JUDGMENT OF THE COURT (Fifth Chamber)

17 February 2011 *

In Case C-11/10,

REFERENCE for a preliminary ruling under Article 267 TFEU from the Hoge Raad der Nederlanden (Netherlands), made by decision of 18 December 2009, received at the Court on 8 January 2010, in the proceedings

Staatssecretaris van Financiën

v

Marishipping and Transport BV,

THE COURT (Fifth Chamber),

composed of J.-J. Kasel (Rapporteur), President of the Chamber, E. Levits and M. Berger, Judges,

* Language of the case: Dutch.

Advocate General: P. Mengozzi,
Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— the Netherlands Government, by C.M. Wissels and B. Koopman, acting as Agents,

— the European Commission, by M. van Beek and L. Bouyon, acting as Agents,

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

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Part One, Section II, C, 1(i) of the combined nomenclature of the Common Customs Tariff constituting 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 Regulations (EC) Nos 2031/2001 of 6 August 2001 (OJ 2001 L 279, p. 1) and 1832/2002 of 1 August 2002 (OJ 2002 L 290, p. 1) ('Regulation No 2658/87').

2 The questions were raised in proceedings between the Staatssecretaris van Financiën (State Secretary of Finance) and Marishipping and Transport BV ('Marishipping'), a company established in the Netherlands, about whether the relief from customs duty provided for pharmaceutical products applies only to goods composed of pure pharmaceutical substances or whether it also applies to products in which other substances have been added.

Legal context

3 Part One, Section II, C, 1(i) of Annex I to Regulation No 2658/87, which contains the rules applicable to the relief from customs duty provided for pharmaceutical products in certain categories, states:

'Relief from customs duty is provided for pharmaceutical products of the following categories:

(i) pharmaceutical substances which are covered by the CAS RN (chemical abstracts service registry numbers) and the international non-proprietary names (INNs) listed in Annex 3.'

4 Part One, Section II, C, 2(i) of Annex I to Regulation No 2658/87 states:

'Special cases:

(i) INNs cover only those substances described in the lists of recommended and proposed INNs published by the World Health Organisation (WHO). Where the number of substances covered by an INN is less than that covered by the CAS RN, only those substances covered by the INN will be subject to duty-free treatment.'

5 The list of pharmaceutical substances which qualify for duty-free treatment includes chitosan (poliglusam).

6 Both chitosan and ascorbic acid have their own international non-proprietary name and CAS number.

The facts in the main proceedings and the questions referred for a preliminary ruling

7 In 2002 and 2003 Marishipping submitted various declarations for the release for free circulation of a product described in the declarations as 'absorbital powder' ('the goods'). The goods were declared under tariff heading 3913 90 80 of the Combined Nomenclature. In 2002 and 2003 imports of goods under that heading were subject

to customs duties of 7.6% and 7.1% respectively. In its declarations, Marishipping claimed relief from customs duty for the goods and referred in that regard to Annex I to Regulation No 2658/87.

8 After inspection, the customs inspector considered that the goods, which were composed of 96% chitosan, 3% ascorbic acid and 1% tartaric acid, did not qualify for duty-free treatment. He considered that the relief from duty for chitosan was limited to the substance in its pure form and could not be applied to goods such as those at issue in the main proceedings. Consequently, he ordered post-clearance recovery of the customs duty on those imports.

9 As is apparent from the order for reference, the other substances contained in the goods, namely ascorbic acid and tartaric acid, protect chitosan against oxidation and were added to the chitosan to improve its storage life. Those two acids do not influence the effectiveness of chitosan. The storage life of chitosan in its pure form can also be improved by vacuum-packing. The goods are intended for use as the primary component in the manufacture of a product which is sold as a slimming product.

10 The Rechtbank te Haarlem (District Court of Haarlem) (Netherlands), the first instance court hearing the action brought by Marishipping against the customs duty recovery notices served by the customs inspector, held that action to be unfounded. Marishipping brought an appeal against that judgment before the Gerechtshof te Amsterdam (Regional Court of Appeal, Amsterdam) (Netherlands) which found, in a judgment of 18 December 2007, that the addition of very low quantities of ascorbic acid and tartaric acid to improve the storage life of the primary substance did not preclude application of the relief provided for pharmaceutical products. Consequently, the Gerechtshof te Amsterdam set aside that judgment and annulled the recovery notices served on Marishipping.

11 In its appeal in cassation, the Staatssecretaris van Financiën claimed that the relevant provisions of Annex I to Regulation No 2658/87 do not permit the relief provided for thereunder to be applied to a pharmaceutical product composed of a basic pharmaceutical substance to which other pharmaceutical substances have been added, irrespective of the proportion of the substances added.

12 The referring court notes that those provisions do not provide expressly that, in order to qualify for duty-free treatment under Part One, Section II, C, 1(i) of Annex I to Regulation No 2658/87, the listed substances have to be in their pure form. However, having regard to the case-law of the Court, and more specifically Case 58/85 *Ethicon* [1986] ECR 1131, paragraph 13, the referring court is uncertain whether it is possible to add other substances to the active pharmaceutical substance and, if so, what limits should then be observed in order for the goods still to qualify for duty-free treatment.

13 Against that background, the Hoge Raad der Nederlanden (Supreme Court of the Netherlands) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

‘1. Is the relief from customs duty for the pharmaceutical substances covered by Part One, Section II, C[, 1] (i), of Annex I to Regulation (EEC) No 2658/87 …, in conjunction with the list of pharmaceutical substances contained in Part Three (annexes), Section II, Annex 3, restricted to the pure form of the (chemical) substances referred to?

2. If other substances may be added to the pharmaceutical substance indicated, what restrictions should apply in that regard?’

Consideration of the questions referred

The first question

14 By its first question, the referring court asks, in essence, whether Part One, Section II, C, 1(i) of Annex I to Regulation No 2658/87 must be interpreted as meaning that a pharmaceutical substance listed in Annex 3 of Part Three of Annex I, to which other substances have been added, in particular pharmaceutical substances, still qualifies for the duty-free treatment which would have applied if such a substance had been in its pure form.

15 In order to provide an answer to that question, it must be noted that neither Part One, Section II, C, 1(i) of Annex I to Regulation No 2658/87 nor Annex 3 of Part Three of Annex I provides expressly that, in order to qualify for the duty-free treatment provided for the pharmaceutical products listed in Annex 3, those products must be in their pure form.

16 It should be pointed out, however, that the provision governing the application of duty-free treatment constitutes a derogation from the principle that goods imported into the European Union are, as a general rule, subject to customs duties and, as such, it must therefore be interpreted strictly.

17 Consequently, in the absence of an express indication or another factor supporting the conclusion that the legislature of the European Union intended to grant duty-free treatment to the pharmaceutical substances listed in Annex 3 which, subject to possible residual impurities contained in those substances, are not in their pure form, Regulation No 2658/87 cannot be interpreted as meaning that pharmaceutical substances to which other substances have been added qualify for that relief.

18 Substances, such as that at issue in the main proceedings, which have been added, in variable quantities, to the basic substance and which do not form part, as such, of that substance or of the product from which that substance was obtained cannot be regarded as constituting such residual impurities.

19 It follows that Regulation No 2658/87 must be interpreted as meaning that goods such as those at issue in the main proceedings, which are composed of a basic pharmaceutical substance, in this instance chitosan, to which other (pharmaceutical) substances have been added, do not qualify for the duty-free treatment provided for in that regulation.

20 It needs to be made clear, first of all, that that interpretation is supported, as noted in particular by the European Commission, by the Guidelines on the Use of INNs for pharmaceutical substances. According to those Guidelines, INNs are, as a rule, selected for well-defined individual substances which may be designated unambiguously by a chemical name (or formula), since the principle behind the INN programme is not to allocate names to mixtures of substances.

21 In the present case, it is apparent from the file that the INN attributed to chitosan does not cover the goods since they contain too high a proportion of other substances.

22 As regards the CAS numbers which are also referred to in Part One, Section II, C, 1(i) of Annex I to Regulation No 2658/87, it must be pointed out that it is also established, as the Netherlands Government and the Commission have noted, that chitosan (CAS 9012-76-4), ascorbic acid (CAS 5081-7) and tartaric acid (CAS 8769-4) all have their own CAS identification number and that a mixture of those substances cannot be identified by a single CAS number.

23 Next, the interpretation given in paragraph 19 above is consistent with the principle that provisions on suspensions of, and relief from, customs duties must correspond to the requirements of legal certainty and take account of the difficulties confronting national customs administrations owing to the wide range and complexity of the tasks which they must carry out (see, to that effect, *Ethicon*, paragraph 12, and Case C-247/97 *Schoonbroodt* [1998] ECR I-8095, paragraph 23).

24 Although the requirement that, in order to qualify for the duty-free treatment provided for in Part One, Section II, C, 1(i) of Annex I to Regulation No 2658/87, pharmaceutical substances must as a rule be in their pure form does not, admittedly, relieve customs authorities of their task of carrying out, where necessary, a chemical analysis of a sample of imported goods, the fact none the less remains that, in carrying out such an analysis, those authorities can limit themselves to researching whether those goods are actually composed exclusively of a substance on the list of pharmaceutical substances which qualify for the relief at issue, without being required to identify the other substances contained in those goods or to determine their proportions in the composition of those goods.

25 Finally, that interpretation is the most appropriate for ensuring a uniform application of the provisions of Regulation No 2658/87 in so far as it leaves only limited discretion to the national customs authorities to determine whether a pharmaceutical substance is in its pure form or not.

26 Having regard to the foregoing considerations, the answer to the first question is that Part One, Section II, C, 1(i) of Annex I to Regulation No 2658/87 must be interpreted as meaning that a pharmaceutical substance listed in Annex 3 of Part Three of Annex I, to which other substances have been added, in particular pharmaceutical substances, no longer qualifies for the duty-free treatment which would have applied if such a substance had been in its pure form.

The second question

27 Having regard to the answer to the first question, it is not necessary to answer the second question.

Costs

28 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 (Fifth Chamber) hereby rules:

Part One, Section II, C, 1(i) of 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, as amended by Commission Regulations (EC) Nos 2031/2001 of 6 August 2001 and 1832/2002 of 1 August 2002, must be interpreted as meaning that a pharmaceutical substance listed in Annex 3 of Part Three of Annex I, to which other substances have been added, in particular pharmaceutical substances, no longer qualifies for the duty-free treatment which would have applied if such a substance had been in its pure form.

[Signatures]