Case C-941/19

Request for a preliminary ruling

Date lodged:

27 December 2019

Referring court:

Krajský soud v Ostravě (Czech Republic)

Date of the decision to refer:

13 December 2019

Applicant:

Samohýl group, a. s.

Defendant:

Generální ředitelství cel

[…]

ORDER

Krajský soud v Ostravě (Regional Court, Ostrava, Czech Republic) […] [composition of court], in the case brought by

the applicant: **Samohýl group, a. s.**
established in […] Lomnice nad Popelkou (Czech Republic)
[…]
[…]

against
the defendant: **Generální ředitelství cel**
established in […] Praga 4 (Czech Republic)

in regard to the action brought against the defendant's decision of 11 September 2018 […] concerning Binding Tariff Information,

makes the following order:

I. The following question **is referred** to the Court of Justice of the European Union for a preliminary ruling pursuant to Article 267 of the Treaty on the Functioning of the European Union:

> Should the product labelled 'Bob Martin Clear 50 mg roztok pro nakapání na kůži — spot-on pro kočky' made available in pipettes (0.5 ml), which contains the active substance fipronil (50 mg per pipette) and the excipients butylated hydroxyanisole E 320, butylated hydroxytoluene E 321, benzyl alcohol and diethylene glycol monoethyl ether, be classified under heading 3004 or heading 3808 of the Combined Nomenclature of the Customs Tariff?

II. The proceedings **are stayed**.

Grounds:

I. Progress of the proceedings to date

1 On 27 May 2015, the applicant lodged an application for binding tariff information (BTI) in respect of 'Bob Martin Clear 50 mg roztok pro nakapání na kůži — spot-on pro kočky' (Bob Martin Clear 50 mg spot-on solution for cats) ('the product') so that the product could be classified under subheading 3004 90 00 of the Combined Nomenclature ('the CN').

2 On 24 June 2015, the Celní úřad pro Olomoucký kraj (Customs Office for the Olomouc Region, Czech Republic) issued binding tariff information according to which the product was classified under CN subheading 3808 91 90 by applying by analogy Commission Regulation (EC) No 455/2007 of 25 April 2007 concerning the classification of certain goods in the Combined Nomenclature (point 1) [of the annex] and the classification opinion of the World Customs Organisation (WCO) 3808 91/2 and 3, and in the grounds it was stated that the applicant's product could not be classified under the proposed CN subheading 3004 90 00 because it did not constitute a medicament within the meaning of heading 3004. The applicant lodged a complaint against that decision. By decision of the Generální ředitelství cel (General Directorate of Customs, Czech Republic) of 17 August 2015, the applicant's complaint was rejected and the contested decision was upheld. The applicant brought **[Or. 2]** an administrative appeal against the decision before the Krajský soud v Ostravě (Regional Court, Ostrava) which, by its judgment of 16 May 2017, annulled the decision of the Generální ředitelství cel (General Directorate of Customs) and referred the case back to the latter for re-examination.

3 Following re-examination of the case, on 17 May 2018 the Celní úřad pro Olomoucký kraj (Customs Office for the Olomouc Region, Czech Republic) issued binding tariff information for the product under consideration, by which it reclassified the product under CN subheading 3808 91 90, referring to General Rules 1, 3(a), 5(b) and 6 for the interpretation of the Combined Nomenclature,

Commission Regulation (EC) No 455/2007 (point 1), the HS (Harmonised System) Explanatory Notes to heading 3808, and the CN Explanatory Notes — Explanatory Notes to Chapter 30 and the wording of CN codes 3808 and 3808 91 90. The applicant lodged a complaint against that decision. By its decision of 11 September 2018, the Generální ředitelství cel (General Directorate of Customs) rejected the complaint and upheld the contested decision.

4 That decision was once again challenged by the applicant, and it brought an action against the decision before the Krajský soud v Ostravě (Regional Court, Ostrava). The applicant argued, inter alia, that the problem in the case was the active substance fipronil, because when the applicant had submitted the product 'Moxiclear 400 + 100 mg', which is in every respect identical to the product 'Bob Martin Clear 50 mg roztok pro nakapání na kůži — spot-on pro kočky', except that it has a different active substance and is intended for dogs suffering from, or at risk from, mixed parasitic infections of an internal or external nature, to the customs office for assessment, that product was classified under subheading 3004 90 00 (see the BTI of 15 October 2018 […]) without its prophylactic or therapeutic effects being examined. Moxiclear, unlike the product under consideration, enters the animal's blood and is released from there.

5 In its defence, the defendant stated that the applicant had confused the purpose of customs classification with the field of veterinary care, since although the product in question might be a veterinary product, it was not necessarily a medicament within the meaning of customs legislation. The defendant further argued that in classifying the product it had applied a legally binding and directly applicable provision which governs the customs classification of a particular product and from which it follows that such classification is binding for a very similar product, namely the product under consideration. If the customs authority had decided to classify the product differently, it would have infringed the legally binding provision and its decision would have been unlawful.

II. Subject matter of the case

6 The subject matter of the dispute between the parties is the customs classification of the applicant's product bearing, in the present case, the trade name 'Bob Martin Clear 50 mg roztok pro nakapání na kůži — spot-on pro kočky,' that is to say, the question whether, in accordance with EU law, that product should be classified under heading 3004 (medicaments) or rather under heading 3808 (insecticides and acaricides) of the Combined Nomenclature of the Customs Tariff.

7 The starting point is — as the Regional Court found on the basis of the documentation submitted to it — that the product is made available in 0.5 ml pipettes, each pipette contains 50 mg of the active substance fipronilum (fipronil) and the other excipients are butylated hydroxyanisole E 320, butylated hydroxytoluene E 321, benzyl alcohol and diethylene glycol monoethyl ether, the product is intended for cats, is applied to the skin and is meant to be used to treat

infestations of fleas (fleas are eliminated within 24 hours) and ticks (which are eliminated within 48 hours or 1 week).

8 In addition, it follows from the document entitled ‘Summary of Product Characteristics’ that the product belongs to the pharmacotherapeutic group ‘Ectoparasiticides for topical use’. Fipronil is described there as an insecticide (flea insecticide) and acaricide (tick insecticide) which inhibits the GABA receptor complex, resulting in uncontrolled activity of the central nervous system and death of insects or acarines. It is important to note that although fipronil used in vitro metabolises in the subcellular liver fraction mainly to sulfone metabolite, this may be of limited importance in vivo, since fipronil is absorbed to a small extent in cats and its concentration on the hair coat decreases with time. The solution is not to be applied to the hair coat but to the skin and should not be rubbed into the skin.

9 According to the ‘sdělení Ústavu pro státní kontrollí veterinárních [biopreparátů a] léčiv’ (Communication from the Institute for State Control of Veterinary Preparations and Medicinal Products) (‘the institute’) of 14 January 2014, the product was authorised to be marketed as a veterinary medicinal product. The applicant has mentioned this fact on several occasions. **[Or. 3]**

10 It is apparent from the ‘odborné[ho] vyjádření ÚSKVBL’ (expert opinion of the institute) of 22 November 2017 that fleas and ticks cause skin diseases, changes in blood morphology, including neurological changes such as paralysis and apathy, and enlargement of the lymph nodes, and at the same time may cause, as carriers, borreliosis, babesiosis, and so on. If parasites are effectively eliminated on an animal, it can be assumed that they cannot cause the aforementioned illnesses in that animal. The product in question works in such a way that it eliminates fleas and ticks.

11 According to the ‘French veterinary opinion 2008–2009 (Ecole Nationale Vétérinaire in Toulouse, in Lyon, and Laboratoire de Parasitologie et Mycologie médicale in Lyon)’ submitted by the applicant, the product is an identical generic form of the product Frontline, manufactured after the end of the patent grace period, has the same composition and indications for use and was given marketing authorisation in the same way. The active substance in the Frontline formulation, as in the product under consideration, is fipronil, and this agent has therapeutic and preventive effects in the sense that it treats infestations of external parasites by eliminating them. Because fipronil accumulates in the sebaceous glands of the animal and is released gradually, it also has a preventive effect.

12 In France, the BTI was issued for a product with the trade name Frontline. All the products in this BTI were classified under HS heading 3808, with reference to Commission Regulation (EC) No 455/2017 (BTI No […] [individual BTI numbers issued in France]). It was further established that Frontline was also authorised to be marketed as a veterinary medicinal product.

13 The customs office also examined existing BTIs issued in regard to identical or similar products in other Member States of the European Union, where the product took the same form (solution put up in pipettes with the same concentration of the active substance fipronil), and found them in the case of BTI Nos […] [individual BTI numbers issued in Slovenia]. All those products are intended for animals and have an insecticidal and acaricidal effect (some also eliminate lice).

14 It is apparent from 'the BTI of 15 October 2018 […]' that Moxiclear 400 + 100 mg, which is a veterinary medicinal product in the form of a solution, is intended for dogs suffering from, or at risk from, mixed parasitic infections of an internal or external nature, which is administered by topical application to the skin and contains the active substances imidacloprid and moxidectin and the excipients butylated hydroxytoluene E 321 and benzyl alcohol, and which is classified under CN subheading 3004 90 00. The product is available in pipettes (0.4 ml), in packages intended for retail sale.

15 In its submissions, the applicant essentially argued that the defendant had assessed the various pieces of evidence separately, and that if it had compared the findings of the Summary of Product Characteristics with the marketing authorisation decision, the institute's expert opinion and the French veterinary opinion, it could not have come to the conclusion that the product is intended for the elimination of insects, but that it is intended to treat flea infestations, and that insecticides are commonly used for the elimination of insects and are currently regarded not as medicaments to treat insect infestations but as agents for their eradication. According to the applicant, however, the institute's expert opinion cited above clearly indicates that the product has therapeutic and preventive effects; it explains what kind of ailments are caused in animals by fleas and ticks and that without treatment to eliminate the cause (flea infestation) it is not possible to cure the symptoms of the disease; and it also confirms that the product has a permanent, long-term effect, which is important from a preventive perspective.

III. The applicable legislation and case-law of the Court of Justice of the European Union

16 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) 2017/1925, should have been applied in the present case and Commission Regulation (EC) No 455/2007 of 25 April 2007 concerning the classification of certain goods in the Combined Nomenclature should have been taken into account. Article 1 of the latter regulation provides that the goods described in column 1 of the table set out in the Annex must be classified within the Combined Nomenclature under the CN codes indicated in

column 2 of that table. In the present case, the customs authority applied point 1 of the Annex, according to which: **[Or. 4]**

Description of the goods	***Classification (CN Code)***	***Reasons***
(1)	***(2)***	***(3)***
A preparation in the form of an alcoholic solution put up in pipettes for retail sale. The composition is as follows: *– fipronil (ISO) 10 g* *– butylated hydroxyanisole (BHA, E 320) 0.02 g* *– butylated hydroxytoluene (BHT, E 321) 0.01 g* *– excipient q.s.p 100 ml* *The preparation, containing a substance showing an insecticide and acaricide activity against parasites such as fleas, ticks and lice, is used externally on pets (dogs and cats).*	*3808 91 90*	*Classification is determined by General Rules 1, 3a and 6 for the interpretation of the Combined Nomenclature and the wording of CN codes 3808, 3808 91 and 3808 91 90.* *See also HS Explanatory Notes to heading 3808 and subheadings 3808 91 to 3808 99.* *The preparation does not have a therapeutic or prophylactic effect, within the meaning of heading 3004.*

17 Contrary to the foregoing, the applicant's line of argument is that the product should be classified under CN subheading 3004 90 00 as follows:

CN Code	***Description***	***Conventional duty (%)***	***Supplementary unit of measurement***
(1)	***(2)***	***(3)***	***(4)***
3004	*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 (including those in the form of transdermal administration systems) or in forms or packings for retail sale*		
…	…	…	…
3004 90 00	*– Other*	*Free*	*–*

18 The Court of Justice has not yet dealt with the classification of the product under consideration or other similar products under Customs Tariff headings 3004 or 3808.

19 Since the basis of the dispute was whether the product could be defined as a 'medicament' within the meaning of customs legislation, the order of the Court of Justice of 9 January 2007, *Juers Pharma*, C-40/06, EU:C:2007:2, in which the Court ruled on a question referred for a preliminary ruling regarding the interpretation of heading 3004 of the CN, must be regarded as relevant. In that order (paragraph 22), the Court of Justice stated that 'with regard to heading 3004 of the CN, first, 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-405/95 *Bioforce* [1997] ECR I-2581, paragraph 18; Case C-270/96 *Laboratoires Sarget* [1998] ECR I-1121, paragraph 28; and Case C-328/97 *Glob-Sped* [1998] ECR I-8357, paragraphs 29 and 30)'.

20 In relation to this definition of a medicament, it is also necessary to take account of the judgment of the Court of Justice of 30 April 2014, *Nutricia*, C-267/13, EU:C:2014:277, in which, in paragraphs 20 to 23 thereof, the Court held that 'in accordance with settled case-law, in order to classify products in Chapter 30 of the CN, it is necessary to examine whether those products have **clearly defined therapeutic or prophylactic characteristics with an effect concentrated on precise functions of the human organism or whether they are capable of being applied in the prevention or treatment of diseases or ailments**. Even where the product in question does not have an intrinsic therapeutic effect, but is used in the prevention or treatment of a disease or ailment, it must, provided that it is specifically intended for such a use, be regarded as having been prepared for therapeutic use (see, inter alia, *TNT Freight Management (Amsterdam)* EU:C:2012:459, paragraphs 40 and 42). **[Or. 5]** It is apparent from the case-law cited in the two preceding paragraphs that **the intended use of a product may constitute an objective criterion for classification if it is inherent to the product, and that inherent character must be capable of being assessed on the basis of the product's objective characteristics and properties** (see, inter alia, *Krings* EU:C:2004:122, paragraph 30 and the case-law cited). According to the case-law of the Court, a product which, on account of its objective characteristics and properties, is clearly intended for medical use may be classified in Chapter 30 of the CN (see *Thyssen Haniel Logistic* EU:C:1995:160, paragraph 14, and *TNT Freight Management (Amsterdam)* EU:C:2012:459, paragraph 41). It must be added that the Court has already held, relying on the actual wording of heading 3004, that the fact that **products are put up in measured doses or that they are packaged for retail sale constitutes a condition of the application of that provision** (see order in Case C-40/06 *Juers Pharma* EU:C:2007:2, paragraph 23 and the case-law cited). It is also important to note that **the question of whether or not an illness is recognised in a measure**

of EU law other than those that refer to classification in the CN is not a decisive factor for the classification of a product under heading 3004 thereof (see, to that effect, order in Case C-206/03 *SmithKline Beecham* EU:C:2005:31, paragraph 44)'.

21 The customs office applied Commission Regulation (EC) No 455/2007, which it considered binding and which it could not derogate from, since an unlawful decision would otherwise have been taken. In that context, however, the Regional Court draws attention to the judgment of the Court of Justice of 15 May 2019, *Korado*, C-306/18, EU:C:2019:414, in which the Court once again held that where, by its answer to the question referred for a preliminary ruling, **it has provided the referring court with all the information necessary to classify a product under the appropriate heading of the CN, it is not necessary to apply the implementing regulation** (see, to that effect, judgment of 26 April 2017, *Stryker EMEA Supply Chain Services*, C-51/16, EU:C:2017:298, paragraph 62). Having regard to the foregoing, it must be assumed that, if the Court of Justice comes to a different/similar conclusion, its judgment takes precedence over the application of the cited regulation.

IV. Analysis and admissibility of the question referred

22 The product was classified under heading 3808 of the CN mainly on the basis of Commission Regulation (EC) No 455/2007, under which products containing the active substance fipronil in the quantity indicated therein are to be classified solely under that heading of the Combined Nomenclature. However, the Regional Court is of the view that, in the present case, account must be taken of the objective characteristics of the product in question and its preventive effect. As has already been stated above, although its only active substance is fipronil, which is classified as an insecticide and acaricide, the product has a preventive effect but no therapeutic effect, and without its use it is impossible to prevent the occurrence of diseases associated with fleas and ticks on the body of a cat.

23 The Regional Court considers that, contrary to the defendant's assertions, the product should not be classified under heading 3808 of the Combined Nomenclature, but under heading 3004, specifically under subheading 3004 90 00. This is because, according to the documents submitted, the product has a prophylactic effect, in other words, it inherently prevents the occurrence of fleas (as well as ticks) on the animal and thus prevents diseases caused precisely by bites from those parasites. Were it not for the initial elimination of the parasites, and thus prevention, it would not be possible to treat the secondary symptoms of infestation by those parasites. According to the Regional Court, the specific effect of the product on the animal's organism is that the active substance present in the product accumulates in the sebaceous glands of the animal (in this case, the cat), from where it is released gradually, and thus it has a preventive effect for a longer period of time after its application and prevents parasitic infestation over a longer period. According to that court, the product in question is used primarily to

prevent secondary diseases caused by flea and tick bites, as stated in paragraph 10 above.

24 Although it is not possible to link the recognition of a product as a veterinary product (medicine) with the recognition of a product as a medicament within the meaning of customs legislation, at this juncture note should be taken of the wording of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, according to which marketing authorisation is to be refused **[Or. 6]** where a medicinal product has no therapeutic effect. A veterinary medicinal product, in accordance with Article 4(1) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, means any substance or combination of substances which fulfils at least one of the following conditions: (a) it is presented as having properties for treating or preventing disease in animals; (b) its purpose is to be used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; (c) its purpose is to be used in animals with a view to making a medical diagnosis; (d) its purpose is to be used for euthanasia of animals. Therefore, since the product has been authorised to be marketed as a veterinary medicinal product, it must be considered to have therapeutic (and possibly prophylactic) effects, and it is not permissible to classify it under heading 3808 instead of heading 3004 of the CN simply because it contains the active substance fipronil.

25 The Regional Court is aware that similar products have, according to the BTI cited in paragraph 13 above, been classified under heading 3808 of the CN. However, there is also a similar product, ‘Moxiclear’, which is intended for dogs and contains a different active substance, but which has the same effect on the body of a dog as the product under consideration has on the body of a cat. The question therefore arises as to whether the purpose of [Commission Regulation] No 455/2007 was also to classify under heading 3808 products similar to the product under consideration, or to classify under that heading only insecticides and acaricides which have a one-off action, do not accumulate in any way in the body of the animal and have no preventive effect, and only eliminate parasites once, immediately after application. This fact also militates in favour of the view of the Regional Court as set out in paragraph 22 above.

26 The product has other characteristics of a medicament within the meaning of heading 3004 of the CN. It is made available in 0.5 ml pipettes, that is, in measured doses, in packages intended for retail sale.

27 Although the Regional Court has already set out its view on the possible answer to the question referred, that answer is not sufficiently clear and indisputable to enable it to give a ruling in the case. In this instance, the interpretation of EU law (the Customs Tariff and the Combined Nomenclature) is necessary for the specific application of the law in the present case. There is no previous case-law of the

Court of Justice, relevant to the answer to the question referred for a preliminary ruling, on the basis of which an interpretation of the law could […] be deduced directly and with absolute certainty. For that reason, the Regional Court has decided to ask the Court of Justice of the European Union for a preliminary ruling on the question referred in the operative part of this order.

V. Stay of proceedings

28 […] [procedural issues relating to national law]

Notice:

[…] [information on the legal remedies available]

Ostrava, 13 December 2019.

[…] [signature][…]