the right to distribute medicinal or other products, granted to dispensing pharmacists, may constitute a barrier to importation;

if a Member State chooses to restrict to pharmacists the right to distribute products of that kind, such a barrier is, in principle and in the absence of any evidence to the contrary, justified in so far as it concerns medicinal products within the meaning of Council Directive 65/65/EEC;

where other products are concerned, however they may be classified in national law, it is for the national court to determine whether a monopoly of the right to market such products granted to pharmacists is necessary for the protection of public health or of consumers and whether those two aims cannot be achieved by measures less restrictive of intra-Community trade.

Costs

47 The costs incurred by the Italian Government and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, in so far as the parties to the main proceedings are concerned, in the nature of a step in the action pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Fifth Chamber),

in answer to the questions referred to it by the Cour d'Appel, Aix-en-Provence, by judgment of 7 November 1988, hereby rules:

(1) (a) Eosin of a strength of 2% and modified alcohol of a strength of 70% are medicinal products within the meaning of the first subparagraph of Article 1(2) 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 when they are presented for treating or preventing disease;

(b) In classifying those products in the light of the second definition of medicinal product given in the second subparagraph of Article 1(2) of Council Directive 65/65/EEC, account must be taken of the adjuvants also entering into the composition of the product, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.

(2) Under Community law as it now stands, the determination of the rules governing the distribution of pharmaceutical products remains a matter for the Member States, provided that the provisions of the Treaty, and in particular those relating to the free movement of goods, are respected.

A monopoly of the right to distribute medicinal or other products, granted to dispensing pharmacists, may constitute a barrier to importation.

If a Member State chooses to restrict to pharmacists the right to distribute products of that kind, such a barrier is, in principle and in the absence of any evidence to the contrary, justified in so far as it concerns medicinal products within the meaning of Council Directive 65/65/EEC.

Where other products are concerned, however they may be classified in national law, it is for the national court to determine whether a monopoly of the right to market such products granted to pharmacists is necessary for the protection of public health or of consumers and whether those two aims cannot be

achieved by measures less restrictive of intra-Community trade.

Moitinho de Almeida Rodríguez Iglesias

Slynn Grévisse Zuleeg

Delivered in open court in Luxembourg on 21 March 1991.

J.-G. Giraud
Registrar

J. C. Moitinho de Almeida
President of the Fifth Chamber