JUDGMENT OF THE COURT (Second Chamber)

2 April 2009 *

In Case C-421/07,

REFERENCE for a preliminary ruling under Article 234 EC from the Vestre Landsret (Denmark), made by decision of 6 August 2007, received at the Court on 13 September 2007, in the criminal proceedings against

Frede Damgaard,

THE COURT (Second Chamber),

composed of C.W.A. Timmermans, President of the Chamber, J.-C. Bonichot, K. Schiemann (Rapporteur), J. Makarczyk and C. Toader, Judges,

Advocate General: D. Ruiz-Jarabo Colomer,
Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 9 October 2008,

* Language of the case: Danish.

after considering the observations submitted on behalf of:

— Mr Damgaard, by S. Stærk Ekstrand, advokat,

— the Danish Government, by B. Weis Fogh, acting as Agent,

— the Belgian Government, by J.-C. Halleux, acting as Agent,

— the Czech Government, by M. Smolek, acting as Agent,

— the Greek Government, by N. Dafniou, S. Alexandriou and K. Georgiadis, acting as Agents,

— the Polish Government, by T. Krawczyk, P. Dąbrowski and M. Dowgielewicz, acting as Agents,

— the United Kingdom Government, by Z. Bryanston-Cross, acting as Agent, and J. Stratford and J. Coppel, Barristers,

— the Commission of the European Communities, by H. Støvlbæk and M. Šimerdová, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 18 November 2008,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 86 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34).

2 The reference was made in the context of criminal proceedings brought by the Anklagemyndigheden (Public Prosecutor) against Mr Damgaard, a journalist, who has been charged with having publicly disseminated information about the properties and availability of a medicinal product the marketing of which is not authorised in Denmark.

Legal context

Directive 2001/83

3 Recitals 2 and 3 in the preamble to Directive 2001/83 state the following:

'(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.'

4 According to recital 40 in the preamble to the same directive:

'The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.'

5 Recital 45 in the preamble to that directive is worded as follows:

'Advertising to the general public, even of non-prescription medicinal products, could affect public health, were it to be excessive and ill-considered. Advertising of medicinal products to the general public, where it is permitted, ought therefore to satisfy certain essential criteria which ought to be defined.'

6 Title III of Directive 2001/83, as amended by Directive 2004/27 ('Directive 2001/83'), concerns the placing of medicinal products on the market, whilst Title IV thereof lays down rules governing their manufacture and importation. Title VII of that directive lays down rules governing wholesale distribution of medicinal products.

7 Article 86 of Directive 2001/83, the first article under Title VIII thereof, entitled 'Advertising', provides:

'1. For the purposes of this Title, "advertising of medicinal products" shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:

— the advertising of medicinal products to the general public,

— advertising of medicinal products to persons qualified to prescribe or supply them,

— visits by medical sales representatives to persons qualified to prescribe [or supply] medicinal products,

— the supply of samples,

— the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,

— sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,

— sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

2. The following are not covered by this Title:

— the labelling and the accompanying package leaflets, which are subject to the provisions of Title V,

— correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product,

— factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims,

— information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.'

8 Article 87 of the same directive provides:

'1. Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted in accordance with Community law.

2. All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics.

3. The advertising of a medicinal product:

— shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties,

— shall not be misleading.'

National legislation

9 Paragraph 27b of the Danish Law on medicinal products (Lægemiddellov, Consolidating Law No 656/1995) provides:

'Advertising of medicinal products which may not lawfully be marketed or supplied in Denmark shall be prohibited.'

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

10 Hyben Total in powder and capsule form, after having been classified as a medicinal product by the Lægemiddelstyrelsen (Danish agency for medicinal products), was previously marketed in Denmark by its manufacturer, Natur-Drogeriet A/S ('Natur-Drogeriet'), as a product relieving or treating gout, gallstones, kidney disorders, bladder disorders, sciatica, bladder bleeding, diarrhoea, stomach cramps, diabetes and kidney stones. The information material on the medicinal product was prepared by Mr Damgaard. Sales of that medicinal product were halted in 1999, however, when marketing authorisation was refused.

11 In 2003, Mr Damgaard stated on his website that Hyben Total contained rosehip powder, which is supposed to relieve the pain caused by various types of gout or

arthrosis, and that the medicinal product was on sale in Sweden and Norway. By decision of 16 June 2003, the Lægemiddelstyrelsen informed Mr Damgaard that those statements constituted advertising contrary to Paragraph 27b of Law No 656/1995 on medicinal products and criminal proceedings were commenced against him.

12 By judgment of 2 December 2005, the Retten i Århus (Århus City Court) (Denmark) found Mr Damgaard guilty under the aforementioned national provision and sentenced him to a fine. He appealed against that judgment before the Vestre Landsret (Western Regional Court) (Denmark), arguing in those proceedings that he was not employed by Natur-Drogeriet and had no interest in that company or in sales of Hyben Total. His activities as a journalist in the health food sector were limited to the communication, to retailers and other interested parties, of information on food supplements. Mr Damgaard did not receive any remuneration from Natur-Drogeriet for the information he disseminated concerning Hyben Total.

13 The Anklagemyndigheden, who brought the proceedings against Mr Damgaard, maintains that that dissemination of information was aimed at encouraging consumers to buy Hyben Total, irrespective of whether there was a link between Mr Damgaard and the manufacturer or seller of that medicinal product. Accordingly, that activity constitutes 'advertising' within the meaning of Article 86 of Directive 2001/83 and must be prohibited, since the marketing of that medicinal product, whose consumption that activity seeks to promote, is prohibited in Denmark.

14 Mr Damgaard contends that the information published on his website did not constitute advertising as contemplated in Article 86 of Directive 2001/83, as that concept must be construed more narrowly, that is, as not covering door-to-door information effected by an independent third party.

15 It is in those circumstances that the Vestre Landsret decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Is Article 86 of Directive 2001/83 … to be interpreted as meaning that dissemination by a third party of information about a medicinal product, including in particular information about the medicinal product's therapeutic or prophylactic properties, is to be understood as constituting advertising, even though the third party in question is acting on his own initiative and completely independently, de jure and de facto, of the manufacturer and the seller?'

The question referred for a preliminary ruling

16 Recital 2 in the preamble to Directive 2001/83 states that the essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health. That aim is reiterated in the various titles of that directive, including Titles III, IV and VII thereof, the provisions of which guarantee that no medicinal product is placed on the market, manufactured or distributed without the necessary authorisations first having been obtained.

17 Similarly, in the area of information and advertising relating to medicinal products, recital 40 in the preamble to Directive 2001/83 states that the provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information. Recital 45 in the preamble to the directive further states that since advertising to the general public of non-prescription medicinal products could affect public health, were it to be excessive and ill-considered, it should therefore, where it is permitted, satisfy certain essential criteria which ought to be defined.

18 Article 87(1) of Directive 2001/83 prohibits any advertising of a medicinal product in respect of which a marketing authorisation has not been granted in accordance with Community law.

19 The public dissemination of information about a medicinal product which is not authorised in a particular Member State may, depending on the context in which that dissemination takes place, influence consumers' behaviour and encourage them to purchase the medicinal product in question, which could affect public health. As the case-file referred to the Court shows, Mr Damgaard stated on his website that Hyben Total was available in Sweden and Norway.

20 Article 86(1) of Directive 2001/83 defines the concept of 'advertising of medicinal products' as 'any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products'. Whilst that definition explicitly emphasises the purpose of the message, it does not provide any indication as to the people who disseminate that information.

21 Thus, the wording of Directive 2001/83 does not rule out the possibility that a message originating from an independent third party may constitute advertising. Nor does the directive require a message to be disseminated in the context of commercial or industrial activity in order for it to be held to be advertising.

22 In that regard, it must be stated that, even where it is carried out by an independent third party outside any commercial or industrial activity, advertising of medicinal products is liable to harm public health, the safeguarding of which is the essential aim of Directive 2001/83.

23 It is for the national court to determine whether Mr Damgaard's actions constituted a form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of Hyben Total.

24 To that end and as the Advocate General observed in point 37 of his Opinion, the situation of the author of a communication about a medicinal product and, in particular, his relationship with the company which manufactures or distributes it, are a factor which, although it may help to determine whether the communication constitutes advertising, must be evaluated together with other circumstances, such as the nature of the activity carried out and the content of the message.

25 Regarding Mr Damgaard's argument alleging infringement of his right to freedom of expression as a result of his criminal conviction, it should be borne in mind that, according to settled case-law, fundamental rights form an integral part of the general principles of law the observance of which the Court ensures.

26 Whilst the principle of freedom of expression is expressly recognised by Article 10 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950, and constitutes one of the fundamental pillars of a democratic society, it nevertheless follows from the wording of Article 10(2) that freedom of expression is also subject to certain limitations justified by objectives in the public interest, in so far as those derogations are in accordance with the law, motivated by one or more of the legitimate aims under that provision and necessary in a democratic society, that is to say justified by a pressing social need and, in particular, proportionate to the legitimate aim pursued (see Case C-71/02 *Karner* [2004] ECR I-3025, paragraph 50).

27 It is common ground that the discretion enjoyed by the national authorities in determining the balance to be struck between freedom of expression and the abovementioned objectives varies for each of the goals justifying restrictions on that freedom and depends on the nature of the activities in question. When the exercise of the freedom does not contribute to a discussion of public interest and, in addition, arises

in a context in which the Member States have a certain amount of discretion, review is limited to an examination of the reasonableness and proportionality of the interference. This holds true for the commercial use of freedom of expression, particularly in a field as complex and fluctuating as advertising (see *Karner*, paragraph 51).

28 If the information disseminated on Mr Damgaard's website, which is at issue in the main proceedings, were to be found to constitute 'advertising' for the purposes of Directive 2001/83, his conviction could be considered reasonable and proportionate, in the light of the legitimate aim pursued, namely the protection of public health.

29 In the light of all the foregoing, the answer to the question referred is that Article 86 of Directive 2001/83 is to be interpreted as meaning that dissemination by a third party of information about a medicinal product, including its therapeutic or prophylactic properties, may be regarded as advertising within the meaning of that article, even though the third party in question is acting on his own initiative and completely independently, de jure and de facto, of the manufacturer and the seller of such a medicinal product. It is for the national court to determine whether that dissemination constitutes a form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.

Costs

30 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Second Chamber) hereby rules:

Article 86 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, is to be interpreted as meaning that dissemination by a third party of information about a medicinal product, including its therapeutic or prophylactic properties, may be regarded as advertising within the meaning of that article, even though the third party in question is acting on his own initiative and completely independently, de jure and de facto, of the manufacturer and the seller of such a medicinal product. It is for the national court to determine whether that dissemination constitutes a form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.

[Signatures]