Reports of Cases

JUDGMENT OF THE COURT (First Chamber)

17 February 2016*

(Reference for a preliminary ruling — Common Customs Tariff — Tariff classification — Combined Nomenclature — Heading 3004 — Effervescent tablets containing 500 mg of calcium — Level of substance per recommended daily dose significantly higher than the recommended daily allowance to maintain general health or well-being)

In Case C-124/15,

REQUEST for a preliminary ruling under Article 267 TFEU from the Finanzgericht Hamburg (Finance Court, Hamburg, Germany), made by decision of 24 February 2015, received at the Court on 12 March 2015, in the proceedings

Salutas Pharma GmbH

v

Hauptzollamt Hanover

THE COURT (First Chamber),

composed of R. Silva de Lapuerta, President of the Chamber, A. Arabadjiev, J.-C. Bonichot, C.G. Fernlund and S. Rodin (Rapporteur), Judges

Advocate General: P. Mengozzi,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— Salutas Pharma GmbH, by M. Niestedt and K. Göcke, Rechtsanwälte,

— the Hauptzollamt Hanover, by T. Röper, acting as Agent,

— the Hungarian Government, by M.Z. Fehér and A.M. Pàlfy, acting as Agents

— the European Commission, by A. Caeiros and M. Wasmeier, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

* Language of the case: German.

Judgment

1 This request for a preliminary ruling concerns the interpretation of the Combined Nomenclature 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 (OJ 1987 L 256, p. 1), as amended by Commission Regulation (EC) No 1006/2011 of 27 September 2011 (OJ 2003 L 282, p. 1), ('the CN').

2 The request has been made in proceedings between Salutas Pharma GmbH ('Salutas Pharma'), a company which manufactures and distributes pharmaceutical products, and the Hauptzollamt Hanover (Principal Customs Office, Hanover, 'the Customs Office'), concerning the tariff classification of effervescent tablets with the trade name 'Calcium-Sandoz Forte 500 mg'.

Legal context

The HS

3 The Customs Cooperation Council, now the World Customs Organisation (WCO) was established by the convention creating that council, concluded in Brussels on 15 December 1950. The Harmonised Commodity Description and Coding System ('the HS') was drawn up by the WCO and established by the International Convention on the Harmonised Commodity Description and Coding System ('the HS Convention') concluded in Brussels on 14 June 1983 and approved, with its amending protocol of 24 June 1986, on behalf of the European Economic Community by Council Decision 87/369/EEC of 7 April 1987 (OJ 1987 L 198, p. 1).

4 Under Article 3(1) of the HS Convention, each Contracting Party undertakes to ensure that its customs tariff and statistical nomenclatures are in conformity with the HS, to use all the headings and subheadings of the HS without addition or modification together with their related codes, and to follow the numerical sequence of that system. Each Contracting Party also undertakes to apply the General Rules for the interpretation of the HS and all the section, chapter and subheading notes of the HS, and not to modify their scope.

5 The WCO is to approve, under the conditions laid down in Article 8 of the HS Convention, the Explanatory Notes and Classification Opinions adopted by the HS Committee.

6 Heading No 21.06 covers '[f]ood preparations not elsewhere specified or included'.

7 The explanatory note relating to that heading states:

'Provided that they are not covered by any other heading of the Nomenclature, this heading covers:

…

(B) Preparations consisting wholly or partly of foodstuffs, used in the making of beverages or food preparations for human consumption. The heading includes preparations consisting of mixtures of chemicals (organic acids, calcium salts, etc.) with foodstuffs (flour, sugar, milk powder, etc.), for incorporation in food preparations …

…

The heading includes, inter alia:

…

(16) 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 packings with indications that they maintain general health or well-being. Similar preparations intended for the prevention or treatment of diseases or ailments are excluded (heading 30.03 or 30.04).

…'

8 Heading 30.04 of the HS thus provides:

'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 (including those in the form of transdermal administration systems) or in forms or packings for retail sale.'

9 The explanatory note relating to heading 30.04 of the HS provides that that 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'.

The CN

10 The CN is based on the HS, from which it takes the six-digit headings and subheadings, only the seventh and eighth digits forming subdivisions specific to the CN.

11 Under Article 12(1) of Regulation No 2658/87, as amended by Council Regulation (EC) No 254/2000 of 31 January 2000 (OJ 2000 L 28, p. 16), the European Commission is required to adopt each year a regulation reproducing the complete version of the CN and the rates of customs duty, as they result from measures adopted by the Council of the European Union or by the Commission. That regulation is to apply from 1 January of the following year.

12 Headings 2106 and 3004 of the CN repeat the wording of headings 21.06 and 30.04 of the HS.

13 Subheading 3004 90 00 of the CN is entitled 'Other'.

14 Additional Note 1 to Chapter 30 of the CN reads as follows:

'Heading 3004 includes herbal medicinal preparations and preparations based on the following active substances: vitamins, minerals, essential amino-acids or fatty acids, in packings for retail sale. These preparations are classified in heading 3004 if they bear on the label, packaging or on the accompanying user directions the following statements of:

(a) the specific diseases, ailments or their symptoms for which the product is to be used;

(b) the concentration of active substance or substances contained therein;

(c) dosage; and

(d) mode of application.

This heading includes homeopathic medicinal preparations when they meet the above mentioned conditions of (a), (c) and (d).

In the case of preparations based on vitamins, minerals, essential amino-acids or fatty acids, the level of one of these substances per recommended daily dose indicated on the label must be significantly higher than the recommended daily allowance to maintain general health or well-being.'

15 The explanatory note relating to additional note 1 to Chapter 30 of the CN, in the European Commission Communication entitled 'Explanatory Notes to the Combined Nomenclature of the European Union' (OJ 2011 C 137, p. 1, 'the explanatory note relating to Chapter 30 of the CN'), provides, in point 3 thereof:

'Vitamins or mineral preparations are preparations based on vitamins of heading 2936, on minerals including trace elements and mixtures thereof. They are used to treat or prevent specific diseases, ailments or their symptoms. Such preparations contain a much higher amount of vitamins or minerals, generally at least three times higher than the recommended daily allowance (RDA).

…'

16 It is also clear from point 3 that the recommended daily allowance for calcium is 800 mg.

The dispute in the main proceedings and the question referred for a preliminary ruling

17 On 2 May 2012, Salutas Pharma applied for the issue of binding tariff information in respect of 'Calcium-Sandoz Forte 500 mg' tablets. It proposed that that product should be classified under subheading 3004 90 00 of the CN.

18 The product at issue in the main proceedings consists of a preparation having calcium as its main ingredient, and is intended to be taken after being dissolved in water. Each tablet contains 500 mg of calcium. Information on the product, in particular, the dose, the area of application, and the active substances it contains can be found on the carton and in the accompanying user directions. The recommended daily dose for adults is 1 to 3 effervescent tablets, that is, 500 to 1 500 mg, and the dose for children is 1 to 2 effervescent tablets that is, 500 to 1 000 mg. The accompanying user directions indicate that the effervescent tablets are used for the prevention and treatment of a calcium deficiency and to support a special therapy for the prevention and treatment of osteoporosis. Salutas Pharma distributes the effervescent tablets exclusively through pharmacies.

19 The Customs Office, which issued a binding tariff information on 8 October 2012, classified that product under subheading 2106 90 92 of the CN, on the ground that it does not fall within heading 3004 of the CN as its dose does not correspond to a level of consumption of calcium which is significantly higher than the recommended daily allowance for maintaining general health or well-being.

20 Following an objection by Salutas Pharma lodged on 26 October 2012, the Customs Office confirmed, on 13 January 2014, the classification decision for the product at issue in the main proceedings under heading 2106 of the CN, holding that the condition in additional note 1 to Chapter 30 of the CN had not been satisfied as the calcium content of the recommended maximum daily dose of that product was not equal to three times the recommended daily allowance for calcium.

21 On 17 February 2014, Salutas Pharma brought an action before the referring court against the decision of 13 January 2014, arguing that the additional note 1 to Chapter 30 of the CN is not valid, in so far as it modifies the content of tariff heading 3004 of the CN. Alternatively, Salutas Pharma pointed out that that additional note does not lay down a requirement that the recommended daily dose of calcium of the product at issue must correspond to three times the necessary daily allowance, having regard, in particular, to the fact that a daily dose of 2 400 mg of calcium, which is three times the recommended daily allowance, exceeds the critical limit for health.

22 The Customs Office claims that the action should be dismissed on the grounds that additional note 1 to Chapter 30 of the CN is binding, and that it is possible to consumer up to 2 500 mg of calcium per day without adverse health effects, so that the calcium content of the maximum recommended daily dose of the effervescent tablets at issue in the main proceedings, that is 1 500 mg, cannot be regarded as being 'significantly higher' within the meaning of the additional note.

23 The referring court observes that those tablets fulfil the conditions laid down by additional note 1, first paragraph, points (a) to (d) to Chapter 30 of the CN and, therefore, their classification depends, first, on the interpretation of the expression 'significantly higher' in the third paragraph of that additional note and, second, on the interpretation of the explanatory note relating to Chapter 30 of the CN.

24 In that connection, that court considers that the explanatory note seems to require that, in order for a preparation such as the product at issue in the main proceedings to be included in that chapter as a 'vitamin or mineral preparation' its vitamin or mineral content must be much higher, generally at least three times higher than the recommended daily allowance. Therefore, as the recommended daily allowance for calcium is 800 mg, the calcium content of the recommended daily dose of a product such as that at issue in the main proceedings enabling it to be classified under heading 3004 of the CN would have to be 2 400 mg. As regards the product at issue in the main proceedings, its maximum content is 1 500 mg per day.

25 However, the referring court observes that the calcium content is more than 85% of the recommended daily allowance of calcium. Also, it considers that such an amount may be treated as 'significantly higher', within the meaning of additional note 1 to Chapter 30, even though it is not three times higher than the recommended daily allowance. It also considers that the explanatory note relating to Chapter 30 of the CN, by its use of the word 'generally', appears to refer to possible exceptions. Therefore, according to that court, it is conceivable that, in order to classify a product under heading 3004 of the CN, a vitamin or mineral content for that product which is less than three times the recommended daily allowance should suffice in exceptional cases.

26 Moreover, that court points out that there are no preparations to be taken orally on the market with a calcium content three times higher than the recommended daily allowance and that it cannot be concluded that, as a general rule, a daily dose of 2 400 mg is harmless to health.

27 However, the referring court observes that, while many factors support an interpretation according to which the 'significantly higher' content of vitamins or minerals must be the subject to a differentiated assessment, depending to the type of vitamin or mineral, it is conceivable that the practical requirements of sound administration require a clear and easily identifiable limit for that content to be set. In that connection, it observes that, for the purposes of the tariff classification of goods, the latter must not be differentiated according to a given standard market practice or medical appropriateness.

28 In those circumstances, the Finanzgericht Hamburg (Finance Court, Hamburg) decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

'Is the [CN] to be interpreted as meaning that effervescent tablets with a calcium content of 500 mg per tablet that are used for the prevention and treatment of a calcium deficiency and to support a special therapy for the prevention and treatment of osteoporosis and for which the maximum recommended daily dose for adults indicated on the label is 3 tablets (= 1 500 mg) are to be classified under subheading 3004 90 00?'

The question referred for a preliminary ruling

29 As a preliminary point, it should be noted 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 and in the section or chapter notes (see, judgments in *Sysmex Europe*, C-480/13, EU:C:2014:2097, paragraph 29 and the case-law cited; *Vario Tek*, C-178/14, EU:C:2015:152, paragraph 21 and the case-law cited, and *Amazon EU*, C-58/14, EU:C:2015:385, paragraph 20 and the case-law cited).

30 Thus, the chapter notes to the CN constitute important means for ensuring the uniform application of the common customs tariff and provide, as such, useful information for its interpretation The content of those notes must therefore be consistent with the provisions of the CN and cannot modify its scope (see judgment in *X and X BV*, C-319/10 and C-320/10, EU:C:2011:720, paragraph 55 and the case-law cited).

31 Furthermore, the explanatory notes drawn up by the Commission as regards the CN and by the WCO as regards the HS are an important aid to the interpretation of the scope of the various tariff headings but do not have legally binding force (see judgment in *Data I/O*, C-297/13, EU:C:2014:331, paragraph 33 and case-law cited).

32 As is apparent from the order for reference, it is not disputed that the product at issue in the main proceedings is a preparation based on mineral substances put up for retail sale. The concentration of the active substance, the dose, mode of administration, and the specific diseases, ailments or their symptoms for which the product is to be used are indicated on the packaging or in the user directions for that product. Therefore, that product satisfies conditions in the first paragraph, points (a), (b), (c) and (d), of additional note 1 to Chapter 30 of the CN.

33 The parties in the main proceedings disagree only as to whether the amount of calcium contained in the recommended daily dose of the product at issue is ‘significantly higher than the recommended daily allowance to maintain general health or well-being’ within the meaning of that additional note.

34 The explanatory note relating to Chapter 30 of the CN is meant to clarify that criterion, by stating that it covers the recommended daily dose, the vitamins or mineral content of which is ‘much higher, generally at least three times higher than the recommended daily allowance’.

35 It must be observed, first, that that explanatory note, which, as stated in paragraph 31 of the present judgment, does not have binding legal force, provides that a product in respect of which the vitamin or mineral content of the recommended daily dose is three times higher than the recommended daily allowance is to be included in that chapter if all the other conditions are also met. Second, as regards the use of the word ‘generally’ in that note, the latter does not exclude products from Chapter 30 of the CN solely because the vitamin or mineral content of their recommended daily dose is not three times higher than the recommended daily allowance.

36 Therefore, the explanatory note relating to Chapter 30 of the CN cannot be interpreted as meaning that the vitamin or mineral content of the recommended daily dose of the products composed of those substances must be three times the recommended daily allowance in order for them to be classified under heading 3004 of the CN.

37 Where the quantity of vitamins, mineral, essential amino-acids and fatty acids contained in the recommended daily dose of a product with the objective characteristics and properties defined by the wording of heading 3004 of the CN is significantly higher than what is necessary or recommended for general dietary purposes, it must be classified under that heading (see, to that effect, *Glob-Sped*, C-328/97, EU:C:1998:601, paragraph 28).

38 In that connection, as regards the product at issue in the main proceedings, it is clear from the order for reference, first, that the calcium content of the recommended daily dose for that product, that is 1 500 mg maximum, is more than 85% of the recommended daily allowance of calcium necessary to maintain general health and well-being, and, second, that regular consumption of doses with a calcium content three times higher than its recommended daily allowance may be harmful to health.

39 In those circumstances, it must be held that the calcium content of the maximum recommended daily dose of a product, such as that at issue in the main proceedings, is significantly higher than that necessary or recommended for general dietary purposes. Provided that such a product also fulfils conditions laid down in the first paragraph, points (a) to (d), of additional note 1 to Chapter 30 of the CN, it falls within heading 3004 of the CN.

40 It follows from all of the foregoing considerations that the CN must be interpreted as meaning that a product, such as effervescent tablets with a calcium content of 500 mg per tablet that is used for the prevention and treatment of a calcium deficiency and to support a special therapy for the prevention and treatment of osteoporosis, and for which the maximum recommended daily dose for adults indicated on the label is 1 500 mg, falls within heading 3004 of that nomenclature.

Costs

41 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. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (First Chamber) hereby rules:

The Combined Nomenclature in Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and the statistical nomenclature and on the Common Customs Tariff, as amended by Commission Regulation (EC) No 1006/2011 of 27 September 2011 must be interpreted as meaning that a product, such as effervescent tablets with a calcium content of 500 mg per tablet that is used for the prevention and treatment of a calcium deficiency and to support a special therapy for the prevention and treatment of osteoporosis, and for which the maximum recommended daily dose for adults indicated on the label is 1 500 mg, falls within heading 3004 of that nomenclature.

[Signatures]