Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

23 November 2016*

(Reference for a preliminary ruling — Consumer information and protection — Regulation (EC) No 1924/2006 — Nutrition and health claims made on foods — Transitional measures — Article 28(2) — Products bearing trade marks or brand names existing before 1 January 2005 — 'Bach flower' remedies — European Union mark RESCUE — Products marketed as medicinal products before January 2005 and as foodstuffs after that date)

In Case C-177/15,

REQUEST for a preliminary ruling under Article 267 TFEU from the Bundesgerichtshof (Federal Court of Justice, Germany), made by decision of 12 March 2015, received at the Court on 21 April 2015, in the proceedings

Nelsons GmbH

v

Ayonnax Nutripharm GmbH,

Bachblütentreff Ltd,

THE COURT (Third Chamber),

composed of L. Bay Larsen, President of the Chamber, M. Vilaras, J. Malenovský, M. Safjan (Rapporteur) and D. Šváby, Judges,

Advocate General: M. Bobek,

Registrar: M. Aleksejev, Administrator,

having regard to the written procedure and further to the hearing on 6 April 2016,

after considering the observations submitted on behalf of:

— Nelsons GmbH, by T. Salomon, B. Goebel and C. Alpers, Rechtsanwälte,

— Ayonnax Nutripharm GmbH and Bachblütentreff Ltd, by B. Ackermann, Rechtsanwältin,

— the Greek Government, by A. Dimitrakopoulou, K. Karavasili, P. Paraskevopoulou , K. Nassopoulou and S. Lekkou, acting as Agents,

— the European Commission, by S. Grünheid, acting as Agent,

* Language of the case: German.

after hearing the Opinion of the Advocate General at the sitting on 22 June 2016,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 4(3), Article 5(1)(a), Article 6(1), Article 10(3) and Article 28(2) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ 2006 L 404, p. 9), and corrigendum OJ 2007 L 12, p. 3), as amended by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008 (OJ 2008 L 39, p. 8) ('Regulation No 1924/2006').

2 The request has been made in proceedings between Nelsons GmbH and Ayonnax Nutripharm GmbH, a company incorporated in Germany, and Bachblütentreff Ltd, a company incorporated in the United Kingdom, concerning flower remedies marketed by Nelsons under the EU mark RESCUE.

Legal context

EU law

Regulation (EC) No 178/2002

3 Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1), entitled 'Definition of "food"', provides:

'For the purposes of this Regulation, "food" (or "foodstuff") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

"Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. …

"Food" shall not include:

(d) medicinal products within the meaning of [Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20] and [Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to medicinal products and laying down additional provisions on homeopathic medicinal products (OJ 1992 L 297, p. 8)];

…'

Regulation No 1924/2006

4 Recitals 1 and 4 of Regulation No 1924/2006 state:

‘(1) An increasing number of foods labelled and advertised in the [Union] bear nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market must be safe and adequately labelled. A varied and balanced diet is a prerequisite for good health and single products have a relative importance in the context of the total diet.

…

(4) This Regulation should apply to all nutrition and health claims made in commercial communications, including inter alia generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities. It should not apply to claims which are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in the press and in scientific publications. This Regulation should also apply to trade marks and other brand names which may be construed as nutrition or health claims.’

5 Article 1 of that regulation, entitled ‘Subject-matter and scope’, provides:

‘1. This Regulation harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.

2. This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.

…

3. A trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the authorisation procedures provided for in this Regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of this Regulation.

…’

6 Article 2 of the regulation, headed ‘Definitions’, provides:

‘1. Within the meaning of this Regulation:

(a) the definitions of “food”, “food business operator”, “placing on the market”, and “final consumer” set out in Articles 2, 3(3), 3(8) and 3(18) of [Regulation No 178/2002] of shall apply;

…

2. The following definitions shall also apply:

1. “claim” means any message or representation, which is not mandatory under [EU] or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;

…

5. “health claims” means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

…’

7 Article 4 of that regulation, entitled ‘Conditions for the use of nutrition and health claims’, provides in paragraph 3:

‘Beverages containing more than 1.2% by volume of alcohol shall not bear health claims.

…’

8 Article 5 of Regulation No 1924/2006, entitled ‘General conditions’, provides, in paragraph 1 thereof:

‘The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled:

(a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific data;

(b) the nutrient or other substance for which the claim is made:

(i) is contained in the final product in a significant quantity as defined in [EU] legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific data …

…’

9 Article 6 of Regulation No 1924/2006, entitled ‘Scientific substantiation for claims’, paragraph 1 provides:

‘Nutrition and health claims shall be based on and substantiated by generally accepted scientific evidence.’

10 Article 10 of Regulation No 1924/2006, relating to health claims and entitled ‘Specific conditions’, provides in paragraphs 1 to 3:

‘1. Health claims shall be prohibited unless they comply with the general requirements in Chapter II and the specific requirements in this Chapter and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14.

…

3. Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14.’

11 Article 28 of that regulation, entitled ‘Transitional measures’, provides in paragraph 2 thereof:

‘Products bearing trade marks or brand names existing before 1 January 2005 which do not comply with this Regulation may continue to be marketed until 19 January 2022 after which time the provisions of this Regulation shall apply.’

German law

12 Under Paragraph 3(1) of the Gesetz gegen den unlauteren Wettbewerb (Law on Unfair Competition), in the version applicable to the dispute in the main proceedings (BGBl. 2010 I, p. 254, 'the UWG'):

'Unfair commercial practices shall be unlawful if they are likely to have a perceptible adverse effect on the interests of competitors, consumers or other market participants.'

13 Paragraph 4 of the UWG provides:

'Other unfair commercial practices

A person shall be regarded as acting unfairly in particular where he

…

11. infringes a statutory provision that is also intended to regulate market behaviour in the interests of market participants.'

14 Paragraph 8(1), first part of sentence, of the UWG provides:

'Where a person engages in an unlawful commercial practice under Paragraphs 3 or 7, an action may be brought against that person to eliminate that practice and, where there is a risk of recurrence, for an injunction requiring him to desist.'

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

15 Nelsons markets preparations made from flowers, known as 'Bach flower remedies', in pharmacies in Germany. They include products commonly called 'RESCUE' remedies, which carry the designation 'Spirituose' ('spirit drink') and have an alcohol content of 27% by volume.

16 Those remedies are sold in dropper bottles, with a volume of either 10 ml or 20 ml, or as a spray ('the remedies at issue in the main proceedings'). The product packaging contains the following dosage instructions:

'ORIGINAL RESCUE TROPFEN (ORIGINAL RESCUE DROPS)

Add four drops to a glass of water and drink at intervals over the course of the day or take four drops undiluted as required.'

and

'RESCUE NIGHT SPRAY

Apply two sprays directly on the tongue.'

17 It is apparent from the order for reference that, before 1 January 2005, Nelsons also marketed the remedies at issue in the main proceedings in Germany as medicinal products, under the EU mark RESCUE, which was, at that time, registered for medicinal products. In 2007, Nelsons also obtained registration of the mark RESCUE as an EU mark for foodstuffs.

18 Furthermore, it is clear from the documents before the Court that, by a judgment of 21 February 2008, the Hanseatisches Oberlandesgericht Hamburg (Higher Regional Court, Hamburg, Germany) held that 'Bach flower' remedies are not medicinal products, but foodstuffs. Following that judgment, Nelsons, which was not a party to the dispute in that case, began marketing the remedies at issue in the main proceedings in Germany not as medicinal products, but as foodstuffs, without making any changes to them.

19 Ayonnax Nutripharm and Bachblütentreff, which also market 'Bach flower' remedies in Germany, brought an action before the Landgericht München I (Regional Court, Munich I, Germany) seeking, primarily, a general prohibition on marketing such flower remedies by Nelsons on the ground that it did not have authorisation to market them and that those remedies were not registered under the legislation on medicinal products.

20 In the alternative, Ayonnax Nutripharm and Bachblütentreff have challenged some of Nelson's advertising messages and the way in which it has presented the remedies at issue in the main proceedings on the German market. Those companies claim that Nelsons has advertised alcoholic beverages, by relying on effects that are beneficial, or in no way detrimental, to health, which constitute acts of unfair competition.

21 By judgment of 20 September 2011, the Landgericht München I (Regional Court, Munich I) ordered Nelsons to desist from using certain advertising messages containing the words 'Bach flowers', and dismissed the action for the remainder.

22 Aynonnax Nutripharm and Bachblütentreff brought an appeal against that judgment before the Oberlandesgericht München (Higher Regional Court, Munich, Germany). By judgment of 31 January 2013, that court held that those companies were entitled to an order prohibiting Nelsons commercial practices, pursuant to Paragraph 3(1), Article 4(11) and Article 8(1) of the UWG with regard to the remedies at issue in the main proceedings, on the ground that the advertising and distribution of those remedies infringed Article 4(3) of Regulation No 1924/2006.

23 Nelsons brought an appeal on point of law before the Bundesgerichtshof (Federal Court of Justice, Germany).

24 That court states, in particular, that, in its view, the words 'RESCUE TROPFEN' and 'RESCUE NIGHT SPRAY' are health claims within the meaning of Article 2(2)(5) of Regulation (EC) No 1924/2006. The target public, which is nowadays familiar with English, understands the meaning of 'RESCUE', which suggests to the consumers concerned that the use of the remedies at issue in the main proceedings is recommended so they can be 'rescued' when facing certain health problems. Thus, there is a connection between 'RESCUE TROPFEN' and 'RESCUE NIGHT SPRAY', on one hand, and an improvement in health, on the other.

25 In that connection, according to the referring court, 'RESCUE TROPFEN' and 'RESCUE NIGHT SPRAY' each contain a reference to general, non-specific benefits for overall good health and health-related well-being, within the meaning of Article 10(3) of Regulation (EC) No 1924/2006. Therefore, the question arises whether the requirements laid down in Article 5(1)(a) and Article 6(1) thereof must be observed for a health claim such as that at issue in the main proceedings.

26 Finally, the referring court asks whether Article 28(2) of Regulation No 1924/2006 applies where a product was marketed before 1 January 2005, not as a foodstuff, but as a medicinal product, so that the provisions of that regulation are not applicable to the remedies at issue in the main proceedings during the transitional period laid down in that provision.

27 In those circumstances the Bundesgerichtshof (Federal Court of Justice) decided to stay the proceedings before it and to refer the following questions to the Court for a preliminary ruling:

‘1. Are liquids with an alcohol content of 27% by volume, which are described as spirit drinks and are sold through pharmacies in 10 ml or 20 ml dropper bottles or as sprays, beverages containing more than 1.2% by volume of alcohol within the meaning of Article 4(3) of Regulation No 1924/2006, where, according to the dosage instructions given on the packaging,

(a) four drops of the liquid are to be added to a glass of water and drunk at intervals over the course of the day or four drops are to be taken undiluted, as required,

(b) two sprays of the liquid sold in spray form are to be applied to the tongue?

2. If Questions 1(a) and 1(b) are to be answered in the negative:

Must evidence within the meaning of Article 5(1)(a) and Article 6(1) of Regulation No 1924/2006 be present also in the case of references to general, non-specific benefits within the meaning of Article 10(3) of that regulation?

3. Does the provision set out in the first half of the sentence contained in Article 28(2) of Regulation No 1924/2006 apply in the case where, prior to 1 January 2005, the product concerned was marketed under its brand name not as a foodstuff but as a medicinal product?’

Consideration of the questions referred for a preliminary ruling

The third question

28 By its third question, which it is appropriate to answer first, the referring court asks essentially whether the first sentence of Article 28(2) of Regulation No 1924/2006 must be interpreted as meaning that that provision applies in the situation in which a product bearing a trade mark or brand name was marketed as a medicinal product before 1 January 2005 and subsequently, although having the same characteristics and bearing the same trade mark or brand name, is marketed as a food stuff after that date.

29 According to Article 28(2) of Regulation No 1924/2006, products bearing trade marks or brand names existing before 1 January 2005 which do not comply with that regulation may continue to be marketed until 19 January 2022, after which time the provisions of that regulation will apply.

30 That provision is thus a transitional measure derogating from Article 1(3) of Regulation 1924/2006, according to which a trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the authorisation procedures provided for in this regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of the regulation.

31 In that connection, it must be recalled that Article 28(2) of Regulation No 1924/2006 refers to products bearing a trade mark or brand name which must be regarded as nutrition or health claims within the meaning of that regulation (see, to that effect, judgment of 18 July 2013, *Green — Swan Pharmaceuticals CR*, C-299/12, EU:C:2013:501, paragraph 36).

32 In the present case, it is clear from the order for reference that, before 1 January 2005, Nelsons were already selling the remedies at issue in the main proceedings as medicinal products using the European Union mark RESCUE, which was then registered for medicinal products. In 2007, Nelsons also registered RESCUE as a European Union mark for foodstuffs.

33 By a judgment delivered in 2008, as mentioned in paragraph 18 of this judgment, a German court held that Bach flower remedies are not medicinal products but are foodstuffs.

34 As a result of that judgment, Nelsons began marketing the remedies at issue in the main proceedings in Germany as foodstuffs, although that was not accompanied by any change to them. Consequently, as the referring court observed, as compared with the situation existing on the day taken into consideration in Article 28(2) of Regulation No 1924/2006, that is the day before 1 January 2005, only the legal classification of the remedies at issue in the main proceedings had changed.

35 Furthermore, in its decision, the referring court states that it considers that 'RESCUE TROPFEN' and 'RESCUE NIGHT SPRAY' are health claims, within the meaning of Article 2(2)(5) of Regulation No 1924/2006, and that RESCUE constitutes a trade mark or brand name within the meaning of Article 28(2) thereof.

36 Therefore, the question which arises is whether remedies such as those at issue in the main proceedings, which were marketed before 1 January 2005 as medicinal products and, subsequent to that date, as foodstuffs are 'products' within the meaning of Article 28(2) of that regulation.

37 In that connection, it must be observed that 'products', within the meaning of that provision, must be understood as referring to 'foodstuffs' for the purposes of Regulation No 1924/2006.

38 First, that regulation, as its title states, concerns nutritional and health claims made on foods. Second, it is clear, in particular, from recital 1 and Article 5(1)(b)(i) of that regulation, that the latter does not expressly distinguish between 'foodstuffs' and 'products', the two words being used interchangeably.

39 In those circumstances, Article 28(2) of Regulation No 1924/2006 must be understood as referring only to foodstuffs bearing a trade mark or brand name which must be considered a nutrition or health claim within the meaning of that regulation (see, to that effect, judgment of 18 July 2013, *Green — Swan Pharmaceuticals CR*, C-299/12, EU:C:2013:501, paragraph 37).

40 In the present case, according to Ayonnax and Bachblütentreff, the Greek Government and the European Commission, since the remedies at issue in the main proceedings were marketed as medicinal products before 1 January 2005, and not as food, they cannot fall within the scope of Article 28(2) of Regulation No 1924/2006.

41 In that connection, it must be observed that, according to Article 2 of Regulation No 178/2002, to which Article 2(1)(a) of Regulation No 1924/2006 refers for the definition of 'food', that definition does not cover 'medicinal products'.

42 Thus, the remedies at issue in the main proceedings, the composition of which has not been changed, cannot be or have been, both, 'foodstuffs' and 'medicinal products'.

43 Therefore, as the Advocate General noted in point 87 of his Opinion, if the remedies at issue in the main proceedings were 'medicinal products', they could not fall within the scope of Regulation No 1924/2006.

44 However, it is clear from the order for reference that the Court is asked about a different situation, in which those remedies are presented as having been objectively 'foodstuffs' within the meaning of that regulation, both during the relevant period with regard to Article 28(2) of that regulation, that is before 1 January 2005, and now.

45 In that case, as is clear from paragraph 39 of the present judgment, the remedies at issue in the main proceedings must be classified as 'products' within the meaning of Article 28(2) of Regulation No 1924/2006.

46 That provision is applicable only to products bearing a trade mark or brand name 'existing' before 1 January 2005.

47 Having regard to the wording of that provision, 'existing' must be understood as meaning that those products had, already before that date, to have the same substantive characteristics and bear the same trade mark or brand name. It is clear from the order for reference that such is the case in the main proceedings.

48 Taking account of the foregoing considerations, the answer to the third question is that Article 28(2), first sentence, of Regulation No 1924/2006 must be interpreted as meaning that that provision applies in the situation in which a foodstuff bearing a trade mark or brand name was, before 1 January 2005, marketed as a medicinal product and then, while having the same physical characteristics and bearing the same trade mark or brand name, as a foodstuff prior to that date.

The first and second questions

49 Having regard to the answer to the third question, and given the nature of the main proceedings, which seek to immediately put an end to Nelsons' commercial practices as far as concerns the remedies at issue in the main proceedings, there is no need to answer the first and second questions.

Costs

50 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 (Third Chamber) hereby rules:

Article 28(2), first sentence, of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, as amended by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008, must be interpreted as meaning that that provision applies in the situation in which a foodstuff bearing a trade mark or brand name was, before 1 January 2005, marketed as a medicinal product and then, although having the same physical characteristics and bearing the same trade mark or brand name, as a foodstuff after that date.

[Signatures]