JUDGMENT OF THE COURT (Second Chamber)
20 March 1986 *

In Case 35/85

REFERENCE to the Court under Article 177 of the EEC Treaty by the tribunal de grande instance, Libourne, for a preliminary ruling in the proceedings brought before that court by the

Procureur de la République

against

Gérard Tissier

on the interpretation of 'medicinal product' in Community law,

THE COURT (Second Chamber)

composed of: K. Bahlmann, President of Chamber, O. Due and F. Schockweiler, Judges,

Advocate General: C. O. Lenz
Registrar: J. A. Pompe, Deputy Registrar

after considering the observations submitted on behalf of

the accused in the main proceedings, acting on his own behalf, in the oral procedure,

the French Government, by Gilbert Guillaume, of the Ministry Foreign Affairs, acting as Agent, in the written procedure,

the Commission of the European Communities, by Michel van Ackere, Legal Adviser, acting as Agent,

after hearing the Opinion of the Advocate General delivered at the sitting on 12 December 1985,

gives the following

* Language of the Case: French.

JUDGMENT

(The account of the facts and issues which is contained in the complete text of the judgment is not reproduced)

Decision

1 By a judgment dated 21 December 1984, which was received at the Court on 8 February 1985, the tribunal de grande instance [Regional Court], Libourne, referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty two questions on the interpretation of the term 'medicinal product' and its definition in Community law.

2 The questions were raised in criminal proceedings brought against Gérard Tissier, managing director of the pharmaceutical firm Laboratoires Solabco (formerly Laboratoires Solco-Neclera), for manufacturing and marketing various products which were described as 'reagents' but which met the definition of 'medicinal product' laid down in Article L 511 of the Public Health Code without having obtained from the Ministry of Health the marketing authorizations required by the legislation in force and without having complied with the provisions of that legislation.

3 Article L 511 of the French Public Health Code defines a medicinal product as 'any substance or combination of substances presented for treating or preventing disease in human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying their physiological functions'.

4 Before the national court the accused denied that the products in question met that definition of a medicinal product. He argued that, under the legislation of other countries, particularly European countries, they are not treated as medicinal products either.

5 In those circumstances the national court decided that it was necessary to refer the following questions to the Court:

'Is there any Community legislation concerning the concept and definition of "medicinal product"?'

Does the specific product described as a "reagent" manufactured and marketed by Dr Tissier possibly meet that definition?'

6 By decision of 3 October 1985 the Court assigned the case to the Second Chamber.

7 The French Government and the Commission lodged written observations. The accused in the main proceedings provided explanations at the hearing.

The jurisdiction of the Court of Justice

8 The French Government contends first of all that the Court has no jurisdiction to give a preliminary ruling on the questions submitted to it because they do not raise questions concerning the interpretation of the Treaty or of acts of the Community institutions but a simple question of information. In the past the Court has adopted a strict approach to such questions declaring that it had no jurisdiction to answer them and a similar approach should be adopted in the present case.

9 As far as that point is concerned, it is for the Court, when faced with questions which are not framed in an appropriate manner or which go beyond its functions under Article 177, to extract from all the information provided by the national court, in particular from the grounds of the decision referring the questions, the points of Community law which require interpretation or whose validity is at issue, having regard to the subject-matter of the dispute. In order to provide a satisfactory answer to a national court which has referred a question to it, the Court of Justice may deem it necessary to consider provisions of Community law to which the national court has not referred in the text of its question. However, it is for the national court to decide whether or not the rule of Community law, as interpreted by the Court of Justice pursuant to Article 177, is applicable in the case brought before it.

10 In this case, it is possible to identify from the documents before the Court, especially the reasoning of the judgment making the reference, those aspects involving the interpretation of Community law; consequently, the questions raised by the national court may be understood as inquiring whether a substance which is

used to make a medical diagnosis and which is intended to be administered, not on its own but mixed with other substances, to human beings or animals may be classified as a medicinal product within the meaning of the definition of that term under Community law.

11 The objections that the Court lacks jurisdiction are therefore unfounded.

Substance

12 It appears from the explanations given by the parties that the type of product in question, which is marketed under the name of 'réactif' (reagent), belongs to the category of 'cold products' which form one of two essential constituents of radiopharmaceuticals. Such preparations apparently contain a 'labelled product' composed of radioactive molecules which enable the radioactivity to be measured and a 'cold product' composed of carrier molecules which convey the labelled product to the organ to be studied for the purposes of a medical diagnosis rather than to any other organ.

13 It also appears from the documents before the Court that those two constituents may be mixed before marketing in which case only one product is placed on the market. However, the two preparations may also be sold separately in which case they are not mixed until immediately before being administered by an injection.

14 Radiopharmaceuticals, of which the 'cold' product is a constituent, are used in x-ray radiography or fluoroscopy on the living body.

15 The accused in the main proceedings takes the view that the products in question are not medicinal products in the proper sense of the term since they are not administered directly to human beings. He maintains that it is the radioactive constituent which is used for making the diagnosis and not the carrier as such, which, in chemical terms, is only an inert solution. It is only after a series of chemical modifications that the final product is formed which then constitutes a medicinal product in the proper sense of the term. According to him, those products are sold only to the specialized departments of public hospitals and are not available to the public.

16 The French Government on the other hand observes that the product in question does come within the Community definition of a medicinal product laid down in Article 1 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 (Official Journal, English Special Edition, 1965-1966, p. 20), which corresponds exactly to the above-mentioned definition in the French Code of Public Health.

17 It submits that the Community definition of a medicinal product is sufficiently wide to include a 'cold product' inasmuch as it is a constituent of a product intended for making a medical diagnosis, although it is not administered as it is to human beings or animals. In its view, any other interpretation may create a serious risk for public health by removing 'cold products' and other similar products from quality control.

18 It further observes that in French law, under the decree of 8 September 1982, reagents are subject to a system of control consisting of rules on labelling and the filing of documents before the reagents are marketed whereas medicinal products constituting pharmaceutical preparations are subject to marketing authorization in accordance with Articles 1 and 3 of Directive 65/65/EEC.

19 That view is largely shared by the Commission which submits that, as a general rule, such products are covered not by the first limb of the definition of a medicinal product, which concerns the presentation of the substance or combination of substances, because they are not for treating or preventing disease, but by the second limb, which concerns the applications of the substance or combination of substances inasmuch as they may be used with a view to making a medical diagnosis in human beings or animals. From that point of view, the substances belonging to the category of products opaque to radiation fall within the definition of 'medicinal product' given in that directive.

20 Article 1 of Council Directive 65/65/EEC provides that for the purposes of that directive 'medicinal product' is to mean

'Any substance or combination of substances presented for treating or preventing disease in human beings or animals.'

That article also provides that:

'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 considered a medicinal product.'

21 The same provision provides that any medicinal product is a 'proprietary medicinal product' if it is

'placed on the market under a special name and in a special pack'.

Article 3 of the directive 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 Member State.'

22 In answering the questions raised by the national court it should first be emphasized that, as Community law stands at present, the harmonization of national legislation on medicinal products for human use covers only proprietary medicinal products, that is to say medicinal products placed on the market under a special name and in a special pack. Other medicinal products as well as pharmaceutical substances or combinations of pharmaceutical substances not meeting the Community definition of medicinal product are not therefore subject to controls and do not require prior marketing authorization under the relevant Community rules. Secondly, subject to Article 30 *et seq.* of the Treaty concerning products imported from other Member States, Community law does not affect the right of Member States to subject such substances to controls or to require prior authorization in accordance with their own national law on medicinal products.

23 As indicated above, it is for the tribunal de grande instance to determine whether, even in those circumstances, the interpretation of the Community concept of a medicinal product may still be relevant in the criminal proceedings pending before it. The Court must therefore examine whether a product such as the product forming the subject-matter of those proceedings falls within that Community concept.

24 Although it is established that a product of the type in question is not 'for treating or preventing disease in human beings or animals' within the meaning of the definition of medicinal product given above, it is necessary to determine the scope of the second limb of that definition, concerning substances for making a medical diagnosis, and in particular to examine whether it covers only substances which can be administered as they are to human beings or animals or also substances which are administered only after processing, for example after having been mixed with other substances.

25 In this regard it should be pointed out that, according to the first recital of the preamble to Directive 65/65, 'the primary purpose of any rules concerning the production and distribution of proprietary medicinal products must be to safeguard public health'. Furthermore, according to the third and fourth recitals, the aim of the provisions of the directive is to remove the obstacles to the establishment and the functioning of the common market in the sector in question created by disparities between national provisions relating *inter alia* to medicinal products.

26 In view of those aims, the definition of medicinal product given in Article 1 of Directive 65/65 may not be interpreted restrictively but must be construed as including substances which are not administered as they are to human beings or animals but which are manufactured separately and are intended to be used mixed with other substances, either as a simple combination of substances or after chemical transformation, or as a carrier substance.

27 In this regard it is also irrelevant whether such a substance is made available to the public or sold only to radiologists working in hospitals or in private practice; users should be able to rely on the quality of the substance without having to carry out checks when mixing it with other substances for administering to human beings or animals.

28 The answer to the question raised must therefore be that a substance which is not presented for treating or preventing disease in human beings or animals but which is used for making medical diagnoses on them must be regarded as a medicinal product within the meaning of Article 1 of Council Directive 65/65 of 26 January

1965 in so far as it is intended to be administered to human beings or animals, either on its own or mixed with other substances.

Costs

29 The costs incurred by the French 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 (Second Chamber),

in answer to the questions submitted to it by the tribunal de grande instance, Libourne, by judgment of 21 December 1984, hereby rules:

A substance which is not presented for treating or preventing disease in human beings or animals but which is used for making medical diagnoses on them must be regarded as a medicinal product within the meaning of Article 1 of Council Directive 65/65/EEC of 26 January 1965 in so far as it is intended to be administered to human beings or animals either on its own or mixed with other substances.

Bahlmann Due Schockweiler

Delivered in open court in Luxembourg on 20 March 1986.

P. Heim
Registrar

K. Bahlmann
President of the Second Chamber