Reports of Cases

JUDGMENT OF THE COURT (Eighth Chamber)

26 April 2017 *

(Reference for a preliminary ruling — Common Customs Tariff — Tariff headings — Classification of goods — Implant screws intended to be inserted in the human body for the treatment of fractures or the stabilisation of prostheses — Combined Nomenclature — Heading 9021 — Implementing regulation (EU) No 1212/2014 — Validity)

In Case C-51/16,

REQUEST for a preliminary ruling under Article 267 TFEU from the Rechtbank Noord-Holland (District Court, North Holland, Netherlands), made by decision of 25 January 2016, received at the Court on 28 January 2016, in the proceedings

Stryker EMEA Supply Chain Services BV

v

Inspecteur van de Belastingdienst/Douane kantoor Rotterdam Rijnmond,

THE COURT (Eighth Chamber),

composed of M. Vilaras, President of the Chamber, M. Safjan and D. Šváby (Rapporteur), Judges,

Advocate General: P. Mengozzi,

Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 12 January 2017,

after considering the observations submitted on behalf of:

— Stryker EMEA Supply Chain Services BV, by H. de Bie, advocaat,

— the Netherlands Government, by M.K. Bulterman and A.M. de Ree, acting as Agents,

— the European Commission, by A. Caeiros and S. Noë, acting as Agents,

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

gives the following

* Language of the case: Dutch.

Judgment

1 This request for a preliminary ruling concerns the interpretation of heading 9021 of the Combined Nomenclature ('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 Implementing Regulation (EU) No 1101/2014 of 16 October 2014 (OJ 2014 L 312, p. 1, 'Regulation No 2658/87'), and the validity of Commission Implementing Regulation (EU) No 1212/2014 of 11 November 2014 concerning the classification of certain goods in the Combined Nomenclature (OJ 2014 L 329, p. 3).

2 The request has been made in proceedings between Stryker EMEA Supply Chain Services BV ('Stryker') and the Inspecteur van de Belastingdienst/Douane kantoor Rotterdam Rijnmond (Inspector of the Tax and Customs Administration, Rotterdam Rijnmond office, 'the customs authorities') concerning the tariff classification of three types of medical implant screw.

Legal context

Classification of goods

3 The CN was established by Regulation No 2658/87. It is based on the International Convention on the Harmonised Commodity Description and Coding System ('the HS'), 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). The CN takes six-digit headings and subheadings from the HS. Only the seventh and eighth digits form subdivisions specific to the CN.

4 Regulation No 2658/87 authorises the European Commission to clarify the content of a tariff heading. Annex I to Regulation No 2658/87 is updated by the Commission on an annual basis. By Implementing Regulation No 1101/2014, the Commission adopted a full version of the CN, applicable from 1 January 2015.

5 In that regard, the CN contains in Part One, Section I, A, a set of general rules for the interpretation of the nomenclature. That section provides:

'Classification of goods in the Combined Nomenclature shall be governed by the following principles:

1. The titles of sections, chapters and sub-chapters are provided for ease of reference only; for legal purposes, classification shall be determined according to the terms of the headings and any relative section or chapter notes …

…

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 … For the purposes of this rule, the relative section and chapter notes also apply, unless the context requires otherwise.

6 Part Two of the CN, entitled 'Schedule of Customs Duties', includes Section XV, entitled 'Base metals and articles of base metal'. Notes 2 and 3 of that section are worded as follows:

'2. Throughout the [CN], the expression "parts of general use" means:
(a) articles of heading 7307, 7312, 7315, 7317 or 7318 and similar articles of other base metal;

…

3. Throughout the [CN], the expression “base metals” means: … steel, … titanium, …’

7 Section XV of the CN includes Chapter 73, entitled ‘Articles of iron or steel’. This chapter includes, inter alia, heading 7318, which is worded as follows:

‘Screws, bolts, nuts, coach screws, screw hooks, rivets, cotters, cotter-pins, washers (including spring washers) and similar articles, of iron or steel.’

8 The HS includes an explanatory note on heading 7318, which provides the following clarification:

‘All these articles are normally threaded in the finished state, with the exception of some bolts which may sometimes be secured by means of a cotter pin, for example. They enable the assembly of two or more parts between them, in such a way that it is possible to separate them subsequently without deterioration.

… metal screws are cylindrical in shape and their thread is very tight and slightly angled; [they] are either with a non-slotted head (with sides) – they are therefore fastened with the aid of a wrench –, or with a slotted head or with a socket.

… metal screws of all kinds are [included] under this heading, regardless of their shape and their use, including [those] of specific shape such as U-bolts (flange bolts), bolts without heads consisting of cylindrical shanks threaded at one end or along the entire length, stud bolts, composed of a short shank threaded at each end.

…

Wooden screws are distinguished … from metal screws by their truncated cone shape and by the fact that they are fitted with a cutting thread which, by rotating, clears its passage into the material. In addition, wooden screws are fitted, in the majority of cases, with a slotted head or a head with a socket and are always used without a nut.

…’

9 Section XV of the CN also includes Chapter 81, entitled ‘Other base metals; cermets; articles thereof’. As part of that chapter, heading 8108 reads as follows:

‘Titanium and articles thereof, including waste and scrap

…

8108 90 — Other

…

8108 90 90 — — Other’

10 Part Two of the CN includes Section XVIII, entitled ‘Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; clocks and watches; musical instruments; parts and accessories thereof’.

11 Section XVIII of the CN contains Chapter 90, entitled ‘Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof’.

12 Note 1 to Chapter 90 states:

‘1. 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 plastics (Chapter 39);

…’

13 The explanatory note to the HS on Chapter 90 provides the following clarification:

‘This chapter covers a very diverse set of instruments and appliances of which, as a general rule, the essential characteristics are the finish of their manufacture and their high degree of precision, which leads, for most of them, to them being used, in particular, … for medical purposes.

…’

14 Heading 9021 is structured as follows:

‘9021 10 — Orthopaedic or fracture appliances

…

9021 10 90 — — Splints and other fracture appliances

…

9021 90 — Other:

…

9021 90 90 — — Other’.

15 The explanatory note to the HS on heading 9021 states:

‘Splints and other fracture appliances are used for holding affected body parts (for the purposes of extension or protection), or for setting fractures. …

Among those appliances, some may be attached to the patient himself (as is the case for, inter alia, cradles of metallic wires, of zinc, of wood, etc., for holding limbs, plaster bandage splints for the elbow, for example, appliances for the ribcage, etc.) or be adapted to a bed, a table or another support (protective bed cradles, so-called extension fracture apparatus with tubular mounts intended to replace cradles or splints, etc.).

Subject to the provisions of note 1(f) to this chapter, the heading also includes plates, nails, etc., which are inserted inside the human body by surgeons to hold together the two parts of a broken bone or for similar treatment of fractures.’

16 The explanatory note to the CN on subheading 9021 39 90 states:

‘This subheading includes:

1. plates which remain in the body (for example, to replace part of a bone or an entire bone);

…’

Implementing Regulation No 1212/2014

17 Implementing Regulation No 1212/2014 classifies a medical implant screw in accordance with the information set out in the Annex thereto.

18 Such a screw is thus described in that annex:

‘A solid, cylindrical, threaded product made of extra hard, colour finished titanium alloy, of a length of approximately 12 mm.

The product has a shank with a constant outer diameter of 3 mm and a head. The shank is wholly threaded with an asymmetrical thread. The head is threaded (allowing it to lock into a compression plate in fixation systems) with a recessed socket drive.

The product corresponds to the ISO/TC 150 standards for implant screws and is presented for use in the field of trauma surgery for setting fractures. It is to be installed in the body using specific tools.

At importation, it is presented in a sterilised packing. The product is marked with a number and therefore traceable throughout production and distribution.’

19 According to the statement of reasons in the Annex to that regulation, classification is determined by general rules 1 and 6 for the interpretation of the CN, note 2(a) to Section XV, note 3 to Section XV, note 1(f) to Chapter 90 and by the wording of CN headings and subheadings 8108, 8108 90 and 8108 90 90.

20 That statement of reasons continues as follows:

‘Due to its objective characteristics, the product entirely corresponds to a screw of base metal, even though it is intended for use in trauma surgery. Regardless of their actual use, screws of base metal are, in accordance with note 2(a) to Section XV, parts of general use. Classification under heading 9021 as splints and other fracture appliances is therefore excluded by virtue of note 1(f) to Chapter 90.

The product is therefore to be classified under CN code 8108 90 90 as other articles of titanium.’

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

21 The dispute in the main proceedings concerns the repeal of three Binding Tariff Informations issued to Stryker by the customs authorities for three types of implant screws intended for insertion in the human body for the treatment of fractures or the stabilisation of prostheses. It is apparent from the order for reference that those screws have the following common characteristics:

— a diameter of 6.5 mm, 6.5 mm and 4 mm, respectively;

— a length of 25 mm, 50 mm and 16 mm, respectively;

— a specially designed screw thread;

— a screw head provided with a socket;

— they are individually packaged in a box together with an instruction manual;

— they are supplied in a sterilised or non-sterilised condition.

22 It is also apparent from the order for reference that those screws have specific characteristics. One of them is made of a titanium alloy, whereas the other two are made of stainless steel. Furthermore, the stainless steel screws are for single-use. Finally, the titanium alloy screw is used for the fixation of an artificial joint, whereas the stainless steel screws are used for the temporary fixation and stabilisation of bones.

23 In view of those characteristics, on the basis of the Binding Tariff Informations issued by the customs authorities, the latter classified those three types of medical implant screw under CN heading 9021 90 90.

24 Following the publication of Implementing Regulation No 1212/2014, the customs authorities repealed those tariff informations by decision of 6 January 2015. The repeal was justified on the ground that, for the purposes of that regulation, a 'screw intended for use in surgery, due to its objective characteristics and properties, should be classified as a part of general use'.

25 Following an unsuccessful complaint lodged with the customs authorities, Stryker brought an action against the repeal decision before the referring court.

26 In support of its action, Stryker claims, in essence, that, given the objective characteristics and properties of the implant screws, including their inherent intended purpose, there is no question of their being 'regular' screws as referred to in CN heading 7318. In addition, Stryker submits that Implementing Regulation No 1212/2014 is invalid because it classified the medical implant screws at issue purely on the basis of their external characteristics, disregarding the inherent intended purpose of those screws, which is contrary to the case-law of the Court of Justice.

27 The customs authorities maintain that the screws at issue in the main proceedings display great similarities to the screw described in that regulation and must therefore be classified as 'parts of general use'.

28 The referring court is of the view that, in the first place, having regard to their objective characteristics and properties, including their inherent intended purpose, the implant screws at issue in the main proceedings are eligible for classification under CN heading 9021.

29 Such a classification results from the objective characteristics and properties of the medical implant screws at issue in the main proceedings. The referring court states, in that regard, that those screws are designed, manufactured and sold as orthopaedic articles for the treatment of fractures in bone structures or the stabilisation of prostheses, that they are supplied with an instruction manual for the surgeon, that they can be inserted in the body only by means of specific medical tools, that the material used (steel or titanium alloy) is specifically designed to minimise the risk of rejection, that the screw thread of such screws is deeper than for 'normal' screws, that the screw head is designed to reduce the risk of inflammation, that they comply with the standards laid down by the International Organisation for Standardisation guaranteeing the quality of medical products and, finally, that they are traceable with regard to recall actions.

30 It is also apparent from the order for reference that the screws at issue in the main proceedings are individually packaged in a small box and may be supplied sterile.

31 Moreover, the referring court states that the implant screws at issue in the main proceedings are solely intended to be inserted in the human body for the treatment of fractures or the stabilisation of prostheses.

32 In the second place, the referring court observes that the screws at issue in the main proceedings correspond to the screw described in the Annex to Implementing Regulation No 1212/2014, which precludes classification under CN heading 9021. The referring court infers from that regulation that, as regards a product falling under 'parts of general use' within the meaning of note 2 to Section XV of the CN, the intended purpose of a product cannot be taken into account for the purposes of its tariff classification.

33 In the third place, the referring court stresses the importance placed by the Commission, which adopted Implementing Regulation No 1212/2014, on the implant screw's outward appearance for the purpose of its classification. That court recognises that, at first sight, such an implant screw resembles a 'normal' screw. However, it observes that a closer inspection reveals that such implant screws have a unique character distinguishing them from normal screws. In that regard, it states that the thread of the implant screws is deeper than that of a normal screw and that the socket in the screw head is not of the kind found in a universal tool, but is tailored to specific medical tools.

34 In those circumstances, the referring court has doubts about whether the Commission exceeded its powers by limiting the scope of CN heading 9021 to the reasons provided in the Annex to Implementing Regulation No 1212/2014.

35 In that context, the Rechtbank Noord-Holland (District Court, North Holland, Netherlands) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Should heading 9021 of the CN be interpreted as meaning that implant screws [such as those at issue in the main proceedings] which are solely intended to be inserted in the human body for the treatment of bone fractures or the stabilisation of prostheses may be classified thereunder?

(2) Is Implementing Regulation No 1212/2014 … valid?'

Consideration of the questions referred

The first question

36 By its first question, the referring court asks, in essence, whether the CN must be interpreted as meaning that medical implant screws such as those at issue in the main proceedings, which are solely intended to be inserted in the human body for the treatment of bone fractures or the stabilisation of prostheses, fall under CN heading 9021.

37 Stryker maintains that, in any event, the three types of screw at issue in the main proceedings fall under CN heading 9021, regardless of whether they are made of steel or titanium. That classification is justified, in essence, first, by the inherent intended purpose of those screws and, secondly, by the objective characteristics specific to those screws, characteristics which the Commission incorrectly failed to regard as relevant.

38 On the other hand, according to the Commission, the decisive criterion is the analysis of the external objective characteristics of those screws. On that basis, the Commission attaches key importance to the fact that, in its view, the screws at issue in the main proceedings 'entirely correspond' to ordinary screws. Therefore, the Commission claims that the purpose of those screws, namely, their use in trauma surgery, is irrelevant. The screws at issue in the main proceedings should therefore be regarded as 'parts of general use of base metal' and cannot, in accordance with note 1(f) to Chapter 90 of the CN, be classified under heading 9021 thereof. Accordingly, the Commission proposes the classification of the screws at issue in the main proceedings according to their physical composition, namely under CN heading 7318 for the steel screws and under CN heading 8108 for the titanium alloy screws.

39 In this regard, it should be recalled that the Court has consistently held that, in the interests of legal certainty and ease of verification, the decisive criterion for the tariff classification of goods is in general to be sought in their objective characteristics and properties, as defined in the wording of the relevant CN heading and of the notes to the sections or chapters (see, in particular, judgment of 18 May 2011, *Delphi Deutschland*, C-423/10, EU:C:2011:315, paragraph 23).

40 In addition, in accordance with equally well-established case-law, the intended use of a product may constitute an objective criterion for classification if it is inherent in the product, and that inherent character must be capable of being assessed on the basis of the product's objective characteristics and properties (see, in particular, judgment of 22 December 2010, *Premis Medical*, C-273/09, EU:C:2010:809, paragraph 43).

41 In the present case, it is apparent from the factual findings made by the referring court, as recalled in paragraph 29 of the present judgment, that the screws at issue in the main proceedings have a specifically shaped head especially adapted for medical tools used for stabilisation, a thread specifically designed to be inserted into bone and to reduce the risk of inflammation and are specially treated to minimise the risk of rejection.

42 Furthermore, it is common ground those screws are specifically developed to be inserted in the body in order to stabilise, respectively, either an artificial joint or bones or parts of bones.

43 It should also be noted that goods such as those at issue in the main proceedings are not referred to expressly either in the wording of the CN headings or the notes to the sections or chapters of the CN.

44 It must nevertheless be observed that the wording of CN heading 9021 mentions, inter alia, splints and other fracture appliances.

45 In that regard, the explanatory notes to the CN and those to the HS provide useful indications for the tariff classification of goods such as those at issue in the main proceedings, even though such explanatory notes serve as an aid to interpretation and are not legally binding (see judgment of 27 April 2006, *Kawasaki Motors Europe*, C-15/05, EU:C:2006:259, paragraph 37 and the case-law cited).

46 In the first place, the explanatory note to the HS on Chapter 90, as recalled in paragraph 13 of the present judgment, states that that chapter covers goods of which the essential characteristics are the finish of their manufacture and their high degree of precision, so that most of those goods are used, in particular, for medical purposes.

47 Therefore, goods of which the essential characteristics are the finish of their manufacture and their high degree of precision, which distinguish them from ordinary goods, are to be classified under CN heading 9021 (see, to that effect, judgment of 7 November 2002, *Lohmann and Medi Bayreuth*, C-260/00 to C-263/00, EU:C:2002:637, paragraph 37).

48 Next, according to the second paragraph of the explanatory notes to the HS on heading 9021, splints and other fracture appliances 'are used for holding affected body parts … or for setting fractures'. Also falling under that heading are 'plates, nails, etc., which are inserted inside the human body by surgeons to hold together the two parts of a broken bone or for similar treatment of fractures'.

49 Finally, the explanatory note on CN subheading 9021 39 90 states that 'plates which remain in the body (for example, to replace part of a bone or an entire bone)' fall under that heading.

50 It follows from the foregoing that goods which are characterised by the finish of their manufacture and their high degree of precision and are capable of being inserted in the body for the purpose of holding affected body parts or setting fractures, characteristics which, consequently, distinguish them from ordinary goods, must be classified under CN heading 9021.

51 In the second place, the criteria for distinguishing simple or ordinary products from those serving a medical purpose include the method of manufacture of the product concerned and the specificity of its purpose (see, to that effect, judgment of 7 November 2002, *Lohmann and Medi Bayreuth*, C-260/00 to C-263/00, EU:C:2002:637, paragraph 39).

52 Concerning the method of manufacture of the product, it is apparent from the factual findings made by the referring court that the medical implant screws at issue in the main proceedings are designed in such a way that, because of the specific shape of their head, they can be inserted in the body only by means of specific medical tools and not by means of regular tools. Furthermore, the stainless steel or titanium material used for those screws is specifically designed to minimise the risk of rejection.

53 As regards the specificity of the purpose of the product, it is also apparent from the order for reference that the purpose of the medical implant screws at issue in the main proceedings is solely to hold together two parts of a broken bone or to stabilise an artificial joint.

54 It is clear that goods such as those at issue in the main proceedings are distinguished from ordinary goods by the finish of their manufacture and their high degree of precision, bearing in mind their method of manufacture and the specificity of their purpose. There is therefore no need, contrary to what the Commission submits, to attach key importance to the outward appearance of medical implant screws such as those at issue in the main proceedings.

55 Therefore, it follows from the objective characteristics and properties of medical implant screws such as those at issue in the main proceedings that such goods are capable of falling under CN heading 9021.

56 In the third place, since, as is apparent from paragraphs 39 to 55 of the present judgment, screws such as those at issue in the main proceedings must, bearing in mind their objective characteristics and properties, be classified under CN heading 9021 as fracture appliances, they cannot be classified under CN headings 7318 or 8108 and do not fall under 'parts of general use' within the meaning of note 1(f) to Chapter 90 and note 2(a) to Section XV of the CN.

57 In the light of all the foregoing considerations, the answer to the first question is that the CN must be interpreted as meaning that medical implant screws such as those at issue in the main proceedings fall under CN heading 9021 as those goods have characteristics which distinguish them from ordinary goods by the finish of their manufacture and their high degree of precision, as well as by their method of manufacture and the specificity of their purpose. In particular, the fact that medical implant screws such as those at issue in the main proceedings can be inserted in the body only by means of specific medical tools, not by means of ordinary tools, is a characteristic to be taken into consideration in order to distinguish those medical implant screws from ordinary products.

The second question

58 By its second question, the referring court asks, in essence, whether Implementing Regulation No 1212/2014 is valid.

59 It is apparent from the case-law, first, that a classification regulation is adopted by the Commission when the classification in the CN of a particular product is such as to give rise to difficulty or to be a matter for dispute and, secondly, that such a regulation is of general application in so far as it does not apply to an individual trader but, in general, to products identical to the one thus classified (see judgment of 19 February 2009, *Kamino International Logistics*, C-376/07, EU:C:2009:105, paragraph 63).

60 It should be noted, as observed by the Commission at the hearing, that the product classified by Implementing Regulation No 1212/2014 is not identical to the medical implant screws at issue in the main proceedings, in view of their objective external characteristics. The screw described in the Annex to that regulation has, inter alia, the following characteristics: a length of approximately 12 mm, a shank with a constant outer diameter of 3 mm, a threaded head and an asymmetrical thread. By contrast, the screws at issue in the main proceedings, as described in the order for reference, have longer lengths, shanks with a larger diameter, non-threaded heads and non-asymmetric threads.

61 Admittedly, according to case-law, the application by analogy of a classification regulation to products similar to those covered by that regulation facilitates consistent interpretation of the CN and the equal treatment of traders (judgment of 4 March 2004, *Krings*, EU:C:2004:122, paragraph 35).

62 However, such an application by analogy is neither necessary nor possible where the Court, by its answer to a question referred for a preliminary ruling, has provided the referring court with all the information necessary to classify a product under the appropriate CN heading.

63 In those circumstances, there is no need to address the second question.

Costs

64 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 (Eighth Chamber) hereby rules:

Heading 9021 of the Combined Nomenclature of the Common Customs Tariff 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, as amended by Commission Implementing Regulation (EU) No 1101/2014 of 16 October 2014, must be interpreted as meaning that medical implant screws such as those at issue in the main proceedings fall under that heading as those goods have characteristics which distinguish them from ordinary goods by the finish of their manufacture and their high degree of precision, as well as by their method of manufacture and the specificity of their purpose. In particular, the fact that medical implant screws such as those at issue in the main proceedings can be inserted in the body only by means of specific medical tools, not by means of ordinary tools, is a characteristic to be taken into consideration in order to distinguish those medical implant screws from ordinary products.

[Signatures]