# JUDGMENT OF THE COURT (Fourth Chamber)
12 March 1998 *

In Case C-270/96,

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 Sarget SA**

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 amending certain Regulations concerning the application of the common market organisation for sugar following the introduction of the Combined Nomenclature (OJ 1988 L 152, p. 23), and on the interpretation of Chapter 30 of the Combined Nomenclature, as established by Annex I to 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: R. Schintgen, President of the Second Chamber, acting for the President of the Fourth Chamber, P. J. G. Kapteyn and J. L. Murray (Rapporteur), Judges,

Advocate General: M. B. Elmer,
Registrar: L. Hewlett, Administrator,

after considering the written observations submitted on behalf of:

— Laboratoires Sarget SA, by François Meunier and Jean-Claude Demoulin, of the Paris Bar,

— the French Government, by Catherine de Salins, Head of Subdirectorate in the Legal Affairs Directorate of the Ministry of Foreign Affairs, and Frédéric Pascal, Central Administrative Attaché in the same Directorate, acting as Agents,

— the Commission of the European Communities, by Michel Nolin, of its Legal Service, acting as Agent,

having regard to the Report for the Hearing,

after hearing the oral observations of Laboratoires Sarget SA, represented by Jean-Dominique Touraille, of the Paris Bar, assisted by Alain Gillet, acting as an expert witness, the French Government, represented by Frédéric Pascal, and the Commission, represented by Michel Nolin, at the hearing on 5 June 1997,

after hearing the Opinion of the Advocate General at the sitting on 17 July 1997,

gives the following

## Judgment

1 By judgment of 12 June 1996, received at the Court on 8 August 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 amending certain Regulations concerning the application of the common market organisation for sugar following the introduction of the Combined Nomenclature (OJ 1988 L 152, p. 23), and on the interpretation of Chapter 30 of the Combined Nomenclature, as established by Annex I to 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, hereinafter 'the CN').

2 That question has arisen in the course of proceedings between Laboratoires Sarget SA (hereinafter 'Sarget') and the Fonds d'Intervention et de Régularisation du Marché du Sucre (Sugar Market Intervention and Stabilisation Fund, hereinafter 'the FIRS') concerning repayment of production refunds granted to Sarget 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 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 the '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, which is applicable to the case in the main proceedings, in Chapter 30 of the CN are included among those chemical products.

5 In 1986, pursuant to Regulation No 1010/86, the FIRS asked potential users to apply for prior approval if they wished to obtain those refunds.

6 By letter of 11 July 1986 Sarget applied to the FIRS for approval of the use of sugar in the manufacture of products which, in its view, were covered by the Annex to Regulation No 1010/86. That application included a declaration, among the products to be manufactured, of the pharmaceutical products Sargenor, Lysivit, Sarvit and Dynamisan, which were declared as falling under CCT heading 3003. Pursuant to that declaration, approval was given on 15 July 1986 by the FIRS, so that Sarget received refunds for the sugar used in the manufacture of those products.

7 By letter of 15 November 1988 Sarget applied for approval to be renewed for the same products, which it then declared as falling under CN heading 3004. Pursuant to that declaration, further approval was given on 17 November 1988.

8 After analysing samples of Sargenor, Lysivit, Sarvit and Dynamisan, the French customs and excise authorities started proceedings against Sarget on 22 June 1990 on the basis that those products should be classified under CN Chapter 21 as

'Miscellaneous edible preparations', a chapter which is not included in the annex to Regulation No 1010/86, as amended, and which therefore covers products not qualifying for production refunds.

9 Subsequently, on 17 February 1995, the FIRS issued Sarget with an enforceable demand for FF 2 545 059.66, corresponding to refunds that it had wrongly received between 1989 and 1991.

10 By application of 18 April 1995, Sarget sought annulment of that revised assessment before the Tribunal Administratif.

11 The national court decided that the dispute before it turned on an interpretation of Community provisions and accordingly stayed the proceedings and asked the Court whether,

'in view of their composition, presentation and functions, ... the products "Sargenor", "Sarvit", "Lysivit" and "Dynamisan" fall within the scope of Council Regulation No 1010/86 of 25 March 1986 on the classification of goods under subheading 30 of the Common Customs Tariff or another subheading'.

12 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.

13 A specific product may thus come within the scope of Regulation No 1010/86, as amended by Article 9 of Regulation No 1714/88, only if it is classifiable under one of the CN headings listed in the annex to that regulation.

14 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 is relevant.

15 The question referred to the Court must therefore be construed as seeking to ascertain whether products composed of ingredients identical to those contained in Sargenor, Lysivit, Sarvit or Dynamisan, and in the same proportions, fall under Chapter 30 of the CN and consequently under Regulation No 1010/86, as amended by Article 9 of Regulation No 1714/88.

16 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, and, with regard to the CN, the judgment of 6 November 1997 in Case C-201/96 *LTM* v *FIRS* [1997] ECR I-6147, paragraph 17). There are also explanatory notes drawn up, as regards the CN, by the European Commission and, as regards the Harmonised 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 which do not have legally binding force (Case C-35/93 *Develop Dr Eisbein* v *Hauptzollamt Stuttgart-West* [1994] ECR I-2655, paragraph 21, and Case C-201/96 *LTM*, cited above, paragraph 17).

17 Heading 3004 of the CN covers 'Medicaments (excluding goods of heading No 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale'.

18 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 headings in Section IV of the CN.

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

20 According to the relevant Explanatory Notes of the Customs Cooperation Council, heading 2106, 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 3003 or 3004 of the CN.

21 Sarget states that Sargenor is registered as a medicament not only in France and in eight Member States but also in 40 other countries in the world. It further considers that the definition of 'medicinal product' [1] in 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, L 229, p. 20) is very close to that given in the case-law of the Court concerning the decisive criteria for the tariff classification of goods in the CN. It considers that compliance with the principle of legal certainty would not be jeopardised if, in this case, the Court took into account *inter alia* the

1 — Translator's note: 'médicament' is translated as 'medicinal product' in Council Directive 65/65/EEC, but as 'medicament' in the CN.

numerous designations under the various bodies of national legislation in order to determine the tariff classification of Sargenor.

22 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'.

23 The concept of a pharmaceutical product in the CN is distinct from that of a medicinal product referred to 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 if it displays the characteristics of such a product. The Court also recognised in that case that, so long as harmonisation 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.

24 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'. The provisions of the CN must therefore be given an identical interpretation by each of the Member States.

25 The fact that, pursuant to the provisions of Directive 65/65, marketing authorisations were granted for the products at issue in the main proceedings by the competent French authorities 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.

26 The same holds true as regards the significance of the presentation of a product for the determination of its classification under the CN. Although, according to the Court's case-law, such a factor is an indication that the products in question are to be treated as medicinal products within the meaning of Directive 65/65 (see, to that effect, the *LTM* judgment, cited above, paragraph 27), the decisive criterion for the tariff classification of goods according to the CN must, as pointed out in paragraph 16 of this judgment, in general be sought in their objective characteristics and properties as defined in the wording of the CN heading.

27 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 their presentation. Accordingly, even if it were possible to regard such a factor as relevant, it would not be decisive as regards the classification of the goods in the CN.

28 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 3004 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.

29 It is therefore necessary to examine whether the products in question have therapeutic and prophylactic characteristics and, in particular, whether they are capable of being applied in the prevention or treatment of diseases or ailments.

## Sargenor and Dynamisan

30 The file shows that at the material time Sargenor existed in three different forms: chewable tablets, effervescent tablets, and a drinkable solution in ampoules, their active ingredients being in principle identical. It appears from the clinical expert's report on Sargenor, which was annexed to Sarget's observations, that a drinkable 5 ml ampoule of Sargenor contained 1 g of arginine-aspartate as the single active ingredient, excipients and sodium.

31 The report also states that adult dosage is two to three ampoules per day and the dosage for children over 30 months one-half to two ampoules per day, according to age. The report adds that as regards arginine-aspartate, exceeding that dosage (either by doubling or tripling the recommended quantity) would, according to the available data, have no harmful effect.

32 Sarget and the French Government maintain that aspartate-arginine has therapeutic and prophylactic effects in the treatment of asthenia, which in their view is a pathological condition.

33 Sarget and the French Government state that Sargenor has long been used to combat functional asthenia, post-infection and post-operative asthenia, and diabetic forms of asthenia. They state that the causes of asthenia are *inter alia* malignant diseases, infections, metabolic disorders and cardiovascular disorders and that certain forms of asthenia accompany psychiatric illness.

34 It appears from the national court's file that Dynamisan exists in two different forms of presentation: a powder to make a drinkable solution, contained in

sachets, and a drinkable solution in the form of ampoules. It contains 3 g of arginine-glutamate, the active ingredient of the product. Arginine-glutamate has the same therapeutic effects as arginine-aspartate. Dynamisan has practically the same composition as Sargenor and the therapeutic indications are identical.

35 Sarget and the French Government emphasise that there are differences between asthenia and fatigue. In their view, fatigue is a state of lassitude following overwork or prolonged effort, whereas asthenia is severe and generalised weakness having no relationship of cause and effect to work or effort.

36 That distinction between asthenia and fatigue was contested by the Commission at the hearing. It maintains that certain doctors consider that asthenia is a state of fatigue.

37 It is not for the Court to establish whether asthenia is a pathological condition distinguishable from normal fatigue. Even if asthenia could be regarded as a pathological condition, that would not be decisive for the purposes of ascertaining whether Sargenor and Dynamisan have clearly-defined therapeutic and prophylactic characteristics, the effect of which is concentrated on precise functions of the human organism, and are capable of being applied in the prevention or treatment of diseases or ailments.

38 It appears from the national court's file that the studies submitted by Sarget and those to which the French Government refers in its observations concern the effect of arginine or arginine-aspartate in various aetiologies and not that of Sargenor or Dynamisan. Moreover, those studies relate, principally, to the effects of arginine and arginine-aspartate on certain pathological conditions, such as cancer, that neither Sargenor or Dynamisan are intended to treat. In any case, Sarget has not established a link between Sargenor and Dynamisan, on the one hand, and the studies on the effects of arginine and arginine-aspartate in the treatment of the pathological conditions dealt with in those studies, on the other.

39 Nor has it been established that Sargenor and Dynamisan had clearly defined therapeutic or prophylactic characteristics with an effect concentrated on precise functions of the human organism or that they are capable of being applied in the prevention or treatment of specific diseases or ailments.

40 Products such as Sargenor and Dynamisan cannot therefore be classified under heading 3004 of the CN.

**Lysivit and Sarvit**

41 It appears from the file that at the material time Lysivit was marketed in a drinkable solution put up in 5 or 10 ml ampoules. One 5 ml ampoule contained 15 μg of vitamin $B_{12}$ and a 10 ml ampoule double that quantity. Lysivit ampoules contained in addition amino acids and preservatives.

42 Lysivit dosage for children is one to three ampoules of 5 ml per day. That dosage gives, on average, 30 μg of vitamin $B_{12}$ per day. Adult dosage is one to four ampoules of 10 ml per day, or an average dosage of two ampoules of 10 ml per day, representing 60 μg of vitamin $B_{12}$ per day, and may go up to 120 μg of vitamin $B_{12}$ per day. For the sake of comparison, the daily vitamin $B_{12}$ intake recommended in the Reports of the Scientific Committee for Food (Thirty-first series), 'Nutrient and energy intakes for the European Community' is 1 μg. Lysivit's vitamin $B_{12}$ content is therefore well in excess of the recommended daily intake.

43 The French Government maintains that Lysivit is used in the treatment of functional asthenia.

44 Sarvit, which has not been marketed since 1987, used to be presented in the form of drinkable ampoules for adults of 5 or 10 ml. Its composition included 500 µg of vitamin $B_{12}$ per ampoule of 10 ml and 250 µg of vitamin $B_{12}$ per ampoule of 5 ml. Sarvit ampoules also contained amino acids and preservatives. Sarvit's vitamin $B_{12}$ content also exceeded the recommended daily intake.

45 The French Government maintains that Sarvit was used in the treatment of functional asthenia.

46 It was stated during the proceedings that a lack of vitamin $B_{12}$ can manifest itself in various ways: malfunctions of the central nervous system, heart muscle malfunction and respiratory disorders. More precisely, it was pointed out that a lack of vitamin $B_{12}$ could manifest itself in the form of pernicious anaemia, an illness characterised by the fact that the organism cannot absorb vitamin $B_{12}$.

47 However, it has not been claimed that Lysivit and Sarvit were marketed for the treatment of those illnesses. Moreover, at the hearing it was explained that the absorption of vitamin $B_{12}$ is effected principally, in the case of pernicious anaemia, by intramuscular injections.

48 It has not been established that either Lysivit or Sarvit had clearly defined therapeutic or prophylactic characteristics with an effect concentrated on precise functions of the human organism or that they were capable of being applied in the prevention or treatment of specific diseases or ailments.

49 Products such as Lysivit and Sarvit cannot therefore be classified under heading 3004 of the CN.

50 In the light of the foregoing considerations, the answer to the question submitted must therefore be that products consisting of ingredients identical to those contained in Sargenor, Dynamisan, Lysivit and Sarvit and in the same proportions cannot be classified under heading 3004 of the CN as established in Annex I to Regulation No 2658/87, and consequently do not come within the scope of Regulation No 1010/86, as amended by Article 9 of Regulation No 1714/88.

## Costs

51 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 proceedings 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 12 June 1996, hereby rules:

**Products consisting of ingredients identical to those contained in Sargenor, Dynamisan, Lysivit and Sarvit and in the same proportions cannot be classified under heading 3004 of the Combined Nomenclature as established in Annex I**

**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, as amended by Article 9 of Commission Regulation (EEC) No 1714/88 of 13 June 1988 amending certain Regulations concerning the application of the common market organisation for sugar following the introduction of the Combined Nomenclature.**

Schintgen Kapteyn Murray

Delivered in open court in Luxembourg on 12 March 1998.

R. Grass H. Ragnemalm

Registrar President of the Fourth Chamber