JUDGMENT OF THE COURT (Sixth Chamber)

24 October 2002 *

In Case C-99/01,

REFERENCE to the Court under Article 234 EC by the Verwaltungsgerichtshof (Austria) for a preliminary ruling in the proceedings pending before that court against

Gottfried Linhart

and

Hans Biffl,

on the interpretation of Articles 30 and 36 of the EC Treaty (now, after amendment, Articles 28 EC and 30 EC) and Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ 1976 L 262, p. 169), as amended by Council Directive 93/35/EEC of 14 June 1993 (OJ 1993 L 151, p. 32), and Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising (OJ 1984 L 250, p. 17),

* Language of the case: German.

THE COURT (Sixth Chamber),

composed of: J.-P. Puissochet, President of the Chamber, R. Schintgen, V. Skouris, F. Macken and J.N. Cunha Rodrigues (Rapporteur), Judges,

Advocate General: L.A. Geelhoed,
Registrar: R. Grass,

after considering the written observations submitted on behalf of:

— Mr Linhart, by G. Legat, Rechtsanwalt,

— Dr Biffl, by C. Hauer, Rechtsanwalt,

— the Austrian Government, by C. Pesendorfer, acting as Agent,

— the Commission of the European Communities, by J. Sack and M. França, acting as Agents,

having regard to the report of the Judge-Rapporteur,

after hearing the Opinion of the Advocate General at the sitting on 7 March 2002,

gives the following

Judgment

1 By order of 29 January 2001, received at the Court on 28 February 2001, the Verwaltungsgerichtshof (Higher Administrative Court) referred to the Court for a preliminary ruling under Article 234 EC two questions on the interpretation of Articles 30 and 36 of the EC Treaty (now, after amendment, Articles 28 EC and 30 EC) and Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ 1976 L 262, p. 169), as amended by Council Directive 93/35/EEC of 14 June 1993 (OJ 1993 L 151, p. 32, hereinafter 'Directive 76/768'), and Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising (OJ 1984 L 250, p. 17).

2 Those questions were raised in proceedings related to actions brought against Mr Linhart and Dr Biffl, who are alleged to have placed incorrectly described cosmetic products on the market.

Legal framework

Community law

3 Article 6(3) of Directive 76/768 provides that:

'Member States shall take all measures necessary to ensure that, in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have.'

4 Article 7a(1) of Directive 76/768 states:

'The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6(1)(a):

...

(f) existing data on undesirable effects on human health resulting from use of the cosmetic product;

(g) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product.'

5 The first subparagraph of Article 4(1) of Directive 84/450 states:

'Member States shall ensure that adequate and effective means exist for the control of misleading advertising in the interests of consumers as well as competitors and the general public.

...'

6 Article 7 of Directive 84/450 provides that:

'This Directive shall not preclude Member States from retaining or adopting provisions with a view to ensuring more extensive protection for consumers, persons carrying on a trade, business, craft or profession, and the general public.'

National law

7 The Bundesgesetz über den Verkehr mit Lebensmittel, Verzehrprodukten, Zusatzstoffen, Kosmetischen Mitteln und Gebrauchsgegenständen (Lebensmittelgesetz 1975) of 23 February 1975 (Federal Act on trade in foodstuffs, products intended for human consumption, additives, cosmetic products and consumer goods, hereinafter 'the LMG') states, in Paragraph 8:

'Foodstuffs, consumer products and additives are:

...

(f) incorrectly described when they are placed on the market accompanied by information which is likely to be misleading as regards matters which are important in the light of trade practices and, in particular, in the light of consumer expectations, such as nature, origin, use, shelf life, date of manufacture, properties, percentage of effective ingredients, quantity, size, number or weight, or in such a form or presentation or bearing prohibited health-related information.'

8 Paragraph 9(1) and (3) of the LMG provides:

'1. In marketing foodstuffs, products intended for human consumption or additives, it is prohibited:

(a) to refer to the prevention, relief or cure of illnesses or symptoms of illness, or to physiological or pharmacological effects, in particular effects which prolong youthfulness, slow down the symptoms of ageing, lead to weight loss or preserve health or to create the impression of any such effect;

(b) to refer to case histories, recommendations by doctors or expert medical opinions;

(c) to use health-related, pictorial or stylised representations of organs of the human body, depictions of members of the health-care professions or of sanatoria or other pictures or illustrations referring to health-care activities;

...

3. The Federal Minister for Health and the Environment shall authorise, by decree and upon request, health-related information for certain foodstuffs or consumer products where that is consistent with the protection of consumers against fraud. The decree shall be revoked where the conditions of the authorisation are no longer met.'

9 Paragraph 26(1) of the LMG prohibits the placing on the market of cosmetic products which:

'(a) are harmful to health under normal or foreseeable conditions of use;

(b) contain pharmacologically active substances or unauthorised colouring agents which do not correspond to the conditions for authorisation or which are present in prohibited quantities;

(c) are damaged;

(d) are incorrectly described;

(e) do not satisfy the rules laid down in Paragraph 27.'

10 Paragraph 26(2) of the LMG states that:

'Paragraph 8(a), (b) and (f) applies by analogy [to trade in cosmetic products], Paragraph 9 applies on condition that information relating to physiological or pharmacological effects which is not misleading, and figurative representations

intended to explain the field of use of the product, have been authorised. If such effects are claimed, the active components [of the product] must be notified to the administration, upon its request.'

The main proceedings and the questions referred for a preliminary ruling

11 Two sets of main proceedings are at the origin of the present order for reference.

12 By decision of 22 February 1999 of the Unabhängiger Verwaltungssenat Wien (Independent Administrative Chamber for Vienna) (Austria), Mr Linhart, the managing director of Colgate Palmolive GmbH, was found guilty of an administrative breach of Paragraph 74(1) in conjunction with Paragraphs 9(1)(a) and 8(f) of the LMG on the ground that the company placed on the market the cosmetic product 'Palmolive flüssige Seife Prima Antibakteriell' (Palmolive liquid antibacterial soap) with the statement that it was 'dermatologically tested' appearing on its packaging.

13 By decision of 9 May 2000, the Unabhängiger Verwaltungssenat im Land Niederösterreich (Independent Administrative Chamber for Lower Austria) (Austria) held Dr Biffl, as the managing director of Haarkos Parfumeriewaren und Kosmetika GmbH, to be in breach of Paragraphs 74(1), 9(1)(b) and 8(f) of the LMG, on the basis that the company had distributed the product 'Keralogie Creme-Peeling Anti Schuppen regulierendes Haarbad' (dandruff-controlling conditioner), whose packaging stated that it was 'dermatologically tested'.

14 In their appeals against those decisions before the Verwaltungsgerichtshof, Mr Linhart and Dr Biffl claimed that the Austrian law in force, on which those decisions were based, was in breach of Community law, in particular the provisions of Directive 76/768, and of the case-law of the Court, in particular as it follows from the judgment in *Unilever* (Case C-77/97 [1999] ECR I-431).

15 The Verwaltungsgerichtshof observes that it is not entirely clear from the Court's case-law whether the Austrian legislation which must be applied in the main proceedings is consistent with the EC Treaty and with Directives 76/768 and 84/450. In the present case, the referring court considers that Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ 2000 L 109, p. 29), according to which labelling must not attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties, is likely to apply to cosmetic products as well.

16 In those circumstances, the Verwaltungsgerichtshof decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Do Articles 28 and 30 EC, Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, as amended by Council Directives 88/667/EEC of 21 December 1988 and 93/35/EEC of 14 June 1993..., in particular Article 6(3) thereof, together with Council Directive 84/450/EEC of 10 September 1984 on the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising... in particular Articles 4

and 7 thereof, preclude national legislation which, in connection with the marketing of cosmetic products, makes it an offence to refer to medical opinions by the use, in particular, of the description 'clinically tested' or 'dermatologically tested', if erroneous ideas as to the characteristics and functioning of the cosmetic product could be engendered in the mind of the consumer as a result of lack of information as to the content and outcome of the opinion in question?

(2) Do Articles 28 EC and 30 EC, Directive 76/768, in particular Article 6(3) thereof, and Directive 84/450, in particular Articles 4 and 7 thereof, preclude national legislation which authorises the use of information as referred to in Question 1 only on condition that prior authorisation is granted by the competent Minister?'

Preliminary observations

17 First of all, it should be borne in mind that Directive 76/768 provided exhaustively for the harmonisation of national rules on the packaging and labelling of cosmetic products (see, *inter alia*, *Unilever*, cited above, paragraph 24, and Case C-220/98 *Estée Lauder* [2000] ECR I-117, paragraph 23).

18 As the Court has already held, where a matter is regulated in a harmonised manner at Community level, any national measure relating thereto must be assessed in the light of the provisions of that harmonising measure and not of Articles 30 and 36 of the Treaty (Case C-150/88 *Parfümerie-Fabrik 4711* [1989] ECR 3891, paragraph 28, Case C-37/92 *Vanacker and Lesage* [1993] ECR I-4947, paragraph 9, and Case C-324/99 *DaimlerChrysler* [2001] ECR I-9897, paragraph 32).

19 It should also be recalled that Article 6(3) of Directive 76/768 requires Member States to take all measures necessary to ensure that, in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that those products have characteristics which they do not have.

20 The present case concerns a specific provision intended to prohibit misleading information exclusively as it relates to the characteristics of cosmetic products, which must therefore be interpreted as a special rule in relation to the general provisions on protection against fraud laid down in Directive 84/450.

21 It follows that, in order to answer the questions referred for a preliminary ruling, the Court must confine itself to interpreting Article 6(3) of Directive 76/768.

The first question

22 By its first question, the referring court is essentially asking whether Article 6(3) of Directive 76/768 precludes national legislation which prohibits reference to expert medical opinions in the marketing of cosmetic products — in particular, the use of the statement 'clinically tested' or 'dermatologically tested' — if, through lack of information as to the content and outcome of such opinions, such a reference is likely to engender erroneous ideas as to the characteristics and functioning of the product in the mind of the consumer.

23 It should be recalled that Article 6(3) of Directive 76/768 requires Member States to take all measures necessary to ensure that, in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have.

24 As a result of the exhaustive nature of that legislation, which has already been referred to in paragraph 17 of the present judgment, Member States are no longer permitted to adopt more stringent national measures intended to prevent misleading advertising relating to the characteristics of cosmetic products.

25 It is settled case-law that, while it is true that Article 36 of the Treaty allows Member States to maintain restrictions on the free movement of goods, the use of that provision is nevertheless precluded where Community directives provide for harmonisation of the measures necessary to achieve the specific objective which would be furthered by recourse to Article 36 (see, *inter alia*, Case C-1/96 *Compassion In World Farming* [1998] ECR I-1251, paragraph 47, and Case C-112/97 *Commission* v *Italy* [1999] ECR I-1821, paragraph 54). That prohibition also applies when the need to protect consumers is put forward (Case C-102/96 *Commission* v *Germany* [1998] ECR I-6871, paragraph 21).

26 The measures which the Member States are required to take for the implementation of Article 6(3) of Directive 76/768 must, however, observe the principle of proportionality (see, in particular, the judgments cited above in *Unilever*, paragraph 27, and *Estée Lauder*, paragraph 26).

27 Paragraph 26(2) of the LMG provides that statements based on medical assessments are prohibited unless non-misleading information on the physiological or pharmacological effects of the product concerned has been authorised.

28 In this case, as may be seen in the order for reference, the statement 'dermatologically tested' on the packaging of the products at issue in the main proceedings was prohibited on the sole ground that those products were placed on the market without any information relating to the contents or outcome of the expert medical opinion which is implicit in that statement.

29 According to the Austrian legislation and national case-law, the absence of explicit references to the contents and outcome of the medical assessment to which the cosmetic products were subject could give consumers the erroneous impression that those products had curative effects.

30 In that context, it should be determined whether the mere statement 'dermatologically tested' appearing on the packaging of a cosmetic product is likely to attribute to that product characteristics which it does not possess, so that the national authorities can prohibit its marketing in accordance with Article 6(3) of Directive 76/768.

31 In that regard, the Court has held that the criterion of the presumed expectations of an average consumer who is reasonably well informed and reasonably observant and circumspect also applies in the context of the marketing of cosmetic products where a mistake as to the product's characteristics cannot pose any risk to public health (*Estée Lauder*, cited above, paragraphs 27 and 28).

32 The application of such a criterion in the main proceedings makes it possible to infer that the statement 'dermatologically tested' which appears on the packaging of certain cosmetic products — in this instance, soaps and hair products — cannot suggest to the average consumer who is reasonably well informed and reasonably observant and circumspect anything other than that the product underwent tests intended to study its effects on the skin and that, as a result, its placing on the market implies that the results of those tests were positive and that the product was well tolerated or at least harmless when applied to the skin.

33 Furthermore, the authenticity of those results is subject to monitoring by the national authorities.

34 Article 7a(1)(f) and (g) of Directive 76/768 requires the person responsible for placing the product on the market to keep information readily accessible to the competent authorities of the Member State concerning the exsiting data on undesirable effects on human health resulting from use of the product in question and proof of the effect claimed for it.

35 In those circumstances, the statement 'dermatologically tested' could not mislead an average consumer who is reasonably well informed and reasonably observant and circumspect by attributing to the products in question characteristics which they do not possess and, in any event, a possible error relating to those characteristics would be unlikely to have an effect on public health.

36 It follows from this that prohibiting the abovementioned statement, in cases where no information on the contents and outcome of the expert medical opinion

appears on cosmetic product packaging, is a national fraud-prevention measure which is stricter than that laid down in Article 6(3) of Directive 76/768.

37 As regards the statement 'clinically tested', which is also mentioned in the order for reference, it is apparent from the documents in the case that that statement bears no relation to the subject of the main proceedings, which only applies to the statement 'dermatologically tested' appearing on the packaging of the products at issue.

38 It follows that there is no need to answer the question relating to the use of the statement 'clinically tested'.

39 In light of the preceding considerations, the answer to the first question must be that Article 6(3) of Directive 76/768 precludes national legislation which prohibits reference to expert medical opinions in the marketing of cosmetic products — in particular, the use of the statement 'clinically tested' or 'dermatologically tested' — if such a reference does not include information relating to the contents and outcome of those assessments.

The second question

40 By its second question, the referring court essentially asks whether Article 6(3) of Directive 76/768 precludes Member State legislation which authorises the use of information as referred to in Question 1 only on condition that prior authorisation is granted by the competent Minister.

41 In that regard, it should be recalled that in accordance with Paragraph 9(3) in conjunction with Paragraph 26(2) of the LMG, the competent Minister is to authorise, by decree and upon request, health-related information for certain cosmetic products when that is compatible with the protection of consumers against fraud.

42 It follows that the placing on the market of cosmetic products bearing the statement 'dermatologically tested', even if, as observed by the Court in paragraph 35 of the present judgment, it is not likely to mislead an average consumer who is reasonably well informed and reasonably observant and circumspect, requires prior authorisation by the national authorities.

43 However, since the statement 'dermatologically tested' is not likely to mislead that consumer, as it does not attribute to the cosmetic products at issue characteristics which they do not possess, the marketing of those products does not fall within the prohibitions in Article 6(3) of Directive 76/768.

44 Consequently, the placing on the market of cosmetic products which satisfy the requirements of Directive 76/768 is subject to the basic principle of the free movement of goods, so that the Member States are not permitted to take measures whose effect is to restrict their marketing.

45 Accordingly, as the Court has already held, the need to obtain the authorisation laid down in Paragraph 9(3) of the LMG constitutes a wholly unjustified obstacle to the free movement of the product in question (*Unilever*, cited above, paragraph 34).

46 The answer to the second question must therefore be that Article 6(3) of Directive 76/768 precludes national legislation which authorises the use of information as referred to in Question 1 only on condition that prior authorisation is granted by the competent Minister.

Costs

47 The costs incurred by the Austrian Government and by the Commission, which have submitted observations to the Court, are not recoverable. 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.

On those grounds,

THE COURT (Sixth Chamber),

in answer to the questions referred to it by the Verwaltungsgerichtshof by order of 29 January 2001, hereby rules:

1. **Article 6(3) of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic**

products, as amended by Council Directive 93/35/EEC of 14 June 1993, precludes national legislation which prohibits reference to expert medical opinions in the marketing of cosmetic products — in particular, the use of the statement 'dermatologically tested' — if that reference does not include information relating to the contents and outcome of those assessments.

2. Article 6(3) of Directive 76/768 as amended by Directive 93/35 precludes national legislation which authorises the use of information as referred to in Question 1 only on condition that prior authorisation is granted by the competent Minister.

Puissochet Schintgen Skouris

Macken Cunha Rodrigues

Delivered in open court in Luxembourg on 24 October 2002.

R. Grass

Registrar

J.-P. Puissochet

President of the Sixth Chamber