ORDER OF THE COURT (First Chamber)

19 January 2005 *

In Case C-206/03,

REFERENCE for a preliminary ruling under Article 234 EC from the High Court of Justice of England and Wales, Chancery Division (United Kingdom), made by decision of 7 December 2000, registered at the Court on 14 May 2003, in the proceedings

Commissioners of Customs & Excise

v

SmithKline Beecham plc,

* Language of the case: English.

THE COURT (First Chamber),

composed of P. Jann (Rapporteur), President of the Chamber, N. Colneric, K. Schiemann, E. Juhász and E. Levits, Judges,

Advocate General: A. Tizzano,
Registrar: R. Grass,

the national court having been informed of its intention to give its decision by reasoned order pursuant to Article 104(3) of its Rules of Procedure,

the persons referred to in Article 23 of the Statute of the Court of Justice having been invited to submit observations in that regard,

after hearing the Advocate General,

makes the following

Order

1 This reference for a preliminary ruling concerns two questions on the interpretation of the Combined Nomenclature ('CN') contained 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 2086/97 of 4 November 1997 (OJ 1997 L 312, p. 1), and of Article 12(5) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ 1997 L 302, p. 1), as amended by Regulation (EC) No 82/97 of the European Parliament and of the Council of 19 December 1996 (OJ 1997 L 17, p. 1, 'the Customs Code').

2 Those questions were raised in proceedings between the Commissioners of Customs and Excise and SmithKline Beecham plc ('SmithKline') concerning the tariff classification of nicotine patches intended to help their users to stop smoking.

The legal background

The relevant provisions of international law

3 The international convention concluded at Brussels on 14 June 1983 established for the Council for Customs Cooperation, now the World Customs Organisation ('WCO'), a harmonised system for the description and coding of commodities ('the harmonised system of the WCO').

4 That convention and the protocol of amendment thereto of 24 June 1986 were approved in the name of the Community by Council Decision 87/369/EEC of 7 April 1987 (OJ 1987 L 198, p. 1).

5 The harmonised system of the WCO served as a basis for the drawing up of the CN by the Community legislature. The CN repeats the headings and subheadings to six figures, only the seventh and eighth figures forming subdivisions particular to it.

The relevant provisions of Community law

The basic rules

6 The CN is divided into titles, sections and chapters.

7 In Title I, the CN lays down rules for its interpretation.

8 According to General Rule 1, '... 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 to the following provisions'.

9 Under General Rule 3(a), when goods are, prima facie, classifiable under two or more headings, 'the heading which provides the most specific description shall be preferred to headings providing a more general description. ...'

10 Title II, Section VI, Chapter 30 of the CN covers 'pharmaceutical products' and Chapter 38 'miscellaneous chemical products'.

11 In Chapter 30 of the CN heading 3004 covers 'medicaments (excluding goods of heading Nos 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or in packings for retail sale'.

12 Heading 3824 of Chapter 38 of the CN covers 'prepared binders for foundry moulds or cores; chemical products and preparations of the chemical or allied industries (including those consisting of mixtures of natural products), not elsewhere specified or included; residual products of the chemical or allied industries, not elsewhere specified or included'.

13 In accordance with Note 1 to Chapter 38, that 'chapter does not cover ... medicaments'.

Rules on procedure

14 According to Article 12(1) of the Customs Code, '[t]he customs authorities shall issue binding tariff information or binding origin information on written request, acting in accordance with the committee procedure'.

15 Article 12(5) provides:

'Binding information shall cease to be valid:

(a) in the case of tariff information:

(i) where a regulation is adopted and the information no longer conforms to the law laid down thereby;

(ii) where it is no longer compatible with the interpretation of one of the nomenclatures referred to in Article 20(6):

— at Community level, by reason of amendments to the explanatory notes to the combined nomenclature or by a judgment of the Court of Justice of the European Communities,

— at international level, by reason of a classification opinion or an amendment of the explanatory notes to the Nomenclature of the Harmonised Commodity Description and Coding System, adopted by the World Customs Organisation established in 1952 under the name "the Customs Cooperation Council";

(iii) where it is revoked or amended in accordance with Article 9, provided that the revocation or amendment is notified to the holder.

The date on which binding information ceases to be valid for the cases cited in (i) and (ii) shall be the date of publication of the said measures or, in the case of international measures, the date of the Commission communication in the "C" series of the *Official Journal of the European Communities*;

...'

16 Under Article 243 of the Customs Code:

'(1) Any person shall have the right to appeal against decisions taken by the customs authorities which relate to the application of customs legislation, and which concern him directly and individually.

...

(2) The right of appeal may be exercised:

(a) initially, before the customs authorities designated for that purpose by the Member States;

(b) subsequently, before an independent body, which may be a judicial authority or an equivalent specialised body, according to the provisions in force in the Member States.'

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

17 SmithKline imports nicotine patches marketed under the name 'Niquitin CQ' ('the product at issue in the main proceedings'), which are designed to be affixed to the body in order to release nicotine at a controlled rate through the skin into the body. They are individually packaged in foil pouches, packed for sale in weekly packs with instructions. The nicotine patches are used in replacement therapy designed to help people stop smoking by reducing the effects of withdrawal.

18 On 8 October 1998 SmithKline applied to the Commissioners for Customs and Excise for binding tariff information in respect of the product at issue in the main proceedings.

19 On 11 October 1998 the Commissioners issued binding tariff information classifying the product under tariff heading 3824 of the CN ('the contested decision').

20 Considering that that classification was incorrect because, in its view, nicotine patches ought to be classified under heading 3004 of the CN, SmithKline challenged that decision before the VAT and Duties Tribunal (United Kingdom), which annulled it. Believing that the classification made in their decision was correct, the Commissioners then brought an appeal against the decision of the VAT and Duties Tribunal before the High Court of Justice of England and Wales, Chancery Division.

21 In those circumstances the High Court decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Is Heading 3004 of [the CN] to be interpreted as including a product in the form of a nicotine patch to be used to assist when trying to stop smoking, consisting of an adhesive plaster impregnated with nicotine which is absorbed through the skin, presented in a foil pack?

(2) In circumstances where

(a) a customs authority of a Member State has given binding tariff information pursuant to Article 12 of [the Customs Code] in respect of a product;

(b) the binding tariff information in question is consistent with a classification opinion previously published by the [WCO] and referred to in a communication by the Commission pursuant to Article 12(5) of the Customs Code;

(c) the importer appeals to a national tribunal pursuant to Article 243 of the Code; and

(d) the Tribunal disagrees with the classification opinion;

is Article 12(5) of the Code to be interpreted as requiring or permitting the Tribunal to annul the customs authority's decision without substituting binding tariff information inconsistent with the classification opinion of the [WCO] but declaring that the product is properly classifiable otherwise than in accordance with that opinion?'

Concerning the questions referred

22 Considering that the answer to be given to the questions referred by the national court may clearly be deduced from case-law, on the one hand, and leaves no room for reasonable doubt, on the other, the Court has, in accordance with Article 104(3) of its Rules of Procedure, decided to give its decision by reasoned order.

23 Before replying to the first question raised, however, it is necessary to settle a question underlying the first, namely, the legal value to be set, in the assessment of a product in the CN, on an opinion of the WCO classifying that product in its harmonised system. If such a classification opinion were binding, the product at issue in the main proceedings would have automatically to be classified in accordance with that opinion.

On the force in law of a classification opinion of the WCO in connection with the classifying of a product in the CN

24 It is to be observed that classification opinions issued by the WCO do not bind the contracting parties, but they do have a bearing on interpretation (see, to this effect, Case 38/75 *Nederlandse Spoorwegen* [1975] ECR 1439, paragraph 24). They must be set aside if their interpretation appears incompatible with the wording of the heading of the CN in question or if it goes manifestly beyond the discretion conferred on the WCO (see, to this effect, *Nederlandse Spoorwegen*, paragraph 25).

25 Likewise, it is settled case-law that the explanatory notes drawn up by the W.C.O. are an important aid to the interpretation of the scope of the various tariff headings but do not have legally binding force (see, inter alia, Case C-201/96 *LTM* [1997] ECR I-6147, paragraph 17; Case C-270/96 *Laboratoires Sarget* [1998] ECR I-1121, paragraph 16; Case C-328/97 *Glob-Sped* [1998] ECR I-8357, paragraph 26; Case C-280/97 *ROSE Elektrotechnik* [1999] ECR I-689, paragraph 16, and Case C-405/97 *Mövenpick Deutschland* [1999] ECR I-2397, paragraph 18).

26 Since the case-law does not draw any distinction between the interpretative value of classification opinions given in respect of the WCO and that of the explanatory notes drafted by that organisation (see, in particular, Case 14/70 *Bakels* [1970] ECR 1001, paragraph 11; Case 12/71 *Henck* [1971] ECR 743, paragraph 7; Case 13/71 *Henck* [1971] ECR 767, paragraph 7; 14/71 *Henck* [1971] ECR 779, paragraph 3; Case 77/71 *Gervais-Danone* [1971] ECR 1127, paragraph 5, and Case 35/75 *Matisa* [1975] ECR 1205, paragraph 2), it is necessary to hold that, just like the explanatory notes,

the WCO's opinions classifying goods in its harmonised system amount, as regards the classification of those goods in the CN, to indications which, while an important aid to the interpretation of the scope of the various tariff headings of the CN, do not have legally binding force.

27 Moreover, contrary to the United Kingdom's argument, the second indent of Article 12(5)(a)(ii) of the Customs Code does not provide that, with regard to the classification of goods in the CN, classification opinions have legally binding force. That provision governs only the specific effects on pre-existing binding tariff information of a new classification opinion adopted by the WCO.

28 In consequence, having regard to the classification in the CN of the product at issue in the main proceedings, an opinion issued by the WCO on the classification of that product in its harmonised system has no legally binding force and is no more than an indication assisting in the interpretation of the scope of the various tariff headings of the CN. If such a classification opinion is contrary to the wording of the heading in the CN, it must therefore be disregarded.

Concerning the first question: the tariff classification

29 By its first question the national court seeks in essence to ascertain whether goods such as the nicotine patches at issue in the main proceedings fall under heading 3004 or heading 3824 of the CN.

30 It is settled case-law 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 (see Case 175/82 *Dinter* [1983] ECR 969, paragraph 10; Case C-459/93 *Thyssen Haniel Logistic* [1995] ECR I-1381, paragraph 8; Joined Cases C-106/94 and C-139/94 *Colin and Dupré* [1995] ECR I-4759, paragraph 22, and *LTM*, paragraph 17).

31 With regard to heading 3004 of the CN, the Court has held that 'medicaments' for the purposes of that heading are products with a clearly defined therapeutic or prophylactic purpose with an effect concentrated on precise functions of the human body (see, to that effect, Case C-177/91 *Bioforce* [1993] ECR I-45, paragraph 12; Case C-404/95 *Bioforce* [1997] ECR I-2581, paragraph 18; *Laboratoires Sarget*, paragraph 28, and *Glob-Sped*, paragraphs 29 and 30).

32 In the circumstances, although the fact that in the Member States in which they are marketed the products in question are authorised to be put on the market as medicaments is not, as is made clear in the general considerations set out in Chapter 30 of the Information from the Commission, published in the *Official Journal of the European Communities* of 15 September 1998, under the title 'Explanatory Notes to the Combined Nomenclature of the European Communities' (OJ 1998 C 287, p. 1), decisive as regards their classification in that chapter, that fact may none the less constitute further evidence that they possess the objective characteristics and properties defined in heading 3004 of the CN (see, to that effect, C-404/95 *Bioforce*, paragraph 16, and *LTM*, paragraphs 23 to 26).

33 With regard to the fact that those products are presented as medicaments or distributed exclusively in pharmacies, it must be borne in mind that there is in neither the wording of heading 3004 nor the notes set out in the introduction to Chapter 30 of the CN for the tariff classification of products in that chapter any reference to either their presentation or places of sale. Accordingly, even if it were possible to regard such factors as relevant, they would not be decisive as regards the classification of the goods in the CN (*LTM*, paragraph 28).

34 On the other hand, the fact that those products are put up in measured doses or that they are packaged for retail sale does constitute, as shown by the actual wording of heading 3004, a condition of the application of that provision.

35 Having regard to the foregoing, it must be held that, for the purposes of classification in the CN, according to the information before the Court, goods such as nicotine patches must be considered to be 'medicaments' within the meaning of heading 3004.

36 It is clear from the documents before the Court, and especially from the scientific experts' reports referred to by SmithKline, that the patches present clearly defined therapeutic or prophylactic characteristics with an effect concentrated on precise functions of the human body.

37 First, they form a recognised treatment for nicotine (or tobacco) addiction and the withdrawal symptoms involved in that addiction.

38 Second, by helping the persons concerned to stop smoking, the use of the patches helps to prevent diseases associated with the consumption of tobacco, as the Commission has noted in particular in its written observations and in its answer to a question raised pursuant to Article 54a of the Court's Rules of Procedure.

39 Furthermore, it is apparent from the order for reference that the nicotine patches at issue in the main proceedings are individually packaged in aluminium pouches and packed for sale in weekly packs together with instructions.

40 In the light of those considerations, the line of argument put forward by the United Kingdom Government to the effect that the goods at issue in the main proceedings ought not to be classified as 'medicaments' within the meaning of heading 3004 of the CN cannot be accepted.

41 With regard to the argument that nicotine patches do not present clearly defined therapeutic or prophylactic characteristics because they administer the same substance, namely, nicotine, as that which causes the addiction, it is to be noted that that circumstance alone cannot prevent the classification of the goods at issue in the main proceedings as medicaments within the meaning of heading 3004 of the CN.

42 Indeed, the documents before the Court show that nicotine administered in the form of patches, as replacement therapy, produces effects different from those caused by nicotine absorbed when tobacco is consumed. Given that the effects of nicotine depend on the speed of its delivery and that that speed is much greater

when nicotine is inhaled and absorbed through the lungs than when it is diffused through the skin, such patches can effectively reduce tobacco addiction.

43 Moreover, it may be recalled that, as SmithKline has stressed, the principle of vaccination is also based on the administering of an attenuated dose of the same micro-organism that is the cause of the disease which the vaccine is designed to prevent.

44 As to the argument that nicotine (or tobacco) addiction cannot be regarded as an illness because, at the time of the material facts, the harmfulness of that addiction was not recognised as such in Community law, it must be stated that, with regard to the classification of a product under heading 3004 of the CN, whether or not an illness is recognised in some Community act other than those that refer to classification in the CN is not a decisive factor.

45 With regard to the argument that Commission Regulation (EEC) No 3565/88 of 16 November 1988 concerning the classification of certain goods in the combined nomenclature (OJ 1988 L 311, p. 25) does not classify nicotine chewing-gum under heading 3004 but under heading 2106, it is to be observed that that classification can have no bearing on the classification of goods of a different kind, such as nicotine patches.

46 So far as the argument that the WCO has decided to classify nicotine patches under heading 3824 of its harmonised system is concerned, it has been held in paragraph 28 above that, having regard to the classification of goods in the CN, classification opinions issued by the WCO have no legally binding force

47 Having regard to all the foregoing, and since, on the one hand, heading 3004 of the CN is, compared to heading 3824 of the CN, the more specific heading and since, on the other hand, it is apparent from the notes to Chapter 38 that the latter does not cover medicaments, it is classification of nicotine patches under heading 3004 of the CN that must prevail.

48 In those circumstances, the reply to be given to the first question has to be that nicotine patches such as those at issue in the main proceedings must be classified under heading 3004 of the CN.

Concerning the second question: the obligation to remedy non-compliance with Community law (Article 10 EC)

49 By its second question the national court in essence raises the issue of the scope of the obligation imposed on national courts to remedy non-compliance with Community law.

50 In particular, it is uncertain whether Community law requires or permits a national court to annul the decision of the competent customs authority without substituting for it binding tariff information which is inconsistent with a classification opinion of the WCO, but declaring that the goods are properly classifiable otherwise than in accordance with that opinion.

51 Established case-law makes it clear that, in keeping with the principle of the duty to cooperate in good faith laid down in Article 10 EC, the Member States are obliged to

nullify the unlawful consequences of a breach of Community law (see, inter alia, Case 6/60 *Humblet* [1960] ECR 559, p. 569, and Joined Cases C-6/90 and C-9/90 *Francovich and Others* [1991] ECR I-5357, paragraph 36). That obligation is incumbent on all the authorities of the Member States concerned within the sphere of their competence (see, to that effect, Case C-8/88 *Germany* v *Commission* [1990] ECR I-2321, paragraph 13).

52 It is thus for the competent authorities and the courts of a Member State to take, within the sphere of their competence, all the measures, general or particular, necessary to remedy the non-compliance of incorrect binding tariff information. Such particular measures include, more particularly, the annulment of the incorrect binding tariff information and the adoption of new information in keeping with Community law.

53 In those circumstances, the detailed procedural rules applicable fall within the ambit of Articles 243 to 246 of the Customs Code and, as an ancillary matter, by virtue of Article 245 of that code and of the principle of the procedural authority of the Member States, within the ambit of the domestic legal order of each Member State, provided that such rules are not less favourable than those governing similar domestic situations (principle of equivalence) and are not framed in such a way as to render impossible in practice the exercise of rights conferred by Community law (principle of effectiveness) (see, to that effect, Case C-312/93 *Peterbroeck* [1995] ECR I-4599, paragraph 12, and Case C-78/98 *Preston and Others* [2000] ECR I-3201, paragraph 31).

54 So far as the dispute in the main proceedings is concerned, if a competent authority has issued incorrect binding tariff information, a national court is required to take, within the sphere of its competence, all the general or particular measures necessary to ensure that such information is annulled and that new binding tariff information consistent with Community law is issued.

55 In that situation, the procedure for and the effects of the decisions adopted by the national court hearing the action fall, within the bounds set by the principles of equivalence and effectiveness, within the ambit of domestic law.

56 In this respect, it is to be observed that, having regard to its very limited scope, the second indent of Article 12(5)(a)(ii) of the Customs Code has no bearing on the duty of national courts to take all the steps necessary to ensure that incorrect binding tariff information is annulled and that new information is issued by the competent customs authority. Indeed, as has been stated in paragraph 27 above, that provision governs only the specific effects on pre-existing binding tariff information of a new classification opinion adopted by the WCO. As a result, it is not contrary to Article 12(5) of the Customs Code for a national court to annul a decision of a customs authority which is consistent with a classification opinion of the WCO and to declare that a product must be classified otherwise than in accordance with that classification opinion.

57 The answer to be given to the second question must therefore be that, if a competent authority has issued incorrect binding tariff information, a national court is required under Article 10 EC to take, within the sphere of its competence, all the measures necessary to ensure that that information is annulled and that new binding tariff information, consistent with Community law, is issued.

In that context, the procedure for and the effects of the decisions adopted by the national court hearing the action fall, within the bounds set by the principles of equivalence and effectiveness, within the ambit of domestic law.

In that regard, it is not contrary to Article 12(5) of the Customs Code for a national court to annul a decision of a customs authority which, while it is consistent with a classification opinion of the WCO, fails to take account of the CN, and to declare that goods must be classified otherwise than in accordance with that classification opinion.

Costs

58 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) rules as follows:

1. **Nicotine patches, such as those at issue in the main proceedings, must be classed under heading 3004 of the Combined Nomenclature, contained 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 Regulation (EC) No 2086/97 of 4 November 1997.**

2. **If a competent authority has issued incorrect binding tariff information, a national court is required under Article 10 EC to take, within the sphere of its competence, all the measures necessary to ensure that that information is annulled and that new binding tariff information, consistent with Community law, is issued.**

In that context, the procedure for and the effects of the decisions adopted by the national court hearing the action fall, within the bounds set by the principles of equivalence and effectiveness, within the ambit of domestic law.

In that regard, it is not contrary to Article 12(5) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code, as amended by Regulation (EC) No 82/97 of the European Parliament and of the Council of 19 December 1996, for a national court to annul a decision of a customs authority which, while it is consistent with a classification opinion of the WCO, fails to take account of the Combined Nomenclature contained in Annex I to Council Regulation (EEC) No 2658/87, as amended by Commission Regulation (EC) No 2086/97, and to declare that goods must be classified otherwise than in accordance with that classification opinion.

[Signatures]