JUDGMENT OF THE COURT (Fifth Chamber)
28 January 1999 *

In Case C-77/97,

REFERENCE to the Court under Article 177 of the EC Treaty by the Handelsgericht Wien (Austria) for a preliminary ruling in the proceedings pending before that court between

Österreichische Unilever GmbH

and

Smithkline Beecham Markenartikel GmbH

on the interpretation of Article 30 of the EC Treaty 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),

THE COURT (Fifth Chamber),

composed of: J.-P. Puissochet, President of the Chamber, J. C. Moitinho de Almeida (Rapporteur), C. Gulmann, D. A. O. Edward and M. Wathelet, Judges,

* Language of the case: German.

Advocate General: G. Cosmas,
Registrar: D. Louterman-Hubeau, Principal Administrator,

after considering the written observations submitted on behalf of:

— Österreichische Unilever GmbH, by Ernst Ploil, Rechtsanwalt, Vienna,

— Smithkline Beecham Markenartikel GmbH, by Gottfried Korn, Rechtsanwalt, Vienna,

— the Austrian Government, by Christine Stix-Hackl, Gesandte in the Federal Ministry of Foreign Affairs, acting as Agent,

— the French Government, by Kareen Rispal-Bellanger, Deputy Head of the Legal Directorate of the Ministry of Foreign Affairs, and Régine Loosli-Surrans, Chargée de Mission in the same directorate, acting as Agents,

— the United Kingdom Government, by Lindsey Nicoll, of the Treasury Solicitor's Department, acting as Agent, and Mark Hoskins, Barrister,

— the Commission of the European Communities, by Pieter van Nuffel and Claudia Schmidt, of its Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Österreichische Unilever GmbH, represented by Ernst Ploil and Markus Boesch, Rechtsanwalt, Vienna, Smithkline Beecham

Markenartikel GmbH, represented by Gottfried Korn and Andreas Frauenberger, Rechtsanwaltsanwärter, Vienna, the French Government, represented by Régine Loosli-Surrans, and the Commission, represented by Claudia Schmidt, at the hearing on 7 May 1998,

after hearing the Opinion of the Advocate General at the sitting on 2 July 1998,

gives the following

Judgment

1 By order of 20 December 1996, received at the Court on 21 February 1997, the Handelsgericht Wien (Commercial Court, Vienna) referred to the Court for a preliminary ruling under Article 177 of the EC Treaty a question on the interpretation of Article 30 of the EC Treaty 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).

2 That question was raised in proceedings between Österreichische Unilever GmbH ('Unilever') and Smithkline Beecham Markenartikel GmbH ('Smithkline') concerning statements appearing on tubes of toothpaste marketed by Smithkline in Austria and in television advertisements broadcast by it in that State.

Relevant Community legislation

3 Directive 76/768, as amended, in particular, by Council Directive 88/667/EEC of 21 December 1988 (OJ 1988 L 382, p. 46) and Council Directive 93/35/EEC of 14 June 1993 (OJ 1993 L 151, p. 32), provides in Article 1:

'1. A "cosmetic product" shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.

2. The products to be considered as cosmetic products within the meaning of this definition are listed in Annex I.

3. Cosmetic products containing one of the substances listed in Annex V shall be excluded from the scope of this directive. Member States may take such measures as they deem necessary with regard to those products.'

4 Article 2 provides:

'A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its label-

ling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorised agent or by any other person responsible for placing the product on the Community market.

The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in this directive.'

5 Under Article 4(1)(a) and (b) of Directive 76/768, Member States are to prohibit the marketing of cosmetic products containing, in particular, substances listed in Annex II and substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down.

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

'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.

Furthermore, any reference to testing on animals must state clearly whether the tests carried out involved the finished product and/or its ingredients.'

7 Under Article 7(1) of Directive 76/768,

'Member States may not, for reasons related to the requirements laid down in this directive and the annexes thereto, refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements of this directive and the annexes thereto.'

8 Article 12 of Directive 76/768 provides:

'1. If a Member State notes, on the basis of a substantiated justification, that a cosmetic product, although complying with the requirements of the directive, represents a hazard to health, it may provisionally prohibit the marketing of that product in its territory or subject it to special conditions. It shall immediately inform the other Member States and the Commission thereof, stating the grounds for its decision.

2. The Commission shall as soon as possible consult the Member States concerned, following which it shall deliver its opinion without delay and take the appropriate steps.

3. If the Commission is of the opinion that technical adaptations to the directive are necessary, such adaptations shall be adopted by either the Commission or the Council in accordance with the procedure laid down in Article 10. In that event, the Member State which has adopted safeguard measures may maintain them until entry into force of the adaptations.'

The Austrian legislation

9 Article 5 of the Lebensmittelgesetz [Bundesgesetz über den Verkehr mit Lebensmitteln, Verzehrprodukten, Zusatzstoffen, kosmetische Mitteln und Gebrauchsgegenständen of 23 January 1975, BGBl. 86 (Federal Law on the marketing of foodstuffs, products intended for human consumption, additives, cosmetic products and utensils, hereinafter 'the LMG')] provides:

'Cosmetic products are substances which are intended to clean, care for or perfume the human body, to act upon its external appearance, to protect the skin or to clean, care for or improve the use of prostheses.'

10 Article 9(1) of the LMG provides:

'In the marketing of foodstuffs, products intended for human consumption or additives, it shall be prohibited:

(a) to refer to the prevention, relief or cure of illnesses or symptoms of illness or to physiological or pharmacological effects, in particular those which preserve youthfulness, inhibit signs of ageing, promote slimming or maintain health, or to create the impression of any such effect;

(b) to refer to case-histories, recommendations made by doctors or medical experts' reports;

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

11 Article 26(1) of the LMG prohibits the marketing of cosmetic products which:

'(a) are harmful to health when used in normal or foreseeable circumstances;

(b) contain pharmacologically active substances or colouring agents which are not authorised, do not conform to the conditions of authorisation or are present in prohibited quantities;

(c) are spoilt or damaged;

(d) are wrongly described; or

(e) do not conform to the rules laid down pursuant to Article 27.'

12 According to Article 26(2) of the LMG:

'Article 8(a), (b) and (f) shall apply *mutatis mutandis* and Article 9 shall apply subject to the proviso that references to physiological or pharmacological effects which are not misleading and illustrations intended to explain the scope of use of the

product concerned are permissible. Where such effects are claimed, the administrative authorities shall upon demand be notified of the active constituents.'

13 Article 27 of the LMG provides:

'1. Where necessary in order to protect consumers against damage to health or deception, the Federal Minister for Health and Environmental Protection shall, taking account of the current state of scientific knowledge and technological progress and after hearing the views of the Codex Committee, lay down by regulation that, in the marketing of cosmetic products, certain substances are to be excluded or that their use is to be restricted, and shall make orders by analogy with points (1) to (3) of Article 10(1). For the purposes of protecting the health of consumers, the Federal Minister for Health and Environmental Protection shall also make orders by analogy with the other provisions of Article 10(1). In that connection, Article 10(2) shall apply *mutatis mutandis*.

2. Where compatible with the protection of consumers against damage to health and deception, the Federal Minister for Health and Environmental Protection shall, taking account of the current state of scientific knowledge and technological progress and after hearing the views of the Codex Committee, authorise by regulation certain substances having pharmacological effects and colouring agents, lay down conditions for their use, prescribe the requisite degree of purity and specify the maximum permitted quantities in cosmetic products.

3. Where compatible with the protection of consumers against damage to health and deception, the Federal Minister for Health and Environmental Protection shall, taking account of the current state of scientific knowledge and technological progress, upon application authorise by decision unauthorised substances having pharmacological effects and colouring agents, lay down conditions for their use, prescribe the requisite degree of purity and specify the maximum permitted quanti-

ties in cosmetic products. The decision shall take effect for a limited period of time not exceeding three years. It shall be revoked if the conditions for authorisation are no longer fulfilled. The application for authorisation shall be accompanied by all the documentation needed to assess the substance.'

14 The Verordnung des Bundesministers für Gesundheit und Konsumentenschutz über die Zulassung von pharmakologisch wirksamen Stoffen für kosmetische Mittel (Regulation of the Federal Minister for Health and Consumer Protection on the authorisation of pharmacologically active substances in cosmetic products, BGBl. 166/1996, hereinafter 'the Kosmetikverordnung'), adopted pursuant to Article 27(2) of the LMG, provides in Article 1:

'Of the groups of active substances specified in Annex 1, only the pharmacologically active substances specified in Annex 2 shall be authorised for cosmetic products falling within the scope of Article 5 of the LMG 1975.'

15 Annex 1 to the Kosmetikverordnung lists the categories of active substances relating to three areas of use, including area A, which comprises substances intended to come into contact with mucous membranes. Those substances are classified in seven sub-categories, including substances with keratinising effect (point 1.1), substances intended to prevent dental caries (point 1.4) and substances preventing the formation of plaque (point 1.5). Annex 2 (sections 1, 4 and 5 of which correspond to points 1.1, 1.4 and 1.5) lays down an exhaustive list of pharmacologically active substances which may be used in those various sub-categories, together with maximum quantities and conditions of use.

The dispute in the main proceedings

16 Smithkline markets in Austria 'Odol-Med 3 (Samtweiß)' toothpastes, which are manufactured in Germany by the firm of Lingner & Fischer and marketed in that country. In statements appearing on the tubes of toothpaste and in television advertisements, Smithkline claims that 'Odol-Med 3 (Samtweiß)' helps to prevent parodontosis, contains or produces a triple prophylactic, provides triple protection against dental caries, plaque and parodontosis and removes or prevents the formation of tartar.

17 In the main proceedings, Unilever is seeking an injunction restraining the making of such statements, which it regards as contrary to the provisions of the Kosmetikverordnung and Article 9 of the LMG. It states in that connection that 'Odol-Med 3 (Samtweiß)' toothpaste contains only one of the decay-inhibiting pharmacologically active substances mentioned in the list in Annex 2 to the Kosmetikverordnung (sodium monofluorophosphate) and none of the substances exhaustively itemised in that list which prevent the formation of tartar or parodontosis. It considers, therefore, that the statements indicating that the toothpaste in question has the effect of preventing the formation of tartar and parodontosis are incorrect and misleading, and that they are therefore not in accordance with the provisions of the Austrian legislation.

18 Unilever further claims that it is not open to Smithkline, by invoking Article 30 of the Treaty, to rely on the fact that 'Odol-Med 3 (Samtweiß)' toothpaste is sold in Germany, since the principle of the free movement of goods enshrined in Article 30 of the EC Treaty is subject to the exception laid down in Article 36 of the Treaty, according to which Member States may enact measures restricting such freedom of movement where they are designed to protect the health of consumers — as is the case with the Kosmetikverordnung — or to prevent deception. Moreover, no Community rules exist with respect to the composition and content required of cosmetic products; consequently, the Kosmetikverordnung cannot be regarded as being contrary to Community law.

19 According to Smithkline, Articles 9 and 26 of the LMG, which contain rules relating to the product, are liable to obstruct intra-Community trade and are, in principle, contrary to Article 30 of the Treaty. As regards the imperative requirements which may justify obstacles to the free movement of goods under Articles 30 and 36 of the Treaty, it maintains that legislation in this sphere has been fully harmonised by Directive 76/768. Where a cosmetic product fulfils the requirements of that directive and the annexes thereto, the Member States may not refuse, prohibit or restrict the marketing of that product.

20 The Handelsgericht Wien observes that the injunction sought by Unilever, which may be granted only pursuant to Article 1 of the Gesetz gegen den unlauteren Wettbewerb (Law against Unfair Competition) and Articles 9 and 26 of the LMG, affects trade between Member States, and that the validity of the national legislation relied on raises a question which must be resolved before it can determine the proceedings before it.

21 In those circumstances, the Handelsgericht Wien has decided to stay proceedings and to refer the following question to the Court for a preliminary ruling:

'Does Article 30 of the EC Treaty in conjunction with Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products preclude a national provision which, as regards advertising in connection with the marketing of cosmetic products, contains prohibitions going beyond the restrictions contained in the directive?'

22 In its written observations, the French Government has raised the question whether the toothpaste at issue in the main proceedings may be regarded as a medicinal product 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 the Commission and the other interveners have replied to

the written question put to them in that regard. However, that issue was not raised by the national court, whose task it is to assess its relevance for the purposes of determining the proceedings, and the Court of Justice does not consider there to be any need to express a view in that connection.

The question referred

23 By its question, the national court is asking, in essence, whether the combined provisions of Article 30 of the Treaty and of Directive 76/768 preclude the application of national rules which prohibit the advertising of a cosmetic product intended to come into contact with mucous membranes, where the product in question is claimed to prevent the formation of tartar and parodontosis but is not in fact composed of any of the active substances listed in those rules as capable of achieving such a result and the party concerned has not obtained authorisation for the use of other substances.

24 It should be borne in mind that Directive 76/768 has brought about the complete harmonisation of national rules on the packaging and labelling of cosmetic products (see Case C-150/88 *Parfümerie-Fabrik 4711* v *Provide* [1989] ECR 3891, paragraph 28, and Case C-315/92 *Verband Sozialer Wettbewerb* v *Clinique Laboratories and Estée Lauder* [1994] ECR I-317, paragraph 11).

25 Article 6(3) of Directive 76/768 *inter alia* requires the 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 do not attribute to those products characteristics they do not have.

26 That provision, contained in a directive which, as is apparent in particular from the second and third recitals in its preamble, is designed to ensure free trade in cosmetic products, thus defines the measures to be taken in the interests of consumer protection and fair trading, which are amongst the imperative requirements identified by the Court in its case-law on the application of Article 30 of the Treaty. Article 6(3) is also aimed at protecting human health, within the meaning of Article 36 of the Treaty, in so far as misleading information regarding the characteristics of such products could affect public health.

27 However, the measures which the Member States are required to take for the implementation of that provision must observe the principle of proportionality (see, in particular, *Verband Sozialer Wettbewerb* v *Clinique Laboratories and Estée Lauder*, cited above, paragraph 16).

28 It is necessary, therefore, to verify whether rules such as those at issue in the main proceedings are necessary in order to safeguard the interests of consumers, ensure fair trading or protect public health.

29 Unilever submits in that respect that the list of active substances contained in the Austrian rules is based on scientific and technological research which has been carried out over many years and which reflects the current state of scientific knowledge concerning the effects of those substances. Manufacturers of cosmetic products which contain active substances not listed in the Kosmetikverordnung may apply for special authorisation for the use of such substances.

30 Having regard to the importance of the public interest concerned, namely the protection of health, Unilever considers that the Austrian rules are in keeping with the principle of proportionality and that there is no less restrictive means of achieving this objective.

31 Unilever and the French Government draw attention in that regard to the wide discretion enjoyed by the Member States in the sphere under consideration.

32 As Smithkline and the Commission have observed, rules such as those at issue in the main proceedings would be compatible with Article 6(3) of Directive 76/768 if the list contained in Annex 2 to the Kosmetikverordnung comprised all active substances which may prevent the formation of tartar or parodontosis. As is apparent from the statements made in that connection by Smithkline at the hearing, which have not been challenged, that is not the case, even if regard is had solely to the substances which currently exist.

33 Thus, the advertising of certain toothpastes may be prohibited even though it is not likely to mislead consumers.

34 It is true that authorisation may be granted. However, the need to obtain such authorisation, which in any event remains valid only for a limited period, constitutes a wholly unjustified obstacle to the free movement of the product in question.

35 It is possible to ensure the protection of consumers, public health and fair trading by adopting measures which are less restrictive of the free movement of goods than the automatic exclusion of advertising by a system that prohibits the advertising of substances not expressly listed in the Kosmetikverordnung. Thus, the controls exercised by the national authorities could take the form, *inter alia*, of an obligation requiring the manufacturer or distributor of the product in question, in the event of any uncertainty, to furnish evidence of the accuracy of the advertisements concerned, in the manner provided for by Article 6 of 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).

36 Furthermore, the measures which the Member States are required to take under Article 6(3) of Directive 76/768 in order to prevent advertisements which attribute to cosmetic products characteristics which those products lack must provide that such advertisements constitute a breach of the law and, in particular, a criminal offence punishable by penalties having a deterrent effect.

37 Consequently, the answer to the question referred must be that Article 6(3) of Directive 76/768 precludes the application of national rules which prohibit the advertising of cosmetic products intended to come into contact with mucous membranes, where the product in question is claimed to prevent the formation of tartar and parodontosis but is not in fact composed of any of the active substances listed in those rules as capable of achieving such a result and the party concerned has not obtained authorisation for the use of other substances.

Costs

38 The costs incurred by the Austrian, French and United Kingdom Governments and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main action, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Fifth Chamber),

in answer to the question referred to it by the Handelsgericht Wien by order of 20 December 1996, hereby rules:

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 precludes the application of national rules which prohibit the advertising of cosmetic products intended to come into contact with mucous membranes, where the product in question is claimed to prevent the formation of tartar and parodontosis but is not in fact composed of any of the active substances listed in those rules as capable of achieving such a result and the party concerned has not obtained authorisation for the use of other substances.

Puissochet Moitinho de Almeida Gulmann

Edward Wathelet

Delivered in open court in Luxembourg on 28 January 1999.

R. Grass J.-P. Puissochet

Registrar President of the Fifth Chamber