JUDGMENT OF THE COURT (Second Chamber)

13 Juillet 2006 *

In Case C-514/04,

REFERENCE for a preliminary ruling under Article 234 EC from the Gerechtshof te Amsterdam (Netherlands), made by decision of 30 November 2004, received at the Court on 15 December 2004, in the proceedings

Uroplasty BV

v

Inspecteur van de Belastingdienst — Douanedistrict Rotterdam,

THE COURT (Second Chamber),

composed of C.W.A. Timmermans, President of the Chamber, J. Makarczyk, R. Schintgen, P. Kūris (Rapporteur) and J. Klučka, Judges,

* Language of the case: Dutch.

Advocate General: J. Kokott,
Registrar: R. Grass,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— Uroplasty BV, by J. Bakker, Adviseur douanezaken,

— the Netherlands Government, by H.G. Sevenster and D.J.M. de Grave, acting as Agents,

— the Commission of the European Communities, by J. Hottiaux, acting as Agent, assisted by F. Tuytschaever, avocat,

after hearing the Opinion of the Advocate General at the sitting on 19 January 2006,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of headings 9021 and 3926 of the Combined Nomenclature ('the CN') 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 2388/2000 of 13 October 2000 (OJ 2000 L 264, p. 1, and corrigendum OJ L 276, p. 92).

2 The questions were raised in the course of proceedings between Uroplasty BV ('Uroplasty') and the Inspecteur van de Belastingdienst — Douanedistrict Rotterdam (Customs Inspector of Rotterdam Customs District, 'the Inspector') concerning the tariff classification of a silicone elastomer in flakes which is developed and intended to be injected and become fixed in the human body in order to treat problems connected with incontinence.

Legal context

3 Council Decision 87/369/EEC of 7 April 1987 concerning the conclusion of the International Convention on the Harmonised Commodity Description and Coding System and of the Protocol of Amendment thereto (OJ 1987 L 198, p. 1) approved, on behalf of the Community, that convention, concluded at Brussels on 14 June 1983, as amended by the Protocol of Amendment of 24 June 1986 to that convention.

4 The CN is based on the Harmonised Commodity Description and Coding System ('the HS') established by the Convention of 14 June 1983. Each subheading of the CN is accompanied by a numerical code, the first six figures of which correspond to the codes given to the headings and subheadings of the HS, to which are added two figures forming the subdivisions specific to the CN.

5 The version of the CN applicable at the time of the facts in the main proceedings is that resulting from the the text of Regulation No 2388/2000.

6 Chapter 30 of Section VI in Part Two of the CN is entitled 'Pharmaceutical products'.

7 Heading 3004 of the CN is worded as follows:

'Medicaments (excluding goods of heading 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:

...

3004 90 — Other:

...

3004 90 99 — — — Other'.

8 Chapter 39 of Section VII in Part Two of the CN is entitled 'Plastics and articles thereof'.

9 Subheading 3910 00 00 of the CN concerns 'Silicones in primary forms'.

10 Heading 3926 of the CN is worded as follows:

'Other articles of plastics or of other materials of headings 3901 to 3914:

...

3926 90 — Other:

...

3926 90 99 — — — — Other'.

11 Note 2 to Chapter 39 of the CN states:

'This chapter does not cover:

...

(r) articles of Chapter 90 (for example, optical elements, spectacle frames, drawing instruments);

...'

12 Note 3 to Chapter 39 of the CN adds:

'Headings 3901 to 3911 apply only to goods of a kind produced by chemical synthesis, falling in the following categories:

...

(d) Silicones (heading 3910);

...'

13 Note 6 to Chapter 39 of the CN states:

'In headings 3901 to 3914, the expression 'primary forms' applies only to the following forms:

(a) liquids and pastes, including dispersions (emulsions and suspensions) and solutions;

(b) blocks of irregular shape, lumps, powders (including moulding powders), granules, flakes and similar bulk forms.'

14 Chapter 90 of Section XVIII in Part Two of the CN is entitled 'Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof'.

15 Heading 9021 of the CN is worded as follows:

'Orthopaedic appliances, including crutches, surgical belts and trusses, splints and other fracture appliances; artificial parts of the body; hearing aids and other appliances which are worn or carried, or implanted in the body to compensate for a defect or disability:

...

9021 30 — Other artificial parts of the body:

...

9021 30 90 — — Other

...

9021 90 — Other:

9021 90 90 — — Other'.

16 Note 1 to Chapter 90 of the CN states:

'This chapter does not cover:

...

(f) parts of general use, as defined in note 2 to Section XV, of base metal (Section XV) or similar goods of plastic (Chapter 39);

...'

17 Note 2 to Chapter 90 of the CN states:

'Subject to note 1 above, parts and accessories for machines, apparatus, instruments or articles of this chapter, are to be classified according to the following rules:

...

(b) Other parts and accessories, if suitable for use solely or principally with a particular kind of machine, instrument or apparatus, or with a number of machines, instruments or apparatus of the same heading (including a machine, instrument or apparatus of heading 9010, 9013 or 9031), are to be classified with the machines, instruments or apparatus of that kind.

...'

18 The general rules for the interpretation of the CN, which are set out in Part One thereof, under Section I, Part A, provide, in particular:

'Classification of goods in the [CN] shall be governed by the following principles.

1. The titles of sections, chapters, and sub-chapters are provided for ease of reference only; or legal purposes, classification shall be determined according to the terms of the headings and any relative section or chapter notes, and, provided such headings or notes do not otherwise require, according the following provisions.

...

6. For legal purposes, the classification of goods in the subheadings of a heading shall be determined according to the terms of those subheadings and any related subheading notes and, mutatis mutandis, to the above rules, on the

understanding that only subheadings at the same level are comparable. For the purposes of this rule, the relative section and chapter notes also apply, unless the context requires otherwise.'

The main proceedings and the questions referred for a preliminary ruling

19 Uroplasty is a company established in the Netherlands which develops, manufactures and sells products in the field of urology and urogynaecology, including the product with the commercial designation 'Macroplastique-implantaat' (Macroplastic implant) which is used in the treatment of stress incontinence and vesicocoureteral reflux. The product is supplied ready for use to doctors and hospitals. For that purpose, Uroplasty imports polydimethilsiloxane flakes produced in the United States.

20 Polydimethilsiloxane is a silicone in the form of an elastomer, the flakes of which it consists varying in structure and dimension, ranging from 0.01 mm to around 5.0 mm. They are packed under sterile conditions and 'sealed' in bags with a total weight of around 1 kg. After its importation, the packaging is opened using a sterile scalpel in a sterile area of premises belonging to Uroplasty.

21 The flakes are next put in single-use syringes, then combined with a sterile hydrogel made up of a mixture in the form of a polyvinylpyrrolidone and water gel.

22 The gel ensures that the flakes are distributed evenly in the liquid and pass easily through the hypodermic needle. The hydrogel is evacuated from the body via the kidneys whereas the flakes persist and are held in place by the connective tissue which has developed for that purpose.

23 On 22 February 2001, Uroplasty applied to the Inspector for the issue of a binding tariff information ('BTI') for 'polydimethilsiloxane in the form of white flakes', which was analysed as such by the revenue department's laboratory. Uroplasty sought its classification under subheading 9021 90 00 of the CN.

24 On 26 April 2001, the Inspector issued a BTI, with No NL-RTD-2001-000743, classifying the product under subheading 3910 00 00 of the CN. Uroplasty objected to that classification.

25 In addition, another BTI with No NL-RTD-2001-000909, which was provided to Uroplasty on 7 May 2001, concerns the syringes filled with a suspension of the product in question in a hydrogel. They were classified by the Inspector under subheading 9021 90 90 of the CN.

26 On 2 October 2001, the Inspector rejected Uroplasty's objection to the BTI No NL-RTD-2001-000743.

27 On 13 November 2001, Uroplasty brought an action before the Tariefcommissie, now the Customs Chamber of the Gerechtshof te Amsterdam (Regional Court of Appeal, Amsterdam), against the Inspectors' rejection.

28 Uroplasty claims that polydimethilsiloxane is identifiable by its special design and purity. It is a medical product the high price of which is due to its manufacturing

process and patent. Polydimethilsiloxane corresponds to the description of 'silicones in primary forms' within the terms of Note 6(b) to Chapter 39 of the CN. However, since Note 2(r) to Chapter 39 states that the Chapter does not cover articles of Chapter 90 (which include, among others, medical or surgical instruments and apparatus), it is not classified under Chapter 39.

29 While the polydimethilsiloxane is certainly the active ingredient, it is used exclusively in the hypodermic syringe. It must therefore, pursuant to Note 2(b) to Chapter 90, be classified under subheading 9021 90 90 of the CN as a 'part' of the ready-for-use product.

30 On the other hand, according to the Inspector, the polydimethilsiloxane cannot be a part of a product since it is presented in the form of flakes which, having regard to Note 6(b) to Chapter 39 of the CN is a common form. The flakes are not present as such in the end product. They are a semi-finished product coming within heading 3910 of the CN as silicones in primary form. Only their mixture with a hydrogel enables them to become an implant which constitutes a new product.

31 Furthermore, the composition and presentation of the polydimethilsiloxane corresponds to that in the notes to Chapter 39 of the CN. Likewise, the price of that product is irrelevant to its classification as are its purity and sterility. Its end use is also irrelevant for the purposes of its classification as silicone.

32 The Inspector added that, since the polydimethilsiloxane is imported and processed under sterile conditions, it is possible that it may be used solely for medical purposes. Finally, since the product remains in the body, it cannot be classified under Chapter 30 of the CN as a pharmaceutical product.

33 It is clear from the referring court's description that the mixture of polydimethilsiloxane with the hydrogel is temporary and intended solely to make it suitable for injection into the human body without changing its characteristics and properties. The polydimethilsiloxane is to be regarded as a finished product in that it is developed and intended for use as a medical/surgical implant.

34 Having regard to the preceding considerations, the referring court considers that the polydimethilsiloxane comes within heading 9021 of the CN but is uncertain, nevertheless, about the general classification rules which are to be applied and the subheading under which it should be classified.

35 Also, pursuant to the general classification rules set out, that court considers that the polydimethilsiloxane should be classified under subheading 9021 30 of the CN and, more precisely, pursuant to General Rule No 6 for the interpretation of the CN, under subheading 9021 30 90.

36 However, if classification under Chapter 90 is not possible, the polydimethilsiloxane cannot be regarded as silicone in primary form within the meaning of heading 3910, but must, on account of its production process, be classified as a product under heading 3926 as being 'other articles' of materials of heading 3910.

37 It was in those circumstances that the Gerechtshof te Amsterdam decided to stay the proceedings and to refer to the Court the following questions for a preliminary ruling:

'1. (a) Must heading 9021 of the [CN] be interpreted as meaning that a product consisting of sterile, white flakes of polydimethilsiloxane, specially developed and intended solely for use as a medical/surgical implant, can be classified under that heading?

(b) If so, under which subheading of heading 9021 of the [CN] must the product be classified?

2. If heading 9021 is not possible in this case, is the product eligible for classification under heading 3926 of the [CN]?

3. If not, classification under which other heading results from the interpretation of the [CN]?'

The questions referred

38 By its first question, the referring court is asking, in essence, whether or not a product such as that in question in the main proceedings which, because of its

nature, quality and form, is specially developed and used solely for a medical application, can be classified under heading 9021 of the CN, and, if so, within which subheading does the product come.

39 The Netherlands Government submits that the polydimethilsiloxane must be classified under heading 3910 of the CN relating to silicones in primary forms, whereas the Commission of the European Communities suggests classification under heading 3004 of the CN relating to medicaments. Finally, Uroplasty suggests classification under subheading 9021 90 90 of the CN relating to other orthopaedic appliances implanted in the body.

40 According to settled case-law, in the interests of legal certainty and ease of verification, the decisive criterion for the classification of goods for customs tariff purposes is in general to be found in their objective characteristics and properties as defined in the wording of the relevant heading of the CN and of the notes to the sections or chapters (see, in particular, Case C-42/99 *Eru Portuguesa* [2000] ECR I-7691, paragraph 13; Case C-495/03 *Intermodal Transports* [2005] ECR I-8151, paragraph 47; Case C-445/04 *Possehl Erzkontor* [2005] ECR I-10721, paragraph 19; and Case C-500/04 *Proxxon* [2006] ECR I-1545, paragraph 21).

41 The Explanatory Notes to the CN and those to the HS are an important aid for interpreting the scope of the various tariff headings but do not have legally binding force. The wording of those Notes must therefore be consistent with the provisions of the CN and cannot alter their scope (see, in particular, Case C-130/02 *Krings* [2004] ECR I-2121, paragraph 28, Case C-467/03 *Ikegami* [2005] ECR I-2389, paragraph 17, and *Proxxon* paragraph 22).

42 For the purposes of classification under the appropriate heading, it is important, finally, to recall that the intended use of a product may constitute an objective criterion in relation to tariff classification if it is inherent in the product, and such inherent character must be capable of being assessed on the basis of the product's objective characteristics and properties (see *Krings* paragraph 30, *Ikegami*, paragraph 23, and Proxxon, paragraph 31).

43 In this case, as the Advocate General observed in paragraph 48 of her Opinion, the polydimethilsiloxane could be classified, either according to its essential characteristics, or according to its objective purpose under one of headings 3910, 3926, 3004 or 9021 of the CN.

44 As a silicone elastomer in flakes the polydimethilsiloxane is presented in the form referred to in Notes 3 and 6(b) to Chapter 39 of the CN. However, contrary to the Netherlands Government's submission, silicone elastomer in flakes cannot be classified under heading 3910 as a 'primary form'.

45 As the Advocate General pointed out in paragraph 50 of her Opinion, the concept of 'primary form', in the light of the structure of Chapter 39 of the CN and of Note 1(f) to Chapter 90 of the CN, encompasses only silicones intended to be processed. Primary forms are raw materials which are particularly suited to processing and are intended for it.

46 Polydimethilsiloxane presents the characteristics and objective properties of a product which, first, is sterile and, second, after being implanted in the body retains

its particular dimensions, varying from 0.01 mm to around 5.0 mm. The product is specially developed and intended only to be implanted in the body for the treatment of sphincter weakness. It follows that polydimethilsiloxane is a finished product which, as such, cannot therefore be classified under heading 3910 of the CN.

47 In addition, contrary to Uroplasty's submission, it must be held that the polydimethilsiloxane is not a part or accessory of a machine, instrument of apparatus within the meaning of Note 2(b) to Chapter 90 of the CN.

48 In view of the foregoing, the polydimethilsiloxane has a therapeutic profile. However, having regard to the terms of General Rule No 1 for the interpretation of the CN and contrary to the Commission's submission, the polydimethilsiloxane cannot be classified under heading 3004 of the CN as 'medicaments'.

49 It follows from the terms of heading 3004 of the CN that the classification of a product thereunder is conditional on its presentation in measured doses or packed for retail sale. The polydimethilsiloxane is imported in bags of a total weight of 1 kg. Its packaging in unit form in syringes for single use results from an operation carried out after importation. It follows that the polydimethilsiloxane, as it is presented to customs, does not come within the definition given in heading 3004 of the CN.

50 Since the product cannot be classified under the preceding headings, it must be determined whether, as the referring court considers, a finished product which is

developed and intended for use as a medical/surgical implant can be classified under heading 9021 of the CN.

51 It is appropriate to point out that the terms of heading 9021 of the CN mention, among others, appliances to be implanted in the body.

52 As the Advocate General explained in paragraph 61 of her Opinion, the term 'appliance' is not restricted to the technical structure of a product. It must therefore be held that the term includes products which are intended to compensate for a defect by being implanted in the body within the meaning of heading 9021 of the CN.

53 It follows from paragraph 46 of this judgement that the characteristics and objective properties of the polydimethilsiloxane are those of a finished product, which is specially developed and intended only to be implanted in the body. By lodging itself definitively in the defective muscle, polydimethilsiloxane enables connective tissues to develop which compensate for the sphincter weakness. It follows that the product must be regarded as an appliance to be implanted in the body within the meaning of heading 9021 of the CN.

54 As regards, secondly, the subheading of heading 9021of the CN under which the polydimethilsiloxane is to be classified, it must be observed that it follows from General Rule No 6 for the interpretation of the CN that the classification of goods in the subheadings of a heading is to be determined according to the terms of those subheadings and any related subheading notes.

55 It is stated in paragraph 46 of this judgment that after the polydimethilsiloxane is implanted in the body, the development of connective tissues results in the strengthening of the sphincter which is incapable of functioning on its own. The function of the polydimethilsiloxane, as pointed out in paragraph 53 of this judgment, is not therefore to replace a defective muscle in the human body as would a prosthesis, but to enable new tissues to develop which palliate the problems connected with incontinence. It follows that, as the referring court correctly considers, the function of the flakes does not correspond to the terms of subheading 9021 30 90 of the CN.

56 It also follows from paragraphs 52 and 53 of this judgment that the product is an appliance to be implanted in the body which, since it does not come within any of the other subheadings of heading 9021 of the CN, must therefore be classified under subheading 9021 90 90 of the CN as 'other appliances'.

57 Having regard to all the foregoing considerations, the reply to the first question must be that Annex I to Regulation No 2658/87, as amended by Regulation No 2388/2000, is to be interpreted as meaning that a product, such as the polydimethilsiloxane, made up of sterile flakes, specially developed and intended only to be implanted in the body for the treatment of a condition and which is packaged at the time of its presentation to customs in l kg bags, is to be regarded as an appliance to be implanted in the body which must be classified under heading 9021 of the CN. Since the purpose of such a product is not to replace an organ but to enable a defective muscle to create connective tissues, it must be classified under subheading 9021 90 90.

58 In the light of the reply to the first question, there is no need to answer the others.

Costs

59 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 (Second Chamber) hereby rules:

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 Regulation (EC) No 2388/2000 of 13 October 2000, is to be interpreted as meaning that a product, such as the polydimethilsiloxane, made up of sterile flakes, specially developed and intended only to be implanted in the body for the treatment of a condition and which is packaged at the time of its presentation to customs in 1 kg bags, is to be regarded as an appliance to be implanted in the body which must be classified under heading 9021 of the Combined Nomenclature. Since the purpose of such a product is not to replace an organ but to enable a defective muscle to create connective tissues, it must be classified under subheading 9021 90 90 of the Combined Nomenclature.

[Signatures]