JUDGMENT OF THE COURT (First Chamber)
10 December 1998 *

In Case C-328/97,

REFERENCE to the Court under Article 177 of the EC Treaty by the Bundesfinanzhof (Germany) for a preliminary ruling in the proceedings pending before that court between

Glob-Sped AG

and

Hauptzollamt Lörrach,

on the interpretation of heading No 3004 of Annex I to Commission Regulation (EEC) No 2505/92 of 14 July 1992 amending Annexes I and II to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ 1992 L 267, p. 1) concerning the classification of vitamin C-based preparations,

THE COURT (First Chamber),

composed of: P. Jann, President of the Chamber, L. Sevón and M. Wathelet (Rapporteur), Judges,

Advocate General: N. Fennelly,
Registrar: L. Hewlett, Administrator,

* Language of the case: German.

after considering the written observations submitted on behalf of:

— Glob-Sped AG, by H.-J. Prieß of the Brussels Bar,

— the French Government, by K. Rispal-Bellanger, Assistant Director in the Legal Affairs Directorate of the Ministry of Foreign Affairs, and F. Pascal, Attaché d'administration centrale in the same directorate, acting as Agents,

— the Commission of the European Communities, by R. Wainwright, Principal Legal Adviser, and K. Schreyer, a national official on secondment to the Commission's Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Glob-Sped AG, represented by H.-J. Prieß, the French Government, represented by C. Vasak, Assistant Secretary in the Legal Affairs Department of the Ministry of Foreign Affairs, acting as Agent, and the Commission, represented by K. Schreyer, at the hearing on 16 July 1998,

after hearing the Opinion of the Advocate General at the sitting on 1 October 1998,

gives the following

Judgment

1 By order of 12 August 1997, received at the Court on 22 September 1997, the Bundesfinanzhof (Federal Finance Court) referred to the Court for a preliminary

ruling under Article 177 of the EC Treaty two questions on the interpretation of heading No 3004 of Annex I to Commission Regulation (EEC) No 2505/92 of 14 July 1992 amending Annexes I and II to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ 1992 L 267, p. 1) concerning the classification of vitamin C-based preparations.

2 The questions were raised in proceedings between Glob-Sped AG ('Glob-Sped') and the Hauptzollamt Lörrach (Principal Customs Office, Lörrach; 'the Hauptzollamt') concerning the tariff classification of two vitamin preparations, namely Taxofit Vitamin C + Ca Brausetabletten and Taxofit Vitamin C Kautabletten.

3 The former preparation is in the form of soluble tablets containing 1 000 mg of vitamin C per tablet. Its packaging bears the following statements:

'To build up resistance in cases of increased risk of infectious illnesses'

'Dosage: save where prescribed otherwise, 1/2 soluble tablet daily for children, 1 tablet for adults, diluted in half-glass or glass of water'

'Medicine, store carefully! Keep out of reach of children! Refer to instructions!'

4 The directions for use, which accompany the product, include the following words:

'To build up resistance: for colds and influenza infections, physical and mental exertion, physical tiredness, and allergic reactions. Traditionally used for strengthening and fortification.'

5 The second preparation is in the form of chewing tablets containing 500 mg of vitamin C per tablet. Its packaging bears the following statements:

'To build up resistance in cases of increased risk of infectious illnesses'

'Dosage: save where prescribed otherwise, chew or suck one tablet per day. During periods of increased risk of infectious illnesses, such as colds or influenza, or in cases of severe physical and mental strain, 2 tablets.'

'Medicine, store carefully! Keep out of reach of children! Refer to instructions!'

6 The directions for use accompanying the product state as follows:

'To be taken as a prophylactic at times of increased risk of infection, in the case of severe physical and mental strain, signs of tiredness, illnesses brought about by vitamin C deficiency. Traditionally used for strengthening and fortification, as a prophylactic.'

'Taxofit Vitamin C Kautabletten build up resistance of the organism in cases of increased risk of infectious illnesses.'

7 Marketing authorisation was granted pursuant to 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) to market both products in Germany as medicaments.

8 On 26 January 1993 Glob-Sped applied to the Hauptzollamt for the release of Taxofit Vitamin C + Ca Brausetabletten and Taxofit Vitamin C Kautabletten into free circulation as 'medicaments' under heading No 3004 50 10 of the combined nomenclature ('CN').

9 By a tariff assessment of 4 June 1993, the Hauptzollamt decided on the strength of an expert study by the Zolltechnische Prüfungs- und Lehranstalt (Customs Testing and Teaching Institution) that the two products should be classified as food preparations under CN heading No 2106 90 99 and demanded payment of customs duties from Glob-Sped of DM 1 466.20.

10 The Finanzgericht (Finance Court) dismissed the action by Glob-Sped on the ground that the properties or composition of the imported products, namely the presence of a strong dose of vitamin C, were not sufficient, in the absence of any indication on the packaging or the accompanying notice as to the products' specific effectiveness in combating certain illnesses, for them to be capable of being classified as medicaments under the Common Customs Tariff, with the result that the vitamin C had to be classified, like other vitamins, under CN heading No 2936.

11 In its appeal on a point of law, Glob-Sped argued that, by reason of both their objective characteristics and their external presentation, especially the information on the packaging and the directions for use, the products at issue in the main proceedings were appropriate and suitable for the treatment or prevention of certain illnesses. In that respect, the applicant cited the judgment in Case C-405/95 *Bioforce* v *Oberfinanzdirektion München* [1997] ECR I-2581, in which, it maintained, the Court held that marketing authorisation for a preparation as a medicament under Directive 65/65 constituted evidence in favour of its tariff classification as a medicament.

12 The Hauptzollamt argued that the information concerning the use and administration of the product were not sufficiently specific. In its submission, neither the packaging nor the accompanying notice contained information as to the specific effectiveness of the tablets against certain illnesses, the preparations in question being aimed primarily at compensating for a possible deficiency in vitamin C. Moreover, the definitions given under the legislation applicable to medicaments were not decisive for the purposes of classifying products under the CN.

13 Uncertain as to the interpretation of the relevant headings of the CN and the scope of the *Bioforce* judgment cited above, the Bundesfinanzhof has decided to refer the following questions to the Court:

'1. Are the comments of the Court of Justice in paragraph 15 of its judgment of 15 May 1997 in Case C-405/95 *Bioforce* v *Oberfinanzdirektion München* to be interpreted as meaning that, in order for a preparation to be regarded as a

product possessing the characteristic properties of a medicament for the purposes of heading No 3004 of the combined nomenclature, it does not have to possess any objective qualities making it suitable for therapeutic or prophylactic uses, but that just the overall presentation of the preparation (information on its use, and its packaging, dispensation and marketing), that is to say its subjective purpose, is sufficient for such a classification?

2. If Question 1 is answered in the negative:

Is the combined nomenclature for 1993 to be interpreted as meaning that vitamin pills such as "Taxofit Vitamin C + Ca effervescent pills" and "Taxofit Vitamin C chewable pills" are to be assigned to heading No 3004 ("medicaments ... consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in ... forms or packings for retail sale"), when they contain 1 000 and 500 mg of vitamin C (ascorbic acid) per pill respectively, are imported in packings for retail sale, are to be used — according to the information on use which is contained in the leaflets enclosed with the packs and indicates a specific dose — *inter alia* "to build up resistance: for colds and influenza infections, ... and allergic processes" and "as a prophylactic at times of increased risk of infection" respectively, and are authorised as medicinal products in the Federal Republic of Germany?'

Relevant Community legislation

14 Council Regulation (EEC) No 2658/87 of 23 July 1987 (OJ 1987 L 256, p. 1) introduced a combined nomenclature. Under Article 12 of that regulation, the Commission is to adopt each year by means of a regulation a complete version of that nomenclature together with the corresponding autonomous and conventional rates of duty of the Common Customs Tariff.

15 For 1993, the Commission adopted Regulation (EEC) No 2505/92.

16 Chapter 30 of the CN refers to pharmaceutical products. Heading No 3004 covers:

'Medicaments ... consisting of mixed or unmixed products for therapeutic or prophylactic uses put up in measured doses or in forms or packings for retail sale'.

17 Subheading No 3004 50 10 refers to 'Other medicaments containing vitamins ...' where they are 'put up in forms or in packings of a kind sold by retail'.

18 According to Note 1(a) in the introduction to Chapter 30 of the CN, that chapter does not cover 'foods or beverages (such as dietetic, diabetic or fortified foods, food supplements, tonic beverages and mineral waters) (Section IV)'.

19 According to the corresponding Explanatory Notes of the Customs Cooperation Council, heading No 3004 90 covers:

'... medicaments consisting of mixed or unmixed products, provided they are: [put up]

...

(b) in packings for retail sale for therapeutic or prophylactic use. This refers to products ... which, because of their packaging and, in particular, the presence of appropriate indications (statement of disease or condition for which they are to be used, method of use or application, statement of dose, etc.) are clearly intended for sale directly to users (private persons, hospitals, etc.) without repacking, for the above purposes.

These indications (in any language) may be given by label, literature or otherwise ...'

20 Those Explanatory Notes also state that:

'... this heading excludes food supplements containing vitamins or mineral salts which are put up for the purpose of maintaining health or well-being but have no indication as to use for the prevention or treatment of any disease or ailment. These products, which are usually in liquid form but may also be put up in powder or tablet form, are generally classified in heading 21.06 or Chapter 22.'

21 Chapter 30 of the Explanatory Notes to the combined nomenclature of the European Communities (OJ 1994 C 342, p. 1) also states, under 'General', 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.'

22 In addition, Chapter 21 of the CN refers to 'Miscellaneous edible preparations'. Heading No 2106 covers 'Food preparations not elsewhere specified or included'.

23 According to the corresponding Explanatory Notes of the Customs Cooperation Council, that heading covers:

'Preparations, often referred to as food supplements, based on extracts from plants, fruit concentrates, honey, fructose, etc. and containing added vitamins and sometimes minute quantities of iron compounds. These preparations are often put up in packagings with indications that they maintain general health or well-being. Similar preparations, however, intended for the prevention or treatment of diseases or ailments are excluded (heading 30.03 or 30.04).'

24 Finally, Chapter 29 of the CN concerns 'organic chemicals'. Heading No 2936 covers:

'Provitamins and vitamins, natural or reproduced by synthesis (including natural concentrates), derivatives thereof used primarily as vitamins, and intermixtures of the foregoing, whether or not in any solvent'.

The second question

25 In its second question, which it is appropriate to examine first, the national court essentially asks whether, taking account of their objective characteristics and properties, products such as Taxofit Vitamin C + Ca Brausetabletten and Taxofit Vitamin C Kautabletten must be classified under CN heading No 3004, as laid down in Annex I to Regulation No 2505/92.

26 It is settled case-law that, in the interests of legal certainty and for 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. There are also explanatory notes drawn up, as regards the CN, by the 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 do not have legally binding force (see, in particular, Case C-201/96 *LTM* v *FIRS* [1997] ECR I-6147, paragraph 17).

27 It is therefore necessary to examine whether the products at issue in the main proceedings exhibit the objective characteristics and properties defined under CN heading No 3004, which, as the Court held in paragraph 13 of the judgment in *Bioforce*, cited above, must be interpreted in the light of medical developments.

28 In that regard, as the documents before the Court show, it is undisputed that the vitamin C content of the products in question is much greater than what is necessary or recommended for general dietary purposes. Furthermore, besides assisting the immune system of the human organism to resist infections in cases of, *inter alia*, asthenia or severe strain, such doses of vitamin C, which the human body is incapable of making for itself, are also recommended as treatment for allergic reactions and severe traumatisms, of the kind which may result from an injury or a surgical operation, or to combat deficiency-related illnesses, such as scurvy or Moeller-Barlow disease.

29 It follows from those findings that the products in question cannot be regarded as food supplements or preparations for the purposes of point 1(a) of the introductory notes to Chapter 30 of the CN, or as referred to in CN heading No 2106, but must be viewed as products with a clearly defined therapeutic or prophylactic profile, the effects of which are focused, in particular, on the functions of the immune system of the human organism.

30 Such a therapeutic or prophylactic effect also excludes the possibility of the products in question being classified under CN heading No 2936 relating to vitamins in general.

31 Nor is it disputed that, as required by the wording of heading No 3004 interpreted in the light of the Explanatory Notes of the Customs Cooperation Council, the products in question are packaged for retail sale and their packaging and explanatory notice bear appropriate indications as to the nature of the ailments against which they are to be used, their method of use and dosage.

32 In those circumstances, there is no need to enquire in addition whether other evidence, such as the fact that the products at issue in the main proceedings were authorised for release on to the German market as medicaments, is capable in this case of confirming the essential characteristic for classification under heading No 3004, namely the specific therapeutic or prophylactic effect characterising the products in question.

33 The answer must therefore be that the combined nomenclature, as laid down in Annex I to Regulation No 2505/92, is to be interpreted as meaning that products such as Taxofit Vitamin C + Ca Brausetabletten and Taxofit Vitamin C Kautabletten are to be classified under heading No 3004.

The first question

34 In view of the answer given to the second question, there is no need to answer the first.

Costs

35 The costs incurred by the French Government and by the Commission, 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 (First Chamber),

in answer to the questions referred to it by the Bundesfinanzhof by order of 12 August 1997, hereby rules:

The Combined Nomenclature, as laid down in Annex I to Commission Regulation (EEC) No 2505/92 of 14 July 1992 amending Annexes I and II to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff is to be interpreted as meaning that products such as Taxofit Vitamin C + Ca Brausetabletten and Taxofit Vitamin C Kautabletten are to be classified under heading No 3004.

Jann Sevón Wathelet

Delivered in open court in Luxembourg on 10 December 1998.

R. Grass P. Jann

Registrar President of the First Chamber