OPINION OF ADVOCATE GENERAL COSMAS
delivered on 2 July 1998 *

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* Original language: Greek.

I — Introduction

1. In this case the Court has been asked by the Handelsgericht Wien to give a preliminary ruling on a question concerning 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. [1] The proceedings pending before the national court concern the marketing in Austria of toothpaste which is manufactured and marketed without restriction in Germany.

II — Facts

2. The parties to the main proceedings are Österreichische Unilever GmbH ('Unilever'), the plaintiff, and Smithkline Beecham Markenartikel GesmbH ('Smithkline'), both of whom market cosmetic products, including toothpaste, in Austria. The defendant sells in Austria the toothpaste 'Odol-Med 3 (Samtweiss)' which is made in Germany by Lingner & Fischer. According to the order for reference, it is stated on the toothpaste tubes and in television advertising that 'Odol-Med 3 (Samtweiss)' is a preventive against parodontosis, contains or produces threefold prophylaxis, gives threefold protection against caries, plaque and parodontosis and removes plaque or reduces the formation of tartar. [2] Unilever specifically seeks the discontinuance of these statements on the ground that they are contrary to national law.

3. Smithkline claims, and the national court agrees, that the marketing in Austria of products such as 'Odol-Med 3 (Samtweiss)' toothpaste is subject to the Law on Foodstuffs ('LMG'), [3] Paragraph 5 of which provides that certain products for the care and cleaning of human teeth, e. g. toothpaste, are cosmetic products which are subject to certain restrictions and prohibitions. In particular, Paragraph 26 of the LMG prohibits the marketing of cosmetic products which contain pharmacologically active substances not authorised, not conforming to the conditions of authorisation or in prohibited quantities, or are wrongly described or contain misleading references to physiological or pharmacological effects. If a toothpaste contains pharmacologically active substances it is also subject to the Regulation of the Federal Minister for Health and Consumer Protection on the authorisation of pharmacologically active substances in cosmetic products ('the Cosmetics Regulation'). [4] That regulation, which was issued on the basis of the power conferred by Paragraph 27(2) of the LMG, has two annexes. Annex 1 specifies seven groups of active substances, including substances with keratinising effect, substances which inhibit caries and substances which inhibit plaque. Annex 2 gives an exhaustive list of the pharmacologically active substances which may be

1 — OJ 1976 L 262, p. 169.

2 — Order for reference of 20 December 1996, p. 2.

3 — Bundesgesetz über den Verkehr mit Lebensmitteln, Verzehrprodukten, Zusatzstoffen, kosmetischen Mitteln und Gebrauchsgegenständen, 23 January 1975, BGBl. 86.

4 — Published on 12 April 1996 in BGBl. 1996, No 166.

used in the individual groups of active substances listed in Annex 1, the maximum quantities of authorised pharmacologically active substances, and the warning statements which must accompany them. In so far as toothpastes are, according to the Cosmetics Regulation, cosmetic products which come into contact with the mucous membranes, Annex 2 to the regulation applies to them and consequently they may contain the specified pharmacologically active substances only in the maximum quantities laid down in the Annex. [5]

4. According to Unilever, the problem with marketing 'Odol-Med 3 (Samtweiss)' in Austria arises from the fact that it contains only sodium monofluorophosphate of the permitted pharmacologically active substances shown in the 'positive list' in Annex 2 of the Cosmetics Regulation, which describes the said substance as inhibiting caries, but it contains none of the substances listed there which are described as preventing the formation of tartar or preventing paradontosis. In Unilever's opinion, the statements concerning the toothpaste in television advertising and on the packaging, that the product has the effect

5 — For the sake of completeness, I think it would be appropriate to set out here the national legislation in full:
Paragraph 5 of the LMG:
Cosmetic products are substances which are intended for the cleaning, care or perfuming of human beings, for producing effects on their external appearance, for protecting the skin, or for the cleaning and care of prostheses or improving their use.
Paragraph 9(1) of the LMG:
In the marketing of foodstuffs, products for consumption and additives, it shall be prohibited
(a) to refer to the prevention, relief or cure of illnesses or symptoms of illnesses or to physiological or pharmacological effects, particularly any which maintain a youthful appearance, inhibit signs of ageing, promote slimming or maintain health, or to create the impression of any such effect;
(b) to refer to case histories, medical recommendations or expert reports;
(c) to use health-related, pictorial or stylised representations of organs of the human body, pictures of members of the medical or nursing professions or of sanatoria, or other pictures or illustrations referring to treatment activities.
Paragraph 26 of the LMG:
(1) It shall be prohibited to market cosmetic products which
(a) are detrimental to health when used for the intended purpose or when used in a way which may be foreseen;
(b) contain pharmacologically active substances or colouring agents which are unauthorised, do not conform with the conditions of authorisation or are in impermissible quantities;
(c) have become unfit for use;
(d) are wrongly described;
(e) do not conform with the requirements pursuant to Paragraph 27.
(2) Paragraph 8(a), (b) and (f) apply *mutatis mutandis*, and Paragraph 9 applies with the proviso that non-misleading references to physiological or pharmacological effects and illustrations for explaining the range of application are permitted. If such effects are claimed, the authorities shall be notified of the active ingredients on demand.
Paragraph 27 of the LMG:
(1) The Federal Minister for Health and the Protection of the Environment shall, where necessary for the protection of consumers against damage to health or against deception, taking account of the current state of scientific knowledge and technology after obtaining the opinion of the Codex Commission, lay down by decree that certain substances are to be excluded or restricted in the marketing of cosmetic products and he shall make orders by analogy with Paragraph 10(1), Nos. 1 to 3. For the protection of consumers against damage to health the Minister shall also make orders by analogy with the other provisions of Paragraph 10(1). In this connection Paragraph 10(2) applies by analogy.
(2) The Federal Minister for Health and the Protection of the Environment shall, where this is compatible with the protection of consumers against damage to health and against deception, taking account of the current state of scientific knowledge and technology after obtaining the opinion of the Codex Commission, authorise by decree certain substances with 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) The Federal Minister for Health and the Protection of the Environment shall, where this is compatible with the protection of consumers against damage to health and against deception, taking account of the current state of scientific knowledge and technology, on application authorise by decree unauthorised substances with 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. The decree must be subject to a time limit, but the period shall not exceed three years. The decree shall be rescinded if the conditions for authorisation are no longer fulfilled. The application for authorisation must be accompanied by all the documentation which enables the substance to be assessed.
Paragraph 1 of the Cosmetics Regulations:
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 in accordance with Paragraph 5(1) of the LMG 1975.
The groups of active substances specified in Annex 1 are as follows:
1. Substances with keratinising effect.
2. Substances with astringent effect.
3. Substances which counteract irritation of the gums.
4. Substances which inhibit caries.
5. Substances which inhibit plaque.
6. Substances which have a toning effect and promote blood circulation.
7. Substances which have a deodorant effect.

of inhibiting tartar, removing plaque and preventing or inhibiting paradontosis are misleading and therefore incompatible with the Cosmetics Regulation and the LMG.

5. Smithkline replies that, firstly, these provisions of national law are incompatible with Article 30 of the EC Treaty as they are an obstacle to trade within the Community and, secondly, they are not covered by the exceptions provided for in Article 36. Directive 76/768 achieved the complete harmonisation of national laws on the marketing of cosmetic products. Therefore Article 30 of the Treaty must be interpreted as meaning that the marketing of cosmetic products which meet all the requirements of Directive 76/768 is permitted without restriction and that the advertising ban enacted by Austria is contrary to Community law. Smithkline concludes that, as the toothpaste in question is lawfully marketed in Germany, Paragraphs 9 and 26 of the LMG are contrary to Article 30 of the EC Treaty as measures having equivalent effect.

6. The national court observes that it would be possible for the court, in accordance with Unilever's application, to prohibit the toothpaste in question on the basis of the relevant provisions of Austrian domestic law, but this would affect trade within the Community. Therefore the national court decided to refer the question of the interpretation of Article 30 of the Treaty and of Directive 76/768 to the Court of Justice for a preliminary ruling, so that a final decision could be given on the compatibility of the national legislation with the abovementioned provisions of Community law.

III — The question referred

7. The question is worded as follows: '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 contains prohibitions of statements in connection with the marketing of cosmetic products which go beyond the restrictions contained in the Directive?'

IV — Is 'Odol-Med 3 (Samtweiss)' toothpaste a medicinal product or a cosmetic product?

8. In the observations which it has submitted in this case, the French Government adds a further dimension to the legal problem before the national court, by reason of which the

question was referred. The French Government contends that in Community law it would be more correct to regard the toothpaste in question as a medicinal product and not a cosmetic product, so that the question of the free movement of the product in the internal market in accordance with Article 30 of the EC Treaty would have to be determined by reference to the secondary legislation concerning the approximation of national laws relating to medicinal products. In the French Government's opinion, therefore, Directives 65/65/EEC, 92/27/EEC and 92/28/EEC are applicable, and not Directive 76/768, to which the national court refers,

9. The Court took the view that, in order to answer the question referred to it, it had to decide first whether the toothpaste in question was a medicinal product or a cosmetic product within the meaning of Community law, and therefore wrote to the parties on 24 March 1998 asking them to give an opinion on whether the product should be regarded as a medicinal product in accordance with the relevant secondary legislation.

10. The correct choice of the appropriate measures of Community law governing the product is of crucial importance to the outcome of the proceedings before the national court. If 'Odol-Med 3 (Samtweiss)' toothpaste is a medicinal product within the meaning of Council Directive 65/65/EEC, as correctly construed, its marketing is subject to very stringent requirements. A medicinal product may be placed on the market in a Member State only when the competent authority of that State has issued an authorisation. [6] Authorisation depends on strict formal requirements and is subject to constant monitoring by the national administrative authorities. In addition, Council Directive 92/27 lays down detailed rules on labelling and package leaflets for medicinal products for human use. The Community rules on the advertising of such products, laid down by Council Directive 92/28, are also especially strict. There is no doubt that the Community measures on cosmetic products, as set out in Council Directive 76/768, are less onerous for those products than the corresponding requirements for medicinal products.

A — *The Community provisions*

11. Article 1 of Council Directive 76/768 defines cosmetic products as follows:

'(1) "Cosmetic product" means any substance or preparation intended for placing in contact

6 — Directive 65/65, Article 3.

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 principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.

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

Annex I is entitled 'Illustrative list by category of cosmetic products'. It includes 'products intended for care of the teeth and the mouth'. [7]

Article 1 of Council Directive 65/65 [8] is worded as follows:

'For the purposes of this Directive, the following shall have the meaning hereby assigned to them:

1. Proprietary medicinal product

Any ready-prepared medicinal product placed on the market under a special name and in a special pack.

2. Medicinal product

Any substance or combination of substances presented for treating or preventing disease in human beings or animals.

Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.'

B — *Arguments of the parties*

12. In their observations, the French Government and the Government of the United Kingdom contend that 'Odol-Med 3 (Samtweiss)' should be classified as a medicinal product. The French Government refers to the Court's *Upjohn* judgment of 16 April 1991, [9] which found that a product with the characteristics of a medicinal product is subject only to Directive 65/65 and the measures amending it. If the toothpaste in question is advertised as a means of treatment, i. e. as

7 — See Annex I of Directive 76/768.

8 — Directive 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).

9 — Case C-112/89 [1991] ECR I-1703.

having the effect of inhibiting paradontosis, it must be regarded as a medicinal product in accordance with the definition in Article 1(2), subparagraph 1, of Directive 65/65. Furthermore, according to the French Government, it is possible that the product in question is also a medicinal product by virtue of function in accordance with Article 1(2), subparagraph 2, if the fluorine concentration exceeds 0.15%. The reasoning of the Government of the United Kingdom follows the same lines.

13. The reply given to the Court's question by the parties to the main proceedings and the Commission is in the negative. Unilever refers firstly to the national law, which states that toothpastes are cosmetic products, which is why the abovementioned provisions of the LMG and the Cosmetics Regulation prohibit cosmetic products such as toothpastes from carrying statements to the effect that they prevent, relieve or treat symptoms of illness. Unilever concludes that toothpastes (other than pharmaceutical toothpastes, which may be regarded as medicinal products) are not a means of treating or preventing disease in human beings and are therefore not in fact medicinal products by virtue of presentation within the meaning of Directive 65/65. Furthermore, toothpastes do not meet the second criterion of Directive 65/65 for classification as a medicinal product because their composition makes them unsuitable for administration 'with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings'. [10]

10 — Article 1(2), second subparagraph, Directive 65/65.

14. In contrast, Smithkline contends that cosmetic products such as 'Odol-Med 3 (Samtweiss)' toothpaste are covered only by Directive 76/768. The product in question obviously falls within the scope of that directive so that there can be no question of another directive, e. g. Directive 65/65, being applicable at the same time. The directive on cosmetic products was adopted after the directive on medicinal products precisely in order to lay down rules for products which, unlike products with pharmaceutical properties, are intended exclusively or principally for the external cleaning of the body. The main purpose of a toothpaste of the type in question is to clean the teeth, whereas its other properties, including possibly pharmaceutical properties, depend directly on the main purpose (i. e. external cleaning) and cannot therefore alter the legal classification of the product as a cosmetic product. In addition, there is no question of misleading consumers because they do not regard toothpaste as a medicinal product.

15. The Commission begins by stating that 'Odol-Med 3 (Samtweiss)' is clearly a cosmetic product within the meaning of Directive 76/768, but then concedes this is not a sufficient answer to the question because, if the same product were also covered by Directive 65/65, its nature as a cosmetic product would be secondary to its nature as a medicinal product. However, the Commission considers that the toothpaste in question is not a medicinal product by virtue of presentation or of function. According to the Commission, the abovementioned statements on the packaging of the toothpaste and in the television advertising do not make it a product which is pre-

sented to consumers as 'treating or preventing disease in human beings'. The so-called 'preventive' effect of 'Odol-Med 3 (Samtweiss)' could not be interpreted as a claim that the product is for 'treating or preventing disease in human beings' within the meaning of Article 1(2), subparagraph 1, of Directive 65/65. Consequently there was no question of classifying the product as a medicinal product by virtue of presentation and it could not be treated as a medicinal product by virtue of function because it does not restore, correct or modify physiological functions in human beings. The Commission refers to the observation in the *Upjohn* judgment that 'substances such as certain cosmetics 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' cannot be included in the category of medicinal products. [11]

C — *My views on the question*

16. The national court has not asked whether the product in question must be classified under Community secondary legislation as a medicinal product or a cosmetic product. However, it must be borne in mind that 'the Court, which is competent under Article 177 of the Treaty to provide courts of the Member States with the elements of interpretation of Community law, may deem it necessary to consider provisions of Community law to which the national court has not referred in its question'. [12]

17. I should like to add that it is clear from the Act on the Accession of Austria to the Community that all the abovementioned directives [13] form part of the *acquis communautaire* within the meaning of Article 2 of the Act of Accession and therefore take full effect in the Austrian legal system.

18. At first sight there can be no doubt, in my opinion, that in principle a product such as the toothpaste in question falls within the definition of 'cosmetic product' given by Directive 76/768, i. e. it is a cosmetic product within the meaning of Article 1(1) of the Directive. Toothpastes are in fact preparations which are intended for 'placing in contact with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours'. That is also the main

11 — See the *Upjohn* judgment cited in footnote 9, paragraph 22.

12 — See the judgments in Case C-241/89 *SARPP* [1990] ECR I-4695, paragraph 8, and Case C-315/92 *Verband Sozialer Wettbewerb* [1994] ECR I-317, paragraph 7.

13 — That is to say, Directives 76/768 (cited in paragraph 1 above), 65/65 (cited in footnote 8), Council Directive 92/28/EEC of 31 March 1992 (OJ 1992 L 113, p. 13), Council Directive 92/27/EEC of 31 March 1992 (OJ 1992 L 113, p. 8), Council Directive 84/450 of 10 September 1984 (OJ 1984 L 250 p, 17) and Directive 89/552/EEC of 3 October 1989 (OJ 1989 L 298, p. 23), which was amended by Directive 97/36/EC of the Parliament and the Council (OJ 1997 L 202, p. 60).

object of 'Odol-Med 3 (Samtweiss)' toothpaste.

19. However, the assumption that the product in question is by definition a cosmetic product within the meaning of Directive 76/768 does not necessarily mean that it falls within the legislative ambit of that Directive. If a product is presented as having not only cosmetic but also medicinal properties (however ancillary or supplementary the latter may be in relation to the former), it is necessary to determine whether it is subject to the Community secondary legislation on medicinal products. It is clear from the Court's case-law that, where a product has the characteristics of a medicinal product and also those of another type of product (foodstuff, cosmetic product, etc.), it is necessary to apply the provisions concerning medicinal products which, being more stringent and offering better protection to health and to consumers, take precedence over all others. [14]

14 — The Court has on several previous occasions considered the problem of choosing the most appropriate measures in Community law for classifying preparations which are in the borderline area between medicinal products and other types of product. See, for example, the following judgments:
Case 227/82 *Van Bennekom* [1983] ECR 3883, concerning health foods, vitamins and mineral products;
Case C-369/88 *Delattre* [1991] ECR I-1487, concerning slimming products, a product presented as facilitating digestion, a product presented as stimulating blood circulation, an anti-itching product, an anti-fatigue product, a product for pains in the joints and a method for stopping smoking;
Case C-60/89 *Monteil and Sammani* [1991] ECR I-1547, concerning 70% modified alcohol and 2% eosin;
the *Upjohn* judgment, cited in footnote 9, concerning a lotion for preventing *alopecia androgenetica*, i. e. natural loss of hair;
Case C-219/91 *Ter Voort* [1992] ECR I-5485, concerning dried plants for teas, which were presented as products with therapeutic qualities or as supplements to medicinal products;
Case C-290/90 *Commission* v *Germany* [1992] ECR I-3317, concerning lotions, imported from another Member State, for cleansing the eyes.

20. In the *Upjohn* judgment the Court stated:

'... while a comparison between the definitions of a cosmetic product and a medicinal product is not to be ruled out in doubtful cases ... a product which has the characteristics of a medicinal product or a proprietary medicinal product still does not fall within the scope of Directive 76/768; it is subject only to the provisions of Directive 65/65 and the directives amending it.

That is, moreover, the only conclusion consistent with the aim, pursued by both directives, of protecting public health, since the legal rules governing proprietary medicinal products are stricter than those governing cosmetic products, in view of the particular risks to public health which the former may represent and which are generally not displayed by cosmetic products.

Consequently, even though it may fall within the definition in Article 1(1) of Directive 76/768, a product must nevertheless be treated as a "medicinal product" and subjected to the relevant rules if it is presented for treating or preventing disease or if it is intended to be administered with a view to restoring, correcting or modifying physiological functions.' [15]

15 — See the *Upjohn* cited in footnote 9, paragraphs 30 to 32.

21. It is therefore necessary to determine how far 'Odol-Med 3 (Samtweiss)' meets the criteria of Directive 65/65, so that conceptually it could be regarded as both a cosmetic product and a medicinal product. If that is so, the Community law on medicinal products will apply (contrary to Smithkline's arguments), and not that relating to cosmetics.

(a) Community definition of 'medicinal product' and the Court's case-law

22. The cases already decided by the Court give the necessary guidance for answering the question whether a product is covered by Directive 65/65. The starting point is always that the Directive gives two definitions of 'medicinal product': one by reference to presentation and one by reference to function; a product is a medicinal product if it satisfies either of those definitions. [16] In my view, the determining factor in deciding the present case is the criterion of the 'presentation' of the product. [17] The Court takes the view that 'the concept of the "presentation" of a product must ... be broadly construed' [18] in order to ascertain the true meaning of the first subparagraph of Article 1(2) of Directive 65/65. Furthermore, the fact that the Directive does not define 'disease' gives even greater scope for determining its ambit. This is also how the Court appears to interpret it, as may be seen from the *Delattre* judgment, cited above. After observing that the Directive 'gives no definition of illness or disease', the Court immediately adds that 'the only possible definitions for those terms are those most commonly accepted on the basis of scientific knowledge'. [19]

23. In addition, a product which in some Member States is regarded as a foodstuff or cosmetic product is regarded in others as a medicinal product. On this point the Court observes that 'at the present stage of development of Community law, it is difficult to avoid the continued existence, for the time being and, doubtless, so long as harmonisation of the measures necessary to protection of health is not more complete, of differences

16 — This was the meaning attached to Article 1(2) of Directive 65/65 by the judgments in the cases *Monteil and Sammani*, *Ter Voort* and *Commission* v *Germany*, cited in footnote 14.

17 — I fail to see how this product could be regarded as a medicinal product by virtue of function. As the Commission correctly argues, the composition of the preparation does not permit the properties specified in Article 1(2), second subparagraph, of Directive 65/65 to be ascribed to it. Moreover there can be no question that the use of the toothpaste here 'significantly affects the metabolism' (see the Court's observations in the *Upjohn* judgment, footnote 9 above, and paragraph 20 of this opinion). Finally, the French Government's statement that the fluorine content in the composition of 'Odol-Med 3 (Samtweiss)' exceeds normal values and therefore the toothpaste is a medicinal product by virtue of presentation has in no way been proved.

18 — See the *Van Bennekom* judgment cited in footnote 14, paragraph 17, and the *Upjohn* judgment cited in footnote 9, paragraph 16.

19 — See the *Delattre* judgment cited in footnote 14, paragraph 12.

in the classification of products as between Member States ...'. [20]

24. Consequently, this survey of the case-law shows that, to determine the true meaning of Article 1(2), subparagraph 1, of Directive 65/65, the Court has chosen the interpretation which ensures the greatest possible protection for health and for consumers. This is why the Court observes in the *Van Bennekom* judgment that 'the directive, by basing itself, in the first Community definition of a medicinal product, on the criterion of the producer's "presentation", *is designed not only to cover medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective or which do not have the effect which consumers would be entitled to expect in view of their presentation*. The directive thereby seeks to preserve consumers not only from harmful or toxic medicinal products as such but also from a variety of products used instead of the proper remedies.' [21] This approach to interpretation is followed and confirmed in later judgments of the Court. [22]

25. It follows that Directive 65/65 is designed not only to regulate preparations suitable for preventing or treating disease in human beings and animals or which are poisonous or dangerous to health, but also to regulate the marketing of products which do not have therapeutic effects but which, for a commercial purpose, are described (i. e. 'presented' within the meaning of the Directive) by the manufacturer or the seller as producing certain effects. [23] This is the interpretation to be given, according to the true intention of the Community legislature, to the Community definition in Directive 65/65 of medicinal products 'by virtue of presentation'. [24]

26. In principle the national authorities are responsible for applying this definition to the products in question in any particular case. As the Court observed in its judgment in *Commission* v *Germany*, 'it is for the national authorities to determine, subject to review by the courts, for each product, whether or not it constitutes a medicinal product, having regard to all of its characteristics, in particular its composition, its pharmacological properties ..., the way in which it is used, the extent

20 — See the *Commission* v *Germany* judgment, cited in footnote 14, paragraph 16. See also the *Monteil and Samanni* judgment (paragraph 27 et seq.) and the *Delattre* judgment (paragraph 28 et seq.), cited in footnote 14.

21 — See the *Van Bennekom* judgment, cited in footnote 14, paragraph 17 (emphasis added).

22 — See the *Upjohn* judgment, cited in footnote 9, paragraph 16, and the *Ter Voort* judgment, cited in footnote 16, paragraph 14.

23 — See the *Ter Voort* judgment, cited in footnote 14, paragraph 25.

24 — Avoidance of the risk that consumers may mistakenly assume that a product is a means of treatment is clearly and directly addressed by Council Directive 80/777/EC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters (OJ 1980 L 229, p. 1). Article 9(2)(a) of this directive provides that 'all indications attributing to a natural mineral water properties relating to the prevention, treatment or cure of a human illness shall be prohibited'. This provision does not apply to the present case, but it shows the importance attached by the Community legislative authority to preventing the use of statements of a pharmacological nature in the marketing of a product which (by nature) is not a medicinal product.

to which it is sold, its familiarity to consumers and the risks which its use may entail'. [25]

27. Particularly in relation to products such as the toothpaste in question, which at first sight are cosmetics or foodstuffs, but which could be regarded as medicinal products by virtue of presentation because of the special way in which they are sold, the Court has taken the 'averagely well-informed consumer' as its criterion when it has to give a decision on such products. This approach consists in assessing the impression which the consumer forms of the specific product. In the *Van Bennekom* case the Court observed that 'a product is "presented for treating or preventing disease" within the meaning of Directive 65/65 not only when it is expressly "indicated" or "recommended" as such, possibly by means of labels, leaflets or oral representation, but also *whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, regard being had to its presentation, have an effect such as is described by the first part of the Community definition*'. [26] In the *Ter Voort* judgment the Court went on as follows: 'the conduct, action and approaches of the manufacturer or seller which disclose his intention to make the product he markets appear to be a medicinal product in the eyes of an average well-informed consumer may therefore be conclusive for the purposes of deciding whether a product should be regarded as a medicinal product by virtue of its presentation'. [27]

28. A second criterion for the correct classification of preparations which are on the borderline between medicinal products and other types of product is their external form. The Court regards this criterion as important, but not decisive. In the *Van Bennekom* judgment the Court observes that 'the external form given to the product in question — such as that of a table, pill or capsule — may ... serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product. Such evidence cannot, however, be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to pharmaceutical products would also be covered'. [28]

29. The *Delattre* judgment offers a typical example of the combined application of the criteria of external form and 'averagely well-informed consumer'. The Court began by observing that the definition of 'medicinal product' in Directive 65/65 must be construed fairly broadly for the following reasons:

'In the first place, "form" must be taken to mean not only the form of the product itself

25 — See *Commission* v *Germany*, cited in footnote 14, paragraph 17.

26 — See the *Van Bennekom* judgment, cited in footnote 14, paragraph 18 (emphasis added).

27 — See the *Ter Voort* judgment, cited in footnote 14, paragraph 26. In paragraph 32 of the same judgment the Court states that it is for the national court to assess whether there is 'an intention on the part of the manufacturer or seller to make the product appear to be a medicinal product in the eyes of an average well-informed consumer'.

28 — See the *Van Bennekom* judgment, cited in footnote 14, paragraph 19.

(tablets, pills or capsules) but also that of the packaging of the product, which may, for reasons of marketing policy, tend to make it resemble a medicinal product. In the second place, account must be taken of the attitude of an averagely well-informed consumer, in whom the form given to a product may inspire particular confidence similar to that normally inspired in him by a proprietary medicinal product, having regard to the safeguards normally associated with the manufacture and marketing of the latter type of product.

In those circumstances, a product may be regarded as a medicinal product by virtue of its presentation if its form and the manner in which it is packaged render it sufficiently similar to a medicinal product ...' [29]

30. Finally, it should be observed that, in cases of doubt where products appear at first sight to be foodstuffs or cosmetics, but could be medicinal products by virtue of presentation, the Court refrains from applying to the facts of the case the rules of Community law which it is asked to interpret. In other words, the Court constantly proceeds on the basis that it is for the national courts to decide, by reference to the facts of the particular case, whether the product in question must be regarded as a medicinal product by virtue of presentation. This is logical in so far as the national court is the more appropriate and competent for deciding what sort of impression the average consumer forms of a product and how it is presented on the national market concerned. [30]

(b) Community-law definition of 'medicinal product' and 'Odol-Med 3 (Samtweiss)' toothpaste

31. I now wish to consider 'Odol-Med 3 (Samtweiss)' toothpaste from the two legal viewpoints mentioned above.

32. Firstly, the doubts as to whether the toothpaste in question must be classified as a cosmetic product or a medicinal product do not arise from the fact that it is presented or described in advertising as preventing only tartar and caries, which is usual for every toothpaste on the market, but from the claim that it has a protective or preventive effect against disorders of the gums. Some of these, particularly paradontosis, are more important and dangerous than others for the health of

29 — See the *Delattre* judgment, cited in footnote 14, paragraph 40 et seq.

30 — Therefore in the *Van Bennekom*, *Upjohn*, *Delattre*, *Monteil and Samanni*, and *Ter Voort* judgments, cited in footnotes 9 and 14, the Court left the final decision to the respective national court after finding that the products in question could possibly fall within the Community definition of 'medicinal product' if the conditions laid down by Article 1 of Directive 65/65 were fulfilled.

the teeth. [31] It seems to me that this is a very important factor in view of the Commission's assertion at the hearing that 'Odol-Med 3 (Samtweiss)' is presented to consumers, like other toothpastes in free circulation on the market, only as a preventive against caries and tartar and therefore there can be no question of presentation as a medicinal product. I take the view that 'Odol-Med 3 (Samtweiss)' could not be subsumed under Directive 65/65 if its presentation referred only to the prevention of caries and tartar because the average consumer is not misled by statements of that kind, which he is accustomed to see on almost all equivalent products on the market. However, as the French Government correctly points out, the possibility that the toothpaste in question may fall within the ambit of Directive 65/65 arises from the claims in its presentation that it is effective against gum disorders.

33. The Court has not been informed of the exact wording on the packaging of 'Odol-Med 3 (Samtweiss)' or of the exact statements made in advertising. The order for reference made by the Handelsgericht Wien states that the toothpaste is presented as 'a *preventive* against paradontosis'. [32] The French Government bases its argument concerning the presentation of 'Odol-Med 3 (Samtweiss)' as a medicinal product on the fact that it is advertised as having a 'paradontosis-*inhibiting*' effect. However, the court is not in a position to decide, by reference to the facts of this case, how the product in question is to be classified according to Community law. [33]

34. In any case there are, as the Commission rightly observes, significant pointers indicating that the toothpaste in question should be classified as a cosmetic product. Firstly, there is the usual impression which the average consumer appears to have, *in abstracte*, of toothpastes, namely that they are products which improve the appearance of the teeth and promote their health, without having a therapeutic effect which would mean that they could be regarded as medicinal products. Secondly, as the documents before the Court show, 'Odol-Med 3 (Samtweiss)' is marketed primarily as a product which has the object and the effect of cleaning the teeth and making them whiter, and the advertisements for the toothpaste are only supplemented by the statement that, while ensuring complete preservation of the teeth, the product prevents certain disorders. The advantageous consequences for dental health complement the main purpose of the toothpaste as a product for beauty and cosmetic care and for cleaning, and therefore it does not differ from the other toothpastes on the market. Thirdly, the product in question is marketed in the form of a toothpaste

31 — *Paradontopathie*: any complaint characterised by a disorder of the periodontium. Such complaints are the main cause of the loss of teeth after the age of 30 (*Larousse Médical*, p. 761, Larousse-Bordas 1998).

32 — The Commission uses the same words in the account of the facts in its written observations, which were received by the Court on 23 May 1997.

33 — It is only in exceptional cases that the facts are made clear to the Court in such a way that it can classify a product according to the appropriate Community definition. This occurred in the judgment in Case C-315/92, cited in footnote 12, and I shall revert to this in the following paragraph of my opinion.

in a presentation which does not differ from that of other toothpastes. Consequently the form and the presentation of the product which, as I have shown, are 'strong evidence' [34] of presentation as a medicinal product, are likely to give the average consumer the impression that he is buying an ordinary toothpaste. Furthermore, as I have also mentioned, ordinary toothpaste is not, in the mind of the average consumer, a medicinal product.

35. In my opinion, these arguments, on which the Commission bases its conclusion that 'Odol-Med 3 (Samtweiss)' should not be classified as a medicinal product, are weighty, but not sufficient to justify that conclusion. Firstly, the fact that the advertising of the product as having favourable effects for the prevention of paradontosis only complements its presentation on the market as having primarily and principally cosmetic and cleaning effects is not in itself sufficient to justify the conclusion, when Community law is applied, that the average consumer will not regard the toothpaste concerned as a specific (albeit ancillary or supplementary) means of preventing disease within the meaning of the first Community-law definition of 'medicinal product' in Article 1 of Directive 65/65. [35]

Secondly, the fact that the product in question, like the other toothpastes on the market which are sold elsewhere than in chemists' shops, is a toothpaste must in fact be regarded as evidence which indicates that 'Odol-Med 3 (Samtweiss)' should be classified as a cosmetic product, but it is not a decisive criterion. As the Court expressly observed in the *Ter Voort* judgment, for the sake of the widest possible protection of health and of consumers, 'a product recommended or indicated as having prophylactic or therapeutic properties is a medicinal product within the meaning of the first subparagraph of Article 1(2) of Directive 65/65, *even if it is generally regarded as a foodstuff and even if in the current state of scientific knowledge it has no known therapeutic effect*'. [36]

36. Therefore, in addition to what has been said above, it is also necessary to consider the criterion of the 'average consumer', namely how the average buyer regards 'Odol-Med 3 (Samtweiss)' toothpaste, taking account of how the product is presented and advertised. This question must be answered by the national court, which is aware of the exact facts of the case, trade customs and consumer habits in Austria, and can therefore make a proper assessment of these factors. However, I think I must point out here that, to classify 'Odol-Med 3 (Samtweiss)' as a medicinal product within the meaning of Directive 65/65, it is not sufficient merely to have regard to the reference, in the presentation of the toothpaste concerned and in the advertising, to its

34 — See the *Van Bennekom* judgment, cited in footnote 14, paragraph 19.

35 — Factors which could induce the average consumer to ascribe pharmaceutical properties to the product in question are, in addition to the reference to 'prevention of paradontosis' and the inclusion of 'Med' in the name of the toothpaste, the words 'clinically tested', all of which appear on the tube. For the last-mentioned, see the *Delattre* judgment, paragraph 41.

36 — See the *Ter Voort* judgment, cited in footnote 14, paragraph 21 (emphasis added).

positive preventive effect in relation to the health of the teeth and the prevention of disease, including paradontosis.

V — National restrictions on the marketing of cosmetic products and Community law

37. When Community law is applied to this case, it will be necessary to distinguish and to choose between two possibilities. Does the presentation or advertising of 'Odol-Med 3 (Samtweiss)' toothpaste on the Austrian market clearly ascribe preventive effects to the product in relation to disorders of the gums in such a way that the average consumer may take the view that it falls outside the general category of toothpaste and can, as a 'medicinal product', give him comprehensive and effective protection? Or is it presented as a product which gives only general protection against tooth decay and gum disorders, in other words, a form of protection which the average consumer can expect from the mere use of a toothpaste as a product which is not regarded as a medicinal product, but only as a cosmetic product with positive effects on health? In the first case, 'Odol-Med 3 (Samtweiss)' must be classified as a medicinal product by virtue of presentation and it will be covered by Directive 65/65, which makes it unnecessary to reply to the question referred by the national court. In the second case, that is to say, if it is found that, because of the way in which it is presented on the Austrian market and the resulting impression in the mind of the average consumer concerning its properties, the product in question cannot be regarded as a medicinal product by virtue of presentation, the directives on cosmetics must be applied and it will be appropriate to reply to the question from the national court. This is what I now propose to do.

38. The question referred by the national court concerns the validity of the prohibition under national law which goes further than the provisions of Directive 76/768. First, it must be observed that, in the context of a reference for a preliminary ruling, the Court cannot give a ruling on the compatibility of national provisions with Community law. It can, however, provide the national court with all appropriate material on the interpretation of Community law to enable it to determine, when giving its decision, whether the national provisions are compatible with Community law. [37]

39. In the present case it is characteristic that, although the parties which have submitted written observations or have appeared before the Court take differing views of the law, ultimately they do not propose replies which contradict each other or are totally incompatible with each other. Apart from Unilever, the parties appear to agree in principle that a national prohibition which exceeds the limits laid down by the relevant Community law, particularly Directive 76/768, is contrary to Community law. However, this does not mean that they have the same ideas on the scope of

37 — See the *Verband Sozialer Wettbewerb* judgment, cited in footnote 12, Opinion of Advocate General Gulmann, paragraph 9.

the discretion, if any, which the Community legislature has granted to the national authorities in Directive 76/768. It is the scope of that discretion which the question referred to the Court seeks to establish.

A — *The relevant provisions of secondary Community law*

40. Article 2 of Directive 76/768 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 labelling, 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.'

Article 4 of Directive 76/768 is worded as follows:

'Without prejudice to their general obligations deriving from Article 2, Member States shall prohibit the marketing of cosmetic products containing:

(a) substances listed in Annex II;

(b) substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down;

...'.

Article 6 of Directive 76/768 provides as follows:

'1. Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the container and packaging bear the following information in indelible, easily legible and visible lettering; the

information mentioned in point (b) may, however, be indicated on the packaging alone.

(a) ...

(g) ...

2. For cosmetic products that are not pre-packaged, are packaged at the point of sale at the purchaser's request, or are pre-packaged for immediate sale, Member States shall adopt detailed rules for indication of the particulars referred to in paragraph 1.

3. 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.'

Article 7(1) of Directive 76/768 is worded as follows:

'1. 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.'

Article 12 of Directive 76/768 provides as follows:

'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.

...'.

B — *The arguments of the parties*

41. Unilever contends that the national laws on cosmetic products were not completely harmonised by Directive 76/768 as it does determine exhaustively which substances may be contained in such products and when statements for the purpose of health protection may or may not be placed on them. In Unilever's submission, a national legislation of the kind in question, which aims to protect health, does not fall within the ambit of secondary Community legislation, particularly Directive 76/768. With regard to Article 30 of the EC Treaty, Unilever contends that the national measures in question fall within the exceptions permitted by Article 36 of the Treaty to the general prohibition of obstacles to the free movement of goods as they concern the protection of health and of consumers.

42. Smithkline contends that Article 6(3) of Directive 76/768 constitutes a complete harmonisation of national laws on the packaging, labelling and advertising of cosmetic products and lays down the restrictions on trade which are necessary to protect health. By virtue of that provision the Member States can prohibit only advertising which attributes to cosmetic products characteristics which they do not possess. On the other hand, national rules such as those of Austrian law, which would excessively restrict advertising for cosmetic products and generally their market presentation beyond the limits laid down by Article 6(3) of the Directive are not compatible with Community law. Furthermore, under Article 7(1) the Member States cannot prohibit or restrict the marketing of cosmetic products which comply with the directive.

43. The Austrian Government contends, firstly, that Directive 76/768 does not regulate exhaustively the composition and the mandatory ingredients of cosmetic products. In any case, Article 6(3) has fully harmonised the national laws concerning their packaging and labelling. This provision was implemented in national law by Paragraph 26 in conjunction with Paragraph 9 of the LMG, thus prohibiting, firstly, the use of statements relating to health (with the exception of non-misleading references to the physiological or pharmacological effects of cosmetic products and figurative representations for explaining their range of application). Secondly, it is prohibited to market products bearing false statements. [38] In addition, for avoiding misleading advertising Austria has a system of 'positive' lists, which permits claims concerning certain characteristics and statements to promote sales of cosmetic products only if the products in question contain substances which, according

38 — For the actual wording of the Austrian provisions, see footnote 5 of this opinion.

to the Cosmetics Regulation, are proved to have the respective positive effects in human beings. Only in this way can consumers be given complete protection against the risk of misleading statements concerning cosmetic products. The Austrian Government adds that, under Paragraph 27(3) of the LMG, special authorisation may be given, upon application, for the use of statements concerning a cosmetic product even if it does not contain any substances which, according to the positive list of the Cosmetics Regulation, conform with such statements. Finally, the Austrian Government stresses that the provisions in question of the LMG do not prohibit the marketing of cosmetic products which contain none of the substances listed in the Cosmetics Regulation. Those provisions merely prohibit the use of statements which have been shown to be incorrect, so as to provide consumers with the widest possible protection. Consequently there can be no question of restricting the free movement of goods.

44. The Government of the United Kingdom contends that under Article 6(3) of Directive 76/768 the Member States have not only a right, but also an obligation to adopt measures to protect consumers against misleading advertising for cosmetic products. Therefore a national measure which is enacted for that purpose cannot be contrary to the Directive. If it were found that the measure in question was not within the scope of the Directive, it would in any case be covered by the grounds of justification set out in Article 36 of the EC Treaty.

45. The French Government proposes that, if the Court finds that the Community law on medicinal products is not applicable, it should rule that the national provisions laying down suitable measures to prevent misleading advertising are justified not only by Article 6(3) of Directive 76/768, but also by Articles 4 and 6 of Council Directive 84/450/EEC relating to the approximation of laws, regulations and administrative provisions of the Member States concerning misleading advertising.

46. The Commission begins by observing that the main problem of interpretation in this case is bound up with the question whether Directive 76/768 regulates the permitted composition of cosmetic products and thus harmonises the national law on that subject. The Commission points out that the Directive has the object of protecting health and therefore prohibits the marketing of cosmetic products containing dangerous or harmful substances. Provision is made for the annexes of the Directive listing the prohibited substances to be constantly updated and amended. As the Community legislature has drawn up a negative list of unauthorised substances and has thereby prohibited the sale and advertising of products containing such substances, it must be presumed that cosmetic substances containing none of those substances can be marketed and advertised freely. Moreover, to give consumers the greatest possible protection, Article 12 lays down an exceptional procedure whereby the marketing of cosmetic

products which contain none of the prohibited substances listed in the annexes may be prohibited. Therefore a national provision which is based on a positive list of permitted substances and which by that means prohibits the marketing and advertising of cosmetic products containing substances other than those on such list is not compatible with Directive 76/768. Regarding the system for applying Articles 30 and 36 of the EC Treaty, the Commission contends that the Directive exhaustively lays down the conditions for unrestricted trade in cosmetic products in the Community and takes account of all the factors in the protection of the public interest, which includes the protection of health and of consumers. Consequently it is unnecessary to examine the national law in question by reference to Articles 30 and 36 of the Treaty.

C — *My views on the preliminary question*

47. I propose first to consider Directive 76/768 in order to determine the extent and degree to which it has harmonised national laws (a), and then I shall look more closely at the precise limits laid down by the directive to the validity of the national rules (b).

(a) The harmonisation brought about by Directive 76/768

48. Although the provisions of Directive 76/768 are sufficiently clearly worded, the parties construe them in quite different ways. In particular, they have divergent opinions on interpretation regarding the scope of the subject-matter of the respective provisions and the degree of harmonisation of national laws which they bring about.

49. I would first observe that the Court has been very cautious in the wording of its judgments concerning Directive 76/768 and has avoided any general formulation to the effect that the Directive brought about a complete harmonisation of national laws, from any point of view whatever, to cosmetic products. [39] The Court's circumspection in determining the scope and the nature of the Directive is understandable because cosmetic products constitute a very wide category of goods which is constantly being developed.

39 — This is the contrary inference from the judgments in Case C-150/88 *Parfumerie-Fabrik Glockengasse* [1989] ECR 3891, paragraph 28; Case C-246/91 *Commission* v *France* [1993] ECR I-2289, paragraph 7, and the *Verband Sozialer Wettbewerb* judgment, cited in footnote 12, paragraph 11. These judgments assume that Directive 76/768 led to complete harmonisation (only) of the national provisions on the packaging and labelling of cosmetic products. Subsequently it became apparent that the Directive on its own had not achieved the complete harmonisation of all national provisions concerning these products.

An over-simplified approach whereby a single source of Community law which, like the Directive, has 15 articles and a number of annexes, covers exhaustively all the problems connected with trade in cosmetic products could jeopardise the protection of health and consumers. In other words, if the Directive were deemed to have a wide scope, which in fact it cannot have, this could frustrate the achievement of its aims, which expressly include the protection of health and of consumers. However, this does not mean that the Directive has not brought about complete harmonisation of the national laws on certain matters connected with the sale of cosmetics. [40]

50. After these preliminary remarks, I now wish to consider the relevant provisions of the Directive in relation to the case-law. As the Commission rightly observes, the main aim of the Community legislature is to ensure the free movement of cosmetic products within a system which permits them to be marketed irrespective of prior approval of their composition, provided they do not contain substances harmful to human beings, dangerous substances or dangerous quantities of substances. That is the purpose of the so-called negative list. The directive has two annexes, one listing substances which are not permitted in cosmetic products, the other listing substances the use of which is subject to certain restrictions. Article 4 of the directive requires the Member States to prohibit the marketing of cosmetic products the composition of which does not conform with the prohibitions and restrictions of the negative list. This is also the only restriction to which such products are subject 'with regard to their composition', apart from the possibility of the exceptional procedure provided for in Article 12. [41]

51. Therefore the safeguarding of the free movement of cosmetic products not containing prohibited (by reason of being listed in annexes II and III of the Directive) substances or quantities of substances is a fundamental principle of the Directive. Consequently, the Member States must not impose on cosmetic products any restrictions concerning their composition other than those laid down by the Directive.

52. In addition, Article 6 of Directive 76/768 lays down provisions on the packaging and labelling of cosmetic products. The Court has consistently held that these provisions constitute a complete harmonisation of national laws on the packaging and labelling of such products. It did so first in the *Parfumerie-Fabrik Glockengasse* judgment [42] and was followed later in the *Commission* v *France* [43] and the *Verband Sozialer Wettbewerb* judgments. [44] Consequently, it is no longer open to the Member States to keep in force or to

40 — See paragraph 52 below.

41 — According to this procedure, if a Member State finds that a cosmetic product, although complying with the requirements of the directive, represents a hazard to health, it may provisionally prohibit the marketing of the product or subject it to special conditions on marketing. At the same time the Commission and the other Member states must be informed and the Member State concerned must state the grounds for its decision.

42 — See the judgment cited in footnote 39, paragraph 28.

43 — See the judgment cited in footnote 39, paragraph 7.

44 — See the judgment cited in footnote 12, paragraph 11.

apply national provisions concerning the packaging and labelling of cosmetic products if those provisions go further than the conditions directly laid down by the Directive. This is the reason why the Community legislature expressly provides in Article 7 of the Directive that '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'.

53. But is Article 6 of the Directive the only Community-law provision applying to the packaging and labelling of cosmetic products, or should Articles 30 and 36 of the EC Treaty also apply? In principle I consider that the reply to this question is that Article 6 of the Directive alone applies. This was also the conclusion reached by the Court in the *Parfumerie-Fabrik Glockengasse* judgment, where it states that 'since the directive has provided exhaustively for the harmonisation of national rules on the packaging and labelling of cosmetic products, it is not necessary to give a ruling on the interpretation of Article 30 of the Treaty as requested by the national court.' [45] The same view is taken in the present case by Smithkline, the Commission, the French Government and the Government of the United Kingdom.

54. However, it can be argued that in the *Verband Sozialer Wettbewerb* judgment, which is the most recent decision on the interpretation of the provisions in question, the Court cast doubt on the conclusion it reached in *Parfumerie-Fabrik Glockengasse*. In particular, although the Court accepts that Directive 76/768 provided exhaustively for the harmonisation of national rules on the packaging and labelling of cosmetic products, it adds that 'this directive must, like all secondary legislation, be interpreted in the light of the Treaty rules on the free movement of goods'. [46] Pursuing this line of reasoning, the Court goes on to consider whether the national legislation implementing the provision of the Directive which require the Member States to take all the appropriate measures for preventing misleading advertising of cosmetic products conforms not only with the limits and conditions laid down by that provision of secondary Community legislation, but also with Articles 30 and 36 of the Treaty, as interpreted by the Court. [47]

55. In any case, it is of some practical importance whether the question of the extent to which a national measure on the packaging and labelling of cosmetic products is compatible with Community law is assessed only by reference to Article 6 of Directive 76/768 or also in the light of Articles 30 and 36 of the EC Treaty. Let me explain:

— On the one hand, Article 6 of the Directive calls upon the Member States to take

45 — See the *Parfumerie-Fabrik Glockengasse* judgment, cited in footnote 38, paragraph 28.

46 — See the *Verband Sozialer Wettbewerb* judgment, cited in footnote 12, paragraph 12.

47 — Ibid., paragraph 17.

action in two areas. First, they must take all necessary measures to prevent the marketing of cosmetic products which do not bear the information and statements prescribed in Article 6(1). Secondly, under Article 6(3), the national authorities must take all necessary measures 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'. As the Government of the United Kingdom correctly observes, the Member States have not only a right, but also an obligation to take appropriate measures to prevent misleading advertising of cosmetic products. The limits of that obligation constitute the main focus and also the difficulty of the question referred by the national court.

— On the other hand, the protection of consumers against the risk of deception also falls in fact within the ambit of primary Community law on the free movement of goods, namely Article 30 et seq. of the EC Treaty. In the *Yves Rocher* judgment [48] the Court observed that 'the protection of consumers against misleading advertising is a legitimate objective from the point of view of Community law'. [49] Similarly in *Mars* [50] the Court stated that 'it is settled law that obstacles to intra-Community trade resulting from disparities between provisions of national law must be accepted in so far as such provisions may be justified as being necessary in order to satisfy overriding requirements relating, *inter alia*, to consumer protection ...'. [51] Consequently, the prohibition of the misleading presentation or misleading advertising of a cosmetic product, which is in substance referred to by Article 6(3) of Directive 76/768, has the direct object of consumer protection which, as I have already said, is a ground justifying restricting the free movement of goods guaranteed by Article 30 of the Treaty. Moreover, such prohibition is also directly connected with the protection of health, which is expressly recognised by primary Community law as justifying restrictions on the free movement of goods (Article 36 of the EC Treaty).

56. However, the assessment of a national measure concerning advertising for a cosmetic product and its presentation generally, by reference to Article 6(3) of Directive 76/768 and Article 30 et seq. of the Treaty gives rise to two serious problems:

— Firstly, the assessment of a national measure of that kind in the light of the objec-

48 — Case C-126/91 [1993] ECR I-2361.

49 — Cited in footnote 48, paragraph 15.

50 — Case C-470/93 [1995] ECR I-1923.

51 — See the judgment cited in footnote 50, paragraph 15.

tives of the relevant provisions of primary Community law does not lead to clear answers, but rather to ambiguous and even contradictory conclusions. [52]

— Secondly — and this seem to me more important — the examination of a national provision by reference to Article 6(3) of the Directive and also to Article 30 et seq. of the Treaty may lead to different conclusions. In particular, the national legislature's options when implementing Article 6(3) are very limited. The national measure may only have as its purpose and subject-matter the prohibition of any presentation of cosmetic products on the market which implies a characteristic which the products in question do not actually have. On the other hand, a national provision prohibiting certain forms of advertising would exceed the limits of the power conferred by the said Community-law rule if that advertising does not imply that the cosmetic products in question have characteristics which they do not have within the meaning of Article 6(3) of the Directive. It is possible, however, that the same national provision, when examined only from the angle of Article 30 et seq. of the Treaty, would be regarded as compatible with Community law. More specifically, it might be classified, on the one hand, as a mere 'method of sales promotion' and would therefore fall outside the scope of Article 30; [53] on the other hand, it might be regarded as a measure necessary for the protection of health, in which case it would fall under the grounds of justification set out in Article 36. [54]

52 — There are two trends in the Court's case-law. Originally it was decided that legislation which restricts or prohibits certain forms of advertising and certain methods of sales promotion may, although it does not directly affect imports, be such as to restrict their volume because it affects marketing opportunities for the imported products. It may therefore constitute an obstacle to imports and fall within the scope of Article 30 of the EC Treaty even if the legislation in question applies to domestic products and imported products without distinction (see the judgments in Case 286/81 *Oosthoek's Uitgevermaatschappij* [1982] ECR 4575, paragraph 15; Case 382/87 *Buet and Others* [1989] ECR 1235, paragraph 7; Case C-362/88 *INNO* [1990] ECR I-667, paragraph 7; Joined Cases C-1/90 and C-176/90 *Aragonesa de Publicidad Exterior and Publivía* [1991] ECR I-4151, paragraph 10, and the *Yves Rocher* case, cited in footnote 48, paragraph 10).
In other cases, however, the Court has found that restrictions on promotion and advertising are mere 'selling arrangements' within the meaning given to this term in the *Keck and Mithouard* judgment and that therefore they do not fall within the ambit of Article 30 of the EC Treaty. In these cases the Court reasoned as follows: 'by contrast, contrary to what has previously been decided, the application to products from other Member States of national provisions restricting or prohibiting certain selling arrangements is not such as to hinder directly or indirectly, actually or potentially, trade between Member States within the meaning of the *Dassonville* judgment so long as those provisions apply to all relevant traders operating within the national territory and so long as they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States. Provided that those conditions are fulfilled, the application of such rules to the sale of products from another Member State meeting the requirements laid down by that State is not by nature such as to prevent their access to the market or to impede access any more than it impedes the access of domestic products. Such rules therefore fall outside the scope of Article 30 of the Treaty' (see the judgment in Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097, paragraphs 16 and 17).
The Court has applied the foregoing judgment to find that the following national provisions are compatible with Community law: provisions prohibiting, firstly, advertising for quasi-pharmaceutical products outside the pharmacy (see the judgment in Case C-292/92 *Hünermund* [1993] ECR I-6787), secondly, the broadcasting of television advertising for the distribution sector by television companies (see the judgment in Case C-412/93 *Leclerc-Siplec* [1995] ECR I-179) and, thirdly, television advertising aimed at children under 12 (see the judgment in Joined Cases C-34/95 to C-36/95 *De Agostini and TV-Shop* [1997] ECR I-3843).
Consequently it is not easy to determine whether a national law restricting or prohibiting advertising falls within Article 30 of the Treaty or not.

53 — See the judgments cited in footnote 52.

54 — See the judgment in Case C-320/93 *Ortscheit* [1994] ECR I-5243, where a prohibition on advertising for certain medicinal products was found to be justified on grounds of the protection of health within the meaning of Article 36.

57. For these reasons — and also to clarify the case-law — I think it preferable for the Court not to embark on the tricky task of judging a national provision concerning the packaging, labelling and advertising of cosmetic products by reference to both Directive 76/768 and the Treaty. In so far as the Court has held that the relevant rules of secondary Community legislation, contained in Article 6 of the Directive, provided exhaustively for the harmonisation of national rules on the packaging and labelling of cosmetic products, those rules are, in my opinion, the only legal basis for determining how far the national provision in question is compatible with Community law. Therefore any reference to Article 30 et seq. of the Treaty must be avoided, particularly with regard to the packaging and labelling of cosmetic products. [55]

58. I also consider that in the *Verband Sozialer Wettbewerb* judgment the Court did not intend to depart from its initial case-law and to reject the exclusive application of Article 6 of Directive 76/768 for the sake of Article 30 et seq. of the Treaty. The Court merely wished to emphasise that national measures implementing the obligation under Article 6(3) of the Directive to take steps against misleading advertising for cosmetic products are compatible with Community law only if they are necessary and conform to the objective pursued, that is to say, they do not unreasonably impede the free movement of goods. In other words, in the *Verband Sozialer Wettbewerb* judgment the Court rightly made it clear that, in enacting national measures to implement the provisions of the Directive which provide for comprehensive harmonisation in the field of the packaging and labelling of cosmetic products, the national legislature still has an obligation to observe the principle of proportionality and to choose the restriction which will have the least effect on the free movement of goods. The national legislature would be under the same obligation if there were no special provision of secondary Community legislation and it were a question of applying Article 30 et seq. of the Treaty directly.

59. Before concluding this part of my examination, I think two further observations are necessary:

— First, the fact that the Court has hitherto accepted that Directive 76/768 constitutes exhaustive harmonisation of the national

55 — Otherwise conflicts may arise. See, for example, the judgment in Case C-349/95 *Loenderloot* [1997] ECR I-6227, in which the Court stated that 'it has been suggested that the national court's questions should be answered within the framework not of Article 36 of the Treaty but of the First Council Directive 89/104/EEC ...', but then went on to observe that 'Article 7 of that directive, like Article 36 of the Treaty, is intended to reconcile the fundamental interest in protecting trade mark rights with the fundamental interest in the free movement of goods, so that these two provisions, which aim to achieve the same result, must be interpreted in the same way' (paragraphs 17 and 18, with further references to the case law).

laws on the packaging and labelling of cosmetic products must not be construed so narrowly that the advertising of those products would be excluded from the ambit of such harmonisation. In other words, the advertising of cosmetic products is also the subject of complete harmonisation brought about by Article 6(3) of Directive 76/768. This means that the only measures in relation to consumer protection which the national authorities may take with regard to such advertising are those which they are authorised by the Community legislature to take under Article 6(3) of the Directive.

— Secondly, it would be wrong to assume that national measures for restricting or prohibiting the advertising and, generally, placing of cosmetic products on the market, provided they are enacted for the purpose of protecting health, are not contrary to Article 6(3) even if they impose restrictions going beyond the limits laid down by that provision. Neither the actual wording of that provision nor the Court's case-law provided support for interpreting it to mean that national measures banning the advertising of cosmetic products in order to protect health fall outside the ambit of Article 6(3). In other words, it cannot be claimed that the protection of health is a ground permitting the adoption of national measures restricting the presentation, placing on the market and advertising of cosmetic products so as automatically to remove such measures from the scope of Article 6(3) and to bring them within the more general ambit of Article 30 et seq. of the Treaty (particularly Article 36). As there is no doubt that complete harmonisation of the rules relating to labelling, advertising and, generally, the presentation of cosmetic products has been achieved, Article 30 et seq. can no longer be invoked in order to gain acceptance for a national measure as complying with the requirements of Community law if that measure relates to the same subject-matter as the Directive and conflicts with it.

60. It is now necessary to examine more closely, on the basis of the foregoing interpretation, the scope for action accorded to the national legislature by the relevant provision of secondary Community law in the form of Article 6(3) of Directive 76/768.

(b) National measures restricting the free movement of cosmetic products from the viewpoint of Directive 76/768

61. The limits within which the national legislature may regulate the cosmetic sector are clear from the foregoing observations. As I have said, the fundamental purpose of the Directive is to ensure the free movement and marketing of cosmetic products which do not contain substances or quantities of substances dangerous or harmful to the health of human beings. Consequently, the Member States cannot in principle impose restrictions 'with regard to their composition' which differ from those exhaustively provided for in the Directive. At the same time, however, the Member States must take the necessary measures to prevent misleading advertising for cosmetic products. Therefore a national measure is compatible with Community law if it prohibits the marketing of such products with false, untrue or misleading statements and, in any case, with a presentation such as to attribute to them characteristics which they do not have.

62. However, what happens where, in order to prevent consumers from being misled, that is to say in the context of implementing Article 6(3) of Directive 76/768, the national authorities take measures which infringe the first fundamental rule of the Directive? In other words, what becomes of a national measure which, to prevent misleading advertising, interferes with the free movement of cosmetic products goods irrespective of their composition? In my opinion, such a measure is not compatible with the letter or the spirit of the Directive. Otherwise, that is to say, if it were accepted that the adoption of measures to prevent misleading advertising necessarily entail setting aside the regime of free movement of cosmetic products irrespective of their composition, this would amount to a recognition that there are fundamental contradictions in the Directive and therefore that the Community legislature had failed completely in its work of regulation. However, not only is there no conflict between the two basic aims of the Directive, namely ensuring the free movement of cosmetic products and preventing their being placed on the market with untrue or misleading statements or advertising, but those two aims can be achieved simultaneously. That is the true intention of the Community legislature, and the Member States are required to comply with it when adopting measures to implement Article 6(3) of the Directive.

63. In addition, according to the prevailing interpretation, the scope for action of the

national authorities with a view to preventing misleading advertising for cosmetic products is particularly limited. As the Court observed in the *Parfumerie-Fabrik Glockengasse* judgment, the obligation under Article 6(3) of the Directive to take all necessary measures 'does not authorise Member States to require information not provided for in the directive on the labelling or packaging of those products'. [56] In the same judgment the Court indeed took the view that the aim of protecting consumers 'may be achieved by means less restrictive of Community trade'. [57] The Court also made the following important observation: 'it appears from a comparison of the national provisions adopted for that purpose that certain Member States have laid down a general prohibition of any indication likely to mislead the consumer. *There is nothing to suggest that such a general prohibition is inadequate to achieve the desired end*'. [58]

64. Exactly the same reasoning can be applied to national measures which, to prevent misleading advertising, set up a system which hinders the free movement of goods and the presentation of cosmetic products by means of restrictions on their composition. To be more precise, national legislation which, for cosmetic products to claim certain characteristics (in connection with labelling, presentation and advertising), requires such products to contain certain substances listed in national sources of law (according to national law, these are the only substances which scientifically correspond to those characteristics) is directly contrary to the intention of the Community legislature that the marketing of a cosmetic product is not to depend on prior authorisation of its composition by the national authorities. In national legislation of this kind the principle of the free movement of cosmetic products containing none of the dangerous of harmful substances exhaustively listed in the Directive is relegated to the status of a mere exception. Conversely, where cosmetic products are free from restrictions under national law only if their composition conforms with the relevant national provisions, [59] this means in reality that a system of prior authorisation for those products has been introduced, contrary to the aim of the Directive.

65. Accordingly, a national system such as that described above is contrary to the require-

56 — See the *Parfumerie-Fabrik Glockengasse* judgment cited in footnote 39, paragraph 19.

57 — Ibid., paragraph 20.

58 — Ibid., paragraph 20.

59 — This applies particularly in cases where national law permits (but only after authorisation has been granted for a specified period) the marketing of a product which contains none of the substances corresponding, according to the existing positive list, to the characteristics which it is claimed to possess.

ments of the Directive. The *ratio* of a positive list of substances which cosmetic products must contain (although it is justified by the aim of improved protection for consumers) in order that certain characteristics may be ascribed to them goes beyond the enabling power conferred by Community law. In a system of this kind, there is no examination in each individual case to establish whether the product produces the effects which are supposed to result from using it. The product must 'automatically' contain the substances which, in the opinion of the national authorities, produce the effects in question. Furthermore, a manufacturer who claims to have found a new substance capable of producing certain effects must obtain a special authorisation before marketing the cosmetic product.

66. The situation which thus arises thus clearly constitutes an obstacle to the free movement of goods even though the national system does not directly hinder such movement but prohibits advertising or generally presenting products as possessing the characteristics in question if the products contain substances not included in the national positive list. The marketing of a product is directly linked to the possibility of making it as attractive as possible to consumers. Accordingly, the free movement of goods also means the freedom to advertise a product. To avoid any misunderstanding, the Community legislature has in its wisdom furthermore expressly prohibited misleading presentation as the sole restriction on the freedom to advertise cosmetic products. [60]

67. From what I have said it follows, in my opinion, that national legislation such as that described above, which is not confined to a general prohibition of misleading advertising, but goes further and sets up a system with a positive list of permitted substances which

60 — It should also be observed that Article 6(3) of Directive 76/768 is in a way a forerunner of Council Directive 84/450/EEC of 10 September 1984 on misleading advertising. A system as strict as that introduced by the Austrian legislature does not appear to be justified by anything in this later directive, the importance of which has been clearly acknowledged by the Court (see the *De Agostini and TV-Shop* judgment cited in footnote 52, paragraph 37). On the contrary, national supervision is based on examining the accuracy of advertisements in *individual cases* and not on the automatic exclusion of an advertisement by a provision to the effect that everything which is not expressly provided for by law may be prohibited. In particular, Article 6 of Directive 85/450 provides as follows:
'Article 6
Member States shall confer upon the courts or administrative authorities powers enabling them in the civil or administrative proceedings provided for in Article 4:
(a) to require the advertiser to furnish evidence as to the accuracy of factual claims in advertising if, taking into account the legitimate interests of the advertiser and any other party to the proceedings, such a requirement appears appropriate on the basis of the circumstances of the particular case; and
(b) to consider factual claims as inaccurate if the evidence demanded in accordance with (a) is not furnished or is deemed insufficient by the court or administrative authority.'

determines whether a cosmetic product can be marketed freely, is contrary to Directive 76/768.

68. Finally, for the sake of completeness, it seems to me necessary to point out that national legislation which completely prohibits advertising for cosmetic products by means of statements relating to health which are not misleading likewise goes beyond the limits of the legislative power conferred upon the national authorities by Article 6(3) of Directive 76/768. On this point I can confine myself to the following observations. If a cosmetic product is advertised in such a way that, in the eyes of consumers, it is connected with the protection of health, there are two possibilities. Either it creates that impression that it is a medicinal product, with the result that the question of the application of Directive 65/65 arises, [61] or the consumer still regards it as an ordinary cosmetic which actually has some connection with human health. In the latter case, provided the advertising is not misleading, the product will not fall within the prohibitions in Article 6(3) of Directive 76/768 and will consequently come within the scope of the freedom of action granted by the Community legislature. A national prohibition of that kind unduly restricts the freedom to trade in cosmetic products and is contrary to Community law. I am led to this conclusion by merely interpreting and applying the relevant provisions of Directive 76/768 which have exhaustively harmonised the law concerning the advertising of cosmetic products, and it is unnecessary to search for legal solutions on the basis of Article 30 et seq. of the EC Treaty. [62]

61 — See paragraph 16 et seq. above.

62 — I think it is appropriate, although not absolutely necessary, to observe that, if Directive 76/768 did not exist and if the problem were examined in the light of Articles 30 and 36 of the EC Treaty, it would not be clear whether a national measure banning advertising for cosmetic products with statements referring to health would be in conformity with Community law. As I said above (see footnote 52), the assessment of national bans on advertising by reference to Article 30 et seq. does not always lead to the same conclusion.
In any case, if the national measure is to be deemed compatible with Community law, it must not restrict advertising generally. In the *Hünermund* judgment cited in footnote 52, the Court stated that a rule of professional conduct prohibiting pharmacists from advertising quasi-pharmaceutical products outside the pharmacy does not fall within the scope of Article 30 of the EC Treaty. However, the Court first observed that 'the prohibition does not affect the right of traders other than pharmacists to advertise those products' (paragraph 19). Likewise in the *Leclerc-Siplec* judgment cited in footnote 52 the Court found that a law or regulation prohibiting televised advertising in the distribution sector is not an obstacle to trade within the Community. This conclusion was reached on the basis that 'such a prohibition does not prevent distributors from using other forms of advertising' (paragraph 19).
In fact, the distinction between a total and a partial ban on advertising is not always adhered to in the case-law. In the *De Agostini and TV Shop* judgment it was held that a complete ban on advertising aimed at children under 12 did not fall within the scope of Article 30 of the EC Treaty.

VI — Conclusion

69. On the basis of all the foregoing considerations, I propose that the Court reply to the question from the national court as follows:

(1) A toothpaste is to be regarded as a cosmetic product within the meaning of Community law and is covered by Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products unless the averagely well-informed consumer may infer with certainty, from the statements on the packaging of the product, from advertising and generally from its presentation for sale, that it is a substance presented for treating or preventing disease 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.

(2) National legislation which, in order to give consumers improved protection against misleading advertising, and for the sake of protecting health, on the one hand, prohibits advertising of cosmetic products by means of misleading statements concerning health and, on the other hand, introduces a national control system on the basis of which a cosmetic product cannot be presented on the market as producing certain effects if its composition does not include the substances which, in the view of the national legislature, alone justify and confirm the claim that it has such effects, it being necessary in that case to obtain special prior authorisation to advertise and to market the product, goes further than the restrictions authorised by Article 6(3) of Directive 76/68 and is therefore incompatible with Community law.