JUDGMENT OF THE COURT (Fourth Chamber)
6 November 1997 *

In Case C-201/96,

REFERENCE to the Court under Article 177 of the EC Treaty by the Tribunal Administratif, Paris, for a preliminary ruling in the proceedings pending before that court between

Laboratoires de Thérapeutique Moderne (LTM)

and

Fonds d'Intervention et de Régularisation du Marché du Sucre (FIRS)

on the interpretation of Council Regulation (EEC) No 1010/86 of 25 March 1986 laying down general rules for the production refund on certain sugar products used in the chemical industry (OJ 1986 L 94, p. 9), as amended by Article 9 of Commission Regulation (EEC) No 1714/88 of 13 June 1988 (OJ 1988 L 152, p. 23), and of Chapters 21 and 30 of the Combined Nomenclature, as established by Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ 1987 L 256, p. 1),

* Language of the case: French.

THE COURT (Fourth Chamber),

composed of: H. Ragnemalm, President of the Chamber, P. J. G. Kapteyn and J. L. Murray (Rapporteur), Judges,

Advocate General: M. B. Elmer,
Registrar: H. A. Rühl, Principal Administrator,

after considering the written observations submitted on behalf of:

— Laboratoires de Thérapeutique Moderne (LTM), by Eric Gicquel and Bernard Sansot, of the Paris Bar,

— the French Government, by Catherine de Salins, Head of Section in the Legal Affairs Directorate of the Ministry of Foreign Affairs, and Philippe Lalliot, Secretary of Foreign Affairs in that Directorate, acting as Agents,

— the Commission of the European Communities, by Michel Nolin, of its Legal Service, acting as Agent, assisted by Hervé Lehman, of the Paris Bar,

having regard to the Report for the Hearing,

after hearing the oral observations of Laboratoires de Thérapeutique Moderne, represented by Eric Gicquel and Bernard Sansot, the French Government, represented by Frédéric Pascal, Attaché in the Central Administration of the Legal Affairs Directorate of the Ministry of Foreign Affairs, acting as Agent, and the Commission, represented by Michel Nolin, at the hearing on 6 February 1997,

after hearing the Opinion of the Advocate General at the sitting on 20 March 1997,

gives the following

Judgment

1 By judgment of 3 April 1996, received at the Court on 12 June 1996, the Tribunal Administratif (Administrative Court), Paris, referred for a preliminary ruling under Article 177 of the EC Treaty a question on the interpretation of Council Regulation (EEC) No 1010/86 of 25 March 1986 laying down general rules for the production refund on certain sugar products used in the chemical industry (OJ 1986 L 94, p. 9), as amended by Article 9 of Commission Regulation (EEC) No 1714/88 of 13 June 1988 (OJ 1988 L 152, p. 23), and of Chapters 21 and 30 of the Combined Nomenclature, as established by Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ 1987 L 256, p. 1).

2 That question arose from a dispute between Laboratoires de Thérapeutique Moderne (hereinafter 'LTM') and the Fonds d'Intervention et de Régularisation du Marché du Sucre (Sugar Market Intervention and Stabilization Fund, hereinafter 'FIRS') concerning repayment of production refunds granted to LTM in its capacity as an undertaking using sugar in the manufacture of certain chemical products.

3 Regulation No 1010/86, as amended by Article 9 of Regulation No 1714/88 following the introduction of the Combined Nomenclature (hereinafter 'the CN'), deals with the granting of refunds to undertakings that use sugar in the manufacture of certain chemical products.

4 For the purpose of developing the market in sugar and providing compensation for the price differential between the Community rate and the world rate, Regulation

No 1010/86 grants production refunds for the manufacture of products containing sucrose. Articles 1 and 2(1) provide that the refund is to be granted by the Member State in the territory of which the processing of the 'basic products' into 'chemical products' listed in the annex to the regulation takes place. The pharmaceutical products referred to in Chapter 30 of the Common Customs Tariff (hereinafter 'the CCT') and, following Regulation No 1714/88, in Chapter 30 of the CN are included among those chemical products.

5 Since the facts underlying the dispute in the main proceedings occurred after the CN had been introduced, the latter alone will be considered in the present judgment.

6 LTM manufactures and distributes products intended for sale exclusively in pharmacies and uses sugar in the manufacture of some of those products, including Alvityl and Strongenol. The two products were the subject of marketing authorizations issued by the French authorities pursuant to the provisions of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20), as being 'medicinal products' within the meaning of Article 1(2) of that directive.

7 From 1989 to 1991, LTM received production refunds from the FIRS pursuant to Regulation No 1010/86 for the sugar which it used in the manufacture of its products entitled 'Alvityl 50 Dragées' and 'Strongenol 20 Ampoules'.

8 In 1991, LTM submitted requests for information to the French customs authorities which were designed to determine the position of Alvityl and Strongenol within the CN. The customs authorities replied that those two products fell to be classified under subheading 21 06 90 99 09 00 Q, relating to 'food preparations not elsewhere specified or included'.

9 On 10 December 1992, following an EAGGF investigation, the customs authorities formed the view that LTM had not been entitled to receive production refunds on the ground that Alvityl and Strongenol were food preparations which fell to be classified under Chapter 21 of the CN and not pharmaceutical products classifiable under Chapter 30 of the CN.

10 Accordingly, on 12 July 1993, the FIRS requested LTM to repay the production refunds allegedly improperly received in the amount of FF 410 347.56 in respect of sugar used between October 1989 and February 1991, and also to pay penalties amounting to FF 50 486.39.

11 By application of 23 November 1993, LTM brought an action before the Tribunal Administratif, Paris, seeking annulment of the claim for repayment made by the FIRS.

12 Since it took the view that the outcome of the dispute depended on an interpretation of the Community provisions, the Tribunal Administratif, Paris, stayed the proceedings in order to ask the Court whether, 'having regard to their composition, presentation and purpose, the products "Alvityl 50 Dragées" and "Strongenol 20 Ampoules" fall within the scope of Council Regulation No 1010/86 of 25 March 1986'.

13 It should be noted at the outset that Regulation No 1010/86 lays down rules relating to the grant of refunds to undertakings using sugar for the manufacture of certain chemical products, and, *inter alia*, the pharmaceutical products coming under Chapter 30 of the CN. However, it is not the purpose of that regulation to classify specific goods under certain headings of the CN; it simply indicates the products, with their CN code, for the manufacture of which a production refund may be granted.

14 A specific product may thus come within the scope of Regulation No 1010/86 only if it is classifiable under one of the CN headings listed in the annex to that regulation.

15 In a case such as that in the main proceedings here, it appears that, of the various chapters, headings and subheadings mentioned in the annex to that regulation, Chapter 30 alone may be relevant.

16 In order to provide the national court with a useful reply, its question must therefore be construed as seeking to ascertain whether products such as 'Alvityl 50 Dragées' and 'Strongenol 20 Ampoules' fall within Chapter 30 of the CN and, consequently, within Regulation No 1010/86.

17 It is settled case-law that, in the interests of legal certainty and ease of verification, the decisive criterion for the classification of goods for customs purposes is in general to be sought in their objective characteristics and properties as defined in the wording of the relevant heading of the CN (see, with regard to the CCT, Case C-459/93 *Hauptzollamt Hamburg-St Annen* v *Thyssen Haniel Logistic* [1995] ECR I-1381, paragraph 8, and Joined Cases C-106/94 and C-139/94 *Colin and Dupré* [1995] ECR I-4759, paragraph 22). There are also explanatory notes drawn up, as regards the CN, by the European Commission and, as regards the Harmonized Commodity Description and Coding System, by the Customs Cooperation Council, which may be an important aid to the interpretation of the scope of the various tariff headings but do not have legally binding force (Case C-35/93 *Develop Dr Eisbein* v *Hauptzollamt Stuttgart-West* [1994] ECR I-2655, paragraph 21, and *Colin and Dupré*, cited above, paragraph 21).

18 Heading 30 04 of the CN covers 'Medicaments (excluding goods of heading No 30 02, 30 05 or 30 06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale'.

19 According to the first note in the introduction to Chapter 30 of the CN, that chapter does not cover dietetic, diabetic or fortified foods, food supplements, tonic beverages and mineral waters, which fall to be classified under their own heading in Section IV of the CN.

20 Within this latter section, Chapter 21 of the CN is entitled 'Miscellaneous edible preparations'.

21 According to the relevant Explanatory Notes of the Customs Cooperation Council, heading 21 06, entitled 'Food preparations not elsewhere specified or included', comprises, *inter alia*, preparations, often referred to as food supplements, based on extracts from plants, fruit concentrates, honey, fructose, etc. and containing vitamins and sometimes minute quantities of iron compounds. However, those notes also state that similar preparations intended for the prevention or treatment of diseases or ailments are excluded from that chapter and come under headings 30 03 or 30 04 of the CN.

22 LTM submits that, since the competent French authorities granted marketing authorizations for Alvityl and Strongenol, both of those products must be classified under Chapter 30 of the CN.

23 In this regard, reference should be made to the general comments preceding the Explanatory Notes to the Combined Nomenclature of the European Communities relating to Chapter 30 of the CN, which state that 'the description of a product as a medicament in Community legislation (other than that relating specifically to classification in the combined nomenclature) or in the national legislation of the Member States, or in any pharmacopoeia, is not the deciding factor in so far as its classification in this chapter is concerned'.

24 The concept of a pharmaceutical product in the CN is distinct from that of a medicinal product appearing in Directive 65/65. The latter directive is designed to eliminate — at least in part — obstacles to trade in proprietary medicinal products within the Community whilst at the same time attaining the essential objective of safeguarding public health (Case 227/82 *Van Bennekom* [1983] ECR 3883, paragraph 14). Thus, with a view to promoting trade and at the same time protecting public health, the directive allows a relatively large spectrum of products to be covered by the control system laid down in the legislation on medicinal products. It should also be noted that, in Case C-369/88 *Delattre* [1991] ECR I-1487, paragraphs 27 and 29, the Court held that, with regard to Directive 65/65, the fact that a product is classified as a foodstuff in another Member State cannot prevent its being classified as a medicinal product in the Member State concerned when it displays the characteristics of such a product. The Court also recognized in that case that, so long as harmonization of the measures necessary to ensure the protection of health is not more complete, differences in the classification of products as between Member States will continue to exist in the context of the directive.

25 In contrast, the eighth recital in the preamble to Regulation No 2658/87 provides that 'it is essential that the combined nomenclature and any other nomenclature wholly or partly based on it ... should be applied in a uniform manner by all the Member States'. According to its final provisions, 'this Regulation shall be binding in its entirety and directly applicable in all Member States'. The provisions of the CN must therefore be given an identical interpretation by each of the Member States.

26 The fact that marketing authorizations were granted for Alvityl and Strongenol by the competent French authorities in accordance with the provisions of Directive 65/65 and, consequently, that those products are regarded as medicinal products under French legislation does not therefore necessarily mean that they must be classified as pharmaceutical products in the CN.

27 The same holds true for the argument relied on by LTM to the effect that Alvityl and Strongenol are medicinal products by virtue of their presentation and are

distributed solely in pharmacies. Although, according to the Court's case-law, such factors are strong indications that the products in question are to be treated as medicinal products within the meaning of Directive 65/65, the decisive criterion for the tariff classification of goods according to the CN must in general be sought, as pointed out in paragraph 17 of this judgment, in their objective characteristics and properties as defined in the wording of the CN heading.

28 The criteria set out in the introductory notes to Chapter 30 of the CN for tariff classification of products in that chapter do not refer to either their presentation or places of sale. Accordingly, even if it were possible to regard such factors as relevant, they would not be decisive as regards the classification of the goods in the CN.

29 Moreover, in Case C-177/91 *Bioforce* v *Oberfinanzdirektion München* [1993] ECR I-45, paragraph 12, the Court ruled that a pharmaceutical product within the meaning of heading 30 04 of the CN has clearly defined therapeutic and, above all, prophylactic characteristics, the effect of which is concentrated on precise functions of the human organism.

30 It is for that reason necessary to examine whether products such as Alvityl and Strongenol have those characteristics and, in particular, whether they are capable of being applied in the prevention or treatment of diseases or ailments.

Alvityl

31 First, it appears from the documents before the Court that, at the material time, one 'Alvityl 50 Dragées' tablet consisted of 6 250 IU of vitamin A, along with smaller quantities of 11 other vitamins. Some of those vitamins, including vitamins

A, B1, B2 and D, were present in amounts several times higher than the levels of the Reference Intake for a Population determined by the Scientific Committee for Food.

32 One Alvityl tablet also contained 550 mg of sugar and 92.5 mg of cocoa, together with excipients, flavourings and coating.

33 Finally, 'Alvityl 50 Dragées' were accompanied by the following information: 'This medicinal product is recommended for the prevention or correction of vitamin deficiencies linked to an inadequate or unbalanced diet'.

34 LTM submits that the clinical synthesis of Alvityl, annexed to its written observations, demonstrates that this product is intended for the treatment and prevention of multivitamin deficiencies.

35 That synthesis, however, also makes it clear that Alvityl cannot be used to combat specific deficiencies of a particular vitamin.

36 During the hearing, the French Government declared, in this regard, that most people who take Alvityl treat themselves by increasing the recommended daily intake of vitamins, each Alvityl tablet corresponding approximately to the recommended daily intake of each vitamin.

37 Furthermore, it has not been established either that Alvityl has clearly defined therapeutic or prophylactic characteristics with an effect concentrated on precise

functions of the human organism or that it is capable of being applied in the prevention or treatment of diseases or ailments.

38 The fact that this product has been given a marketing authorization issued by the competent State authorities, that it is a medicinal product according to its presentation under the provisions of Directive 65/65 and that it is distributed exclusively in pharmacies does not compensate for the lack of these essential characteristics.

39 In those circumstances, a product such as Alvityl cannot be classified under heading 30 04 of the CN as a medicament consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale.

40 The product here at issue does, on the other hand, have an effect on the general state of health and has the characteristics of a food supplement containing vitamins intended to maintain general health or well-being within the meaning of the Explanatory Notes of the Customs Cooperation Council. As pointed out in paragraphs 20 and 21 of this judgment, there is a separate heading in the CN, namely heading 21 06, which is reserved for products having such characteristics.

Strongenol

41 It is, first of all, apparent from the documents before the Court that Strongenol is a combination of amino acids, mineral salts and trace elements. It contains iron ribonucleate, globin amino extract, sodium vanadate, copper glycocollate, iodine and excipients.

42 Second, the therapeutic indications relating to Strongenol are as follows: 'debility or reduced physical and mental efficiency, convalescence, overwork, poor appetite, weight loss and ageing'.

43 Third, the therapeutic indications on the notice attached to the product describe, in general terms, a series of very different conditions.

44 Finally, the clinical synthesis of Strongenol includes the warning that the iron which it contains cannot correct anaemia caused by iron deficiency, but risks concealing its symptoms and delaying its treatment.

45 Although LTM states that a serious insufficiency of iodine intake in a foetus may lead to death at the time of birth, it has not been demonstrated that Strongenol is capable of being applied in the prevention or treatment of such a medical condition or in the prevention or treatment of any other disease or ailment. More generally, it has not been shown that Strongenol has a clearly defined therapeutic and, above all, prophylactic effect on precise functions of the human organism, as required by the abovementioned judgment in *Bioforce*.

46 It should be repeated that the fact that a product has been given a marketing authorization issued by the competent State authorities, that it is a medicinal product according to its presentation under the provisions of Directive 65/65 and that it is distributed exclusively in pharmacies does not in any case compensate for the lack of these essential characteristics.

47 Strongenol cannot therefore be classified under heading 30 04 of the CN.

48 It should also be borne in mind that, in paragraph 11 of the judgment in *Thyssen Haniel Logistic*, cited above, the Court held that amino acids, as basic constituents of proteins, may be regarded as nutritional substances. While the Customs Cooperation Council's Explanatory Notes to heading 30 04 state that the provisions of the heading text do not apply to foodstuffs or beverages, which fall to be classified under their own appropriate headings, they point out that proteins feature among the major nutritional substances in food. Moreover, food products are classified under Chapter 21 of the CN.

49 The answer to the question submitted must therefore be that products consisting of ingredients identical to those contained in 'Alvityl 50 Dragées' and 'Strongenol 20 Ampoules' and in the same proportions cannot be classified under heading 30 04 of the CN, as established in the annex to Regulation No 2658/87, and consequently do not come within the scope of Regulation No 1010/86.

Costs

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

On those grounds,

THE COURT (Fourth Chamber),

in answer to the question referred to it by the Tribunal Administratif, Paris, by judgment of 3 April 1996, hereby rules:

Products consisting of ingredients identical to those contained in 'Alvityl 50 Dragées' and 'Strongenol 20 Ampoules' and in the same proportions cannot be classified under heading 30 04 of the Combined Nomenclature, as established in the annex to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff, and consequently do not come within the scope of Council Regulation (EEC) No 1010/86 of 25 March 1986 laying down general rules for the production refund on certain sugar products used in the chemical industry.

Ragnemalm Kapteyn Murray

Delivered in open court in Luxembourg on 6 November 1997.

R. Grass H. Ragnemalm

Registrar President of the Fourth Chamber