European Court of Justice, 30 April 2009, BIOS v Saarland

PHARMACEUTICAL LAW

Not a medicinal product by function here it constitutes a risk to health

- **A product which includes in its composition a substance which has a physiological ef-fect when used in a particular dosage is not a medicinal product by function where, having regard to its content in active substances and under normal conditions of use, it constitutes a risk to health without, however, be-ing capable of restoring, correcting or modifying physiological functions in human beings.**

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European Court of Justice, 30 April 2009
(M. Ilešič, A. Borg Barthet and E. Levits)
JUDGMENT OF THE COURT (Fifth Chamber)
30 April 2009 (*)
(Directive 2001/83/EC – Article 1(2)(b) – Concept of 'medicinal product by function' – Dosage of the product – Normal conditions of use – Risk to health – Ability to restore, correct or modify physiological functions in human beings)
In Case C-27/08,
REFERENCE for a preliminary ruling under Article 234 EC from the Bundesverwaltungsgericht (Germany), made by decision of 25 October 2007, received at the Court on 25 January 2008, in the proceedings
BIOS Naturprodukte GmbH
v
Saarland,
intervening party:
Vertreter des Bundesinteresses beim Bundesverwaltungsgericht,
THE COURT (Fifth Chamber),
composed of M. Ilešič, President of the Chamber, A. Borg Barthet (Rapporteur) and E. Levits, Judges,
Advocate General: V. Trstenjak,
Registrar: K. Sztranc-Sławiczek, Administrator,
having regard to the written procedure and further to the hearing on 28 January 2009,
after considering the observations submitted on behalf of:
– BIOS Naturprodukte GmbH, by C. Sachs and J. Sachs, Rechtsanwälte,
– Saarland, by L. Schreiner, acting as Agent,
– the Spanish Government, by J. Rodríguez Cárcamo and J. López-Medel Bascones, acting as Agents,
– the Italian Government, by R. Adam, acting as Agent, and P. Gentili, avvocato dello Stato,
– the Netherlands Government, by C.M. Wissels and D.J.M. de Grave, acting as Agents,
– the Polish Government, by M. Dowgielewicz, acting as Agent,
– the United Kingdom Government, by V. Jackson and H. Walker, acting as Agents, and J. Coppel, Barrister,
– the Commission of the European Communities, by M. Šimerdová and G. Wilms, acting as Agents,
having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,
gives the following
Judgment
1 This reference for a preliminary ruling concerns the interpretation of Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34) ('Directive 2001/83').
2 The reference has been made in the course of proceedings between BIOS Naturprodukte GmbH ('BIOS Naturprodukte') and Saarland concerning the classification of a product referred to as 'Weihrauch H 15-Tabletten' (H 15 incense tablets) for the purpose of its marketing in German territory.
Legal context
Community legislation
3 Under Article 1(2) of Directive 2001/83, 'medicinal product' is to be understood to mean:
'…
(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis'.
National legislation
4 The term 'medicinal product' is defined in Paragraph 2(1) of the Law on medicinal products (Arzneimittelgesetz), in its version of 11 December 1998 (BGBl. 1998 I, p. 3586) ('the AMG').
5 In accordance with Paragraph 69(1) of the AMG, the competent authorities are to take the necessary steps to eliminate infringements that have been found and to prevent new ones. They may, in particular, prohibit the placing on the market of medicinal products if the authorisation or registration required for such products is absent.
The dispute in the main proceedings and the question referred for a preliminary ruling
6 BIOS Naturprodukte placed on the market in Germany a product called 'Weihrauch H 15-Tabletten' as a food supplement.

7 That preparation, which is based on Indian incense extract, is produced in India and imported into Austria, where it is marketed as a food product. In addition to various excipients, each tablet contains 400 mg of Indian incense extract. According to the information which features on the packaging, the recommended dosage is one tablet to be taken daily with a little liquid after a meal.

8 By decision of 23 January 2002, Saarland, pursuant to Paragraph 69(1) of the AMG, prohibited BIOS Naturprodukte from continuing to offer that product on the German market on the ground that it was a medicinal product which had not received prior marketing authorisation. Referring to comparable legislation in India, that decision placed the product in the category of medicinal products for which a marketing authorisation is required.

9 BIOS Naturprodukte brought an action against that decision in which it submitted that the product in issue in the main proceedings is a food supplement and not a medicinal product. Before the Verwaltungsgericht (Administrative Court), it argued that the product concerned is neither a medicinal product by presentation, since it is expressly described as a food supplement on the packaging and no reference is made to any therapeutic or prophylactic effects, nor a medicinal product by function, since the recommended daily dose of 400 mg has no pharmacological action, as shown by two expert reports which it provided. It also indicated that, in line with the traditional use of incense extract as an aroma and a spice, the product concerned served a nutritional purpose.

10 By judgment of 20 May 2003, the Verwaltungsgericht dismissed that action on the ground that, in view of its purpose, the product at issue in the main proceedings was, in the perception of the trade, predominantly regarded as a medicinal product.

11 By judgment of 3 February 2006, the Oberverwaltungsgericht (Higher Administrative Court) dismissed the appeal brought by BIOS Naturprodukte on the ground that the product in issue in the main proceedings was to be regarded as a medicinal product since it satisfies the definition of medicinal product set out in Article 1(2) of Directive 2001/83.

12 Having regard to its designation as a food supplement and the fact that there was no evidence whatsoever of any therapeutic purpose, the Oberverwaltungsgericht found that the product concerned in the main proceedings was not a medicinal product by presentation. None the less, that court reached the conclusion, on the basis of recent results of scientific research, that it was a medicinal product by function. It stated in that regard that incense extract has an anti-inflammatory effect when used in daily doses of between 800 mg and 1 600 mg and that incense extract may, by contrast, have the opposite effect of aiding inflammatory processes when used in low doses, as is the case of the product concerned in the main proceedings.

13 The Oberverwaltungsgericht, which, however, accorded no importance to the therapeutic effects of the incense extract used in stronger doses than that recommended, took the view that it was necessary, in the light of the objective of health protection, to find that the negative effects of a product used in an insufficient dosage also came under pharmacological action.

14 BIOS Naturprodukte brought proceedings for judicial review against the judgment of the Oberverwaltungsgericht.

15 The Bundesverwaltungsgericht takes the view that the question arises in the case in the main proceedings not only as to whether a product can be regarded as a medicinal product by function where it contains an ingredient capable, in a particular dose, of bringing about physiological changes, but where the dosage of the product concerned remains, in normal conditions of use, below that dose, but also as to whether a risk to health linked to use of a product, arising precisely from the use of an insufficient dose of that product, may result in that product having to be classified as a medicinal product.

16 As it took the view that the resolution of the dispute before it depended on the interpretation of Article 1(2) of Directive 2001/83, the Bundesverwaltungsgericht decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

‘Is the definition of medicinal product in Article 1(2) of Directive 2001/83 ... to be interpreted to the effect that a product intended for human consumption and described as a food supplement is a medicinal product by function if it contains substances which pose a risk to health in the low dose contained in the product when the recommended intake printed on the packaging is observed, without being capable of producing therapeutic effects, but which have therapeutic effects in high doses?’

The question referred for a preliminary ruling

17 By its question, the national court asks, essentially, whether Article 1(2) of Directive 2001/83 is to be interpreted as meaning that a product which includes in its composition a substance which has a physiological effect when it is used in a particular dosage is a medicinal product by function since, regard being had to its content in active substances and under normal conditions of use, it constitutes a risk to health without, however, being capable of restoring, correcting or modifying physiological functions in human beings.

18 First of all, it should be pointed out that, for the purpose of determining whether a product falls within the definition of a medicinal product by function for the purposes of Directive 2001/83, the national authorities, acting under the supervision of the courts, must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological, immunological or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (Case C-140/07 Hecht-Pharma [2009] ECR I-0000, paragraph 39).

19 It follows that products containing a substance which has a physiological effect cannot automatically be classified as medicinal products by function unless the competent administration has made an assessment, with due diligence, of each product individually, taking account, in particular, of that product's specific pharmacological, immunological or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge (Hecht-Pharma, paragraph 40).

20 The pharmacological, immunological or metabolic properties of a product constitute, in fact, the factor on the basis of which it must be ascertained, in the light of the potential capacities of the product, whether it may, for the purposes of Article 1(2)(b) of Directive 2001/83, be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions (see, to that effect, Case C-319/05 Commission v Germany [2007] ECR I-9811, paragraph 59).

21 In that regard, it should be borne in mind that the capacity to restore, correct or modify physiological functions should not lead to the classification as medicinal products by function of products which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions (Hecht-Pharma, paragraph 41).

22 When that assessment is being made, the normal conditions of use of the product in question should be taken into account (see, to that effect, Case C-150/00 Commission v Austria [2004] ECR I-3887, paragraph 75), and the fact that it is capable of having a significant physiological effect when used at a higher dosage than that indicated in the instructions or on the packaging is irrelevant in that regard.

23 It follows from the foregoing considerations that, apart from the case of substances or combinations of substances intended for the purpose of making a medical diagnosis, a product cannot be regarded as being a medicinal product by function where, having regard to content and if used as intended, it is incapable of appreciably restoring, correcting or modifying physiological functions in human beings (see, to that effect, Hecht-Pharma, paragraph 42).

24 This conclusion is not invalidated by the fact that the product in question, under normal conditions of use, may involve a risk to health.

25 In that regard, it should be borne in mind, first, that the fact that the use of a product presents a risk to health is not an indication that it is pharmacologically effective. The risk to health, although it must be taken into consideration in the classification of a product as a medicinal product by function, is none the less an autonomous factor (see Commission v Germany, paragraph 69).

26 Second, a risk to health is only one aspect of the product which must be taken into consideration by the competent national authorities for the purpose of assessing whether it is a medicinal product within the meaning of Article 1(2)(b) of Directive 2001/83, and cannot be the only determining factor (see, to that effect, Commission v Austria, paragraph 65).

27 Consequently, the answer to the question referred is that Article 1(2) of Directive 2001/83 must be interpreted as meaning that a product which includes in its composition a substance which has a physiological effect when used in a particular dosage is not a medicinal product by function where, having regard to its content in active substances and under normal conditions of use, it constitutes a risk to health without, however, being capable of restoring, correcting or modifying physiological functions in human beings.

Costs

28 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 (Fifth Chamber) hereby rules:

Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, must be interpreted as meaning that a product which includes in its composition a substance which has a physiological effect when used in a particular dosage is not a medicinal product by function where, having regard to its content in active substances and under normal conditions of use, it constitutes a risk to health without, however, being capable of restoring, correcting or modifying physiological functions in human beings.