JUDGMENT OF THE COURT
20 May 1992 *

In Case C-290/90,

Commission of the European Communities, represented by Jörn Sack, Legal Adviser, acting as Agent, assisted by Roberto Hayder, official in the Federal Ministry for Economic Affairs of the Federal Republic of Germany, seconded to the Commission's Legal Service under an exchange scheme for national civil servants, with an address for service in Luxembourg at the office of Guido Berardis, of the Commission's Legal Service, Wagner Centre, Kirchberg,

applicant,

v

Federal Republic of Germany, represented by Ernst Röder and Claus-Dieter Quassowski, acting as Agents, with an address for service at the Embassy of the Federal Republic of Germany in Luxembourg, 20-22, Avenue Emile Reuter,

defendant,

APPLICATION for a declaration that, by making the sale of eye lotions imported from a Member State dependent upon authorization to place them on the market as medicinal products under 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 and under the Law on Medicinal Products adopted in implementation of the directive, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EEC Treaty.

* Language of the case: German.

THE COURT,

composed of: O. Due, President, R. Joliet, F. A. Schockweiler and F. Grévisse (Presidents of Chambers), G. F. Mancini, J. C. Moitinho de Almeida, G. C. Rodríguez Iglesias, M. Zuleeg and J. L. Murray, Judges,

Advocate General: W. Van Gerven,
Registrar: D. Triantafyllou, Administrator,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 6 February 1992,

after hearing the Opinion of the Advocate General at the sitting on 13 March 1992,

gives the following

Judgment

1 By application lodged at the Court Registry on 20 September 1990, the Commission of the European Communities brought an action pursuant to Article 169 of the EEC Treaty for a declaration that, by making the sale of eye lotions imported from a Member State dependent upon authorization to place them on the market as medicinal products under 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) and under the Law on Medicinal Products adopted in implementation of the directive, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EEC Treaty.

2 The products which are the subject of the present dispute are eye lotions which may be used as first aid at the workplace to remove from the eyes dust and dangerous chemical substances.

3 These eye lotions may be used when a harmful substance (acid or alkaline) has come into contact with the eye. They neutralize that substance by chemical reaction and eliminate it mechanically — through rinsing.

4 A complaint from a French manufacturer (the Prevor company, whose registered office is in Valmondois) brought to the Commission's attention the fact that the German authorities regard those products, in so far as they are used as eye lotion, as medical products within the meaning of Directive 65/65 and the German Law of 1976 on Medicinal Products. The German authorities accordingly make the sale of those products subject to obtaining authorization to market them as medicinal products.

5 Those eye lotions have been marketed for approximately 15 years in France as well as in other Member States without being subject to prior authorization to place them on the market as medicinal products.

6 Reference is made to the Report for the Hearing for a fuller account of the facts of the case, 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 Commission maintains first of all that the eye lotions in question may not be classified as medicinal products in the light of the Community definition of that concept.

8 According 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, a 'medicinal product' is '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 animals'.

9 That directive thus contains two definitions of the term 'medicinal product', one relating to 'presentation' and the other to 'function'. A product constitutes a medicinal product if it is covered by one or other of those definitions.

10 The German Government relies on the following arguments in support of the view that the lotions in question should be classified as medicinal products according to function:

— they are intended to prevent physical damage from being caused to the eye (corrosion);

— they combat pain and spasms in the eyelid as a result of contact with a chemical irritant;

— they are used inside the eye and not just on the surface; since neutralization of the chemical attacking the eye takes place inside the body, they cannot be merely cleansing agents;

— they stimulate the secretion of lachrymal fluid and therefore modify an organic function;

— given the importance of the organ which they are intended to protect, their effectiveness should be subject to testing in order to ensure that they do in fact afford protection;

— one of those products (Previn) contains ethylenediaminetetraacetic acid (hereinafter referred to as 'EDTA'), which, according to a study referred to by the German Government (Slansky H. et al, 'Prevention of Corneal Ulcers', *Tr. Am. Acad. Ophth. Otol.*, Vol. 75, (Nov-Dec 1971) p. 1208), has a therapeutic effect on corneal ulcers.

11 The German Government considers that the lotions in question are also medicinal products by virtue of their presentation on the ground that, since they are to be used once the eye has been injured, the average well-informed consumer should infer from that that they have prophylactic or therapeutic properties.

12 Against that, the Commission argues that the eye lotions in question have no a therapeutic effect since they only prevent injury by purely mechanical means. The Commission also disputes that the lotions induce tears and work inside the eye. The easing of the pain is the result merely of the neutralization and removal of the irritant substance and not of the action of the lotions *per se*. It disputes that EDTA alone can cure ulcers; the United States study referred to by the German Government ascribes therapeutic properties to EDTA in combination with calcium which is not present in the Previn solution. Those eye lotions cannot therefore constitute medicinal products by virtue of their function.

13 The Commission also maintains that they cannot constitute medicinal products by virtue of their presentation either. It refers in this connection to the packaging of the products in question, the advertising leaflets issued by the manufacturer and the fact that the products are not prescribed by a doctor: they are available in the workplace close to potential risk centres.

14 It should be observed first of all that the two definitions of medicinal products, namely the definition relating to 'presentation' and that relating to 'function', cannot be regarded as strictly separate from one another. 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 which is not 'presented' as such, falls in principle within the scope of the second Community definition of a medicinal product (judgment in Case 227/82 *Van Bennekom* [1983] ECR 3883, paragraph 22).

15 Furthermore, 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 merely a first stage in the approximation of national legislation on the production and distribution of pharmaceutical products.

16 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 (see, most recently, the judgments in Case C-60/89 *Monteil and Samanni* [1991] ECR I-1547, paragraphs 27 and 28, and C-369/88 *Delattre* [1991] ECR I-1487, paragraphs 28 and 29).

17 In those circumstances, and as is clear from the above judgments and the judgment in Case C-112/89 *Upjohn* [1991] ECR I-1703, paragraph 23, it is for the national authorities to determine, subject to review by the courts, for each product, whether or not it constitutes a medicinal product, having regard to all of its characteristics, in particular its composition, its pharmacological properties — as they may be ascertained in the current state of scientific knowledge — the way in which it is used, the extent to which it is sold, its familiarity to consumers and the risks which its use may entail.

18 It is not disputed that the lotions in question are intended for use after a substance has accidentally come into contact with the eye in order to prevent potentially serious consequences and that their ineffectiveness may have harmful consequences.

19 Furthermore, the lotions in question are classified as medicinal products by the Council of Europe's European Pharmacopoeia Commission (under the heading 'Solutiones Ophthalmicæ', January 1991 version).

20 In those circumstances, having regard to the arguments it has put forward, the Commission has not demonstrated that the German authorities have exceeded the bounds of their discretion in classifying the lotions in question as medicinal products.

21 The Commission maintains in the second place that, even if the eye lotions in question could be regarded as medicinal products, the German Government would have committed an act of arbitrary discrimination since it has made them subject to a stricter system of rules than that applied to similar products placed on the domestic market under cover of an authorization allegedly obtained by virtue of a transitional provision of German law.

22 For its part, the German Government maintains that there are no longer any products on the German market which benefit from the transitional system in question and that, accordingly, there can be no discrimination. It adds that the absence of discrimination is corroborated by the fact that the firm manufacturing the lotions in question has never sought an authorization which would have enabled it to benefit from the abovementioned transitional provision.

23 In this connection, suffice it to note that, since no authorization was sought for the eye lotions in question, they cannot be considered to have been discriminated against in relation to products for which authorization was sought.

24 In those circumstances, there is no need to examine the other submissions relied on by the defendant. The application of the Commission must be dismissed as unfounded.

Costs

25 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs. Since the Commission has failed in its submissions, it must be ordered to pay the costs.

On those grounds,

THE COURT

hereby:

1. Dismisses the application;

2. Orders the Commission to pay the costs.

Due Joliet Schockweiler Grévisse Mancini

Moitinho de Almeida Rodríguez Iglesias Zuleeg Murray

Delivered in open court in Luxembourg on 20 May 1992.

J.-G. Giraud — Registrar

O. Due — President