Court of Justice EU, 5 May 2011, MSD v Merckle

ADVERTISING LAW

Advertising for medicinal products:

- **Not prohibited: faithful reproduction of packaging and leaflet information.**
- **Prohibited: selected or rewritten information since such manipulation of information can be explained only by an advertising purpose**

It follows that, if the dissemination of information relating to medicinal products, which are available only on medical prescription, on the manufacturer's website consists solely in the faithful reproduction of the packaging of the medicinal product, in accordance with Article 62 of Directive 2001/83, and in a literal and complete reproduction of the package leaflet or the summary of the product's characteristics approved by the authorities with competence in relation to medicinal products, and if it is not accompanied by any additional element which supports its classification as advertising, the objective of protecting health pursued by the prohibition on advertising of such medicinal products does not appear to lead to such a dissemination being classified as prohibited advertising for the purposes of Article 88(1)(a) of Directive 2001/83.

44 A different classification must, however, be adopted where the information relating to the medicinal product is selected or rewritten by the manufacturer, since such manipulation of information can be explained only by an advertising purpose.

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Court of Justice EU, 5 May 2011

(K. Lenaerts, D. Šváby, R. Silva de Lapuerta, G. Arestis and J. Malenovský)

Judgement of the Court (Third Chamber)

5 May 2011 (*)

(Medicinal products for human use – Directive 2001/83/EC – Prohibition on the advertising to the general public of medicinal products available only on prescription – Definition of 'advertising' – Information communicated to the competent authority – Information accessible on the internet)

In Case C-316/09,

REFERENCE for a preliminary ruling under Article 234 EC from the Bundesgerichtshof (Germany), made by decision of 16 July 2009, received at the Court on 10 August 2009, in the proceedings

MSD Sharp & Dohme GmbH

v

Merckle GmbH,

THE COURT (Third Chamber),

composed of K. Lenaerts, President of the Chamber, D. Šváby (Rapporteur), R. Silva de Lapuerta, G. Arestis and J. Malenovský, Judges, Advocate General: V. Trstenjak, Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 23 September 2010,

after considering the observations submitted on behalf of:

– MSD Sharp & Dohme GmbH, by U. Karpenstein and F. Fellenberg, Rechtsanwälte,

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

– the Danish Government, by B. Weis Fogh and C. Vang, acting as Agents,

– the Hungarian Government, by M. Fehér and K. Szíjjártó, acting as Agents,

– the Polish Government, by M. Dowgielewicz, acting as Agent,

– the Portuguese Government, by L. Inez Fernandes and A.P. Antunes, acting as Agents,

– the Swedish Government, by A. Falk, acting as Agent,

– the United Kingdom Government, by S. Hathaway, acting as Agent,

– the European Commission, by M. Šimerdová and G. Wilms, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 24 November 2010,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 88(1)(a) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34) ('Directive 2001/83').

2 The reference has been made in proceedings between MSD Sharp & Dohme GmbH ('MSD') and Merckle GmbH concerning an action by which the latter seeks an injunction restraining MSD from disseminating on its website information relating to three prescription-only medicinal products that it manufactures, namely Vioxx, Fosamax and Singulair, on the ground that that dissemination constitutes advertising to the general public prohibited by Directive 2001/83.

Legal context

European Union law

3 Recitals 2, 40, 44 and 45 in the preamble to Directive 2001/83 are worded as follows:

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

...

(40) 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.

...

(44) Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities [OJ 1989 L 298, p. 23] prohibits the television advertising of medicinal products which are available only on medical prescription in the Member State within whose jurisdiction the television broadcaster is located. This principle should be made of general application by extending it to other media.

...

(45) 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.'

4 Article 1 of Directive 2001/83 states:

'For the purposes of this Directive, the following terms shall bear the following meanings:

...

24. Outer packaging: The packaging into which is placed the immediate packaging.

25. Labelling: Information on the immediate or outer packaging.

26. Package leaflet: A leaflet containing information for the user which accompanies the medicinal product.

...'

5 The inclusion in the packaging of all medicinal products of a package leaflet is obligatory except in the cases provided for in Article 58 of the directive. Article 59 of Directive 2001/83 provides that the package leaflet is to be drawn up in accordance with the summary of the product characteristics and must include the information to be mentioned therein.

6 Under Article 61 of Directive 2001/83:

'1. One or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet, shall be submitted to the authorities competent for authorising marketing when the marketing authorisation is requested. The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.

2. The competent authority shall refuse the marketing authorisation if the labelling or the package leaflet do not comply with the provisions of this Title or if they are not in accordance with the particulars listed in the summary of product characteristics.

3. All proposed changes to an aspect of the labelling or the package leaflet covered by this Title and not connected with the summary of product characteristics shall be submitted to the authorities competent for authorising marketing. If the competent authorities have not opposed a proposed change within 90 days following the introduction of the request, the applicant may put the change into effect.

...'

7 Article 62 of Directive 2001/83 provides:

'The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and 59(1) and other information compatible with the summary of the product characteristics which is useful for the patient, to the exclusion of any element of a promotional nature.'

8 According to Article 71(1) of that directive:

'Medicinal products shall be subject to medical *prescription where they:*

– are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision, or

– are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or

– contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation,

...'

9 Under Article 86 of Directive 2001/83, at the beginning of Title VIII thereof, entitled 'Advertising':

'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,

– ...

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.'

10 Article 87 of that directive states:

'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.'
11 Article 88(1)(a) of Directive 2001/83 provides:
'Member States shall prohibit the advertising to the general public of medicinal products which:
(a) are available on medical prescription only, in accordance with Title VI'.
National law
12 Paragraph 10 of the Law on the advertising of medicines (Heilmittelwerbegesetz), in the version published on 19 October 1994 (BGBl. 1994 I, p. 3068), as amended by the Law of 26 April 2006 (BGBl. 2006 I, p. 984), provides:
'(1) As regards prescription-only medicines, advertising may be sent only to doctors, dentists, veterinarians, pharmacists or persons authorised to trade in medicinal products.
(2) Medicinal products intended to treat, in humans, insomnia or psychological problems, or which are psychotropic, may not be advertised otherwise than in professional circles.'
The dispute in the main proceedings and the question referred for a preliminary ruling
13 The parties in the main proceedings are pharmaceutical companies and are in competition with each other. MSD presented its Vioxx, Fosamax and Singulair medicinal products which were available only on prescription on its website which was accessible by way of a link which was not password-protected, and was accordingly freely accessible, reproducing the packaging of the product, the therapeutic indication and the leaflet containing instructions for use of the product.
14 Merckle GmbH takes the view that such conduct constitutes an infringement of Paragraph 10(1) of the Law on the advertising of medicines, as amended, which prohibits advertising to the general public of medicinal products which are available only on prescription, as well as conduct contrary to the rules on competition. It sought an order from the Landgericht (Regional Court) requiring MSD, on penalty of certain fines, to desist from disseminating on the internet for commercial purposes promotional material on prescription-only medicinal products in such a way that that information is also freely available to those outside the medical professions.
15 The Landgericht upheld that application. The Oberlandesgericht (Higher Regional Court) dismissed MSD's appeal against the Landgericht's judgment, stating that the information published by MSD on its website, even if it is merely factual and is not typically commercial in nature, falls within the definition of advertising of medicinal products, which is to be interpreted broadly.
16 According to the referring court, the outcome in the appeal on a point of law (Revision) brought before it by MSD depends on whether Article 88(1)(a) of Directive 2001/83 also prohibits advertising to the general public of the type at issue in the present case, which contains only information communicated to the competent authority under the marketing authorisation procedure for the medicinal products concerned and which, in any event, is accessible to anyone who purchases them, where that information is not presented to the person concerned without his asking for it, but is accessible on the internet only by a person who takes steps to obtain it.
17 The referring court explains that the publications on the internet also fall within the scope of Title VIII of Directive 2001/83 when they are intended to promote sales and that it matters little whether they are presentations promoting the medicinal product concerned or other information relating to it. It observes that, in accordance with Article 86(2) of that directive, the provisions of Title VIII thereof do not concern the labelling and the package leaflet if the latter are used in their respective functions. According to its own case-law, information constitutes advertising if the mandatory information which must appear on the labelling and in the package leaflet cease to be in the distinctive form provided for by the legislation on pharmaceutical products and are used as an independent communication.
18 In that context, the Bundesgerichtshof (Federal Court of Justice) seeks to ascertain whether a teleological interpretation of the prohibition of advertising must lead to a restrictive interpretation of that prohibition laid down in Article 88(1)(a) of Directive 2001/83, so that that prohibition does not apply to the type of advertising to the general public which is the subject of the dispute in the main proceedings. In that connection, account must be taken, in particular, of the fact that the information is disseminated by the manufacturer, and that such information may make it possible to avoid or reduce the risk of uninformed self-medication.
19 In those circumstances, the Bundesgerichtshof decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:
'Does the scope of application of Article 88(1)(a) of Directive 2001/83 … extend to the advertising to the general public of medicinal products which are available only on prescription where that advertising contains only information which was placed before the authorising authority in the course of the marketing authorisation procedure and which is accessible in any event to every person acquiring the product, and where that information is not made available to an interested party on an unsolicited basis but can be accessed only through the internet when the party concerned takes steps to do so?'
Consideration of the question referred
The subject of the reference for a preliminary ruling
20 MSD takes the view that the question referred for a preliminary ruling does not concern only the interpretation of Article 88(1)(a) of Directive 2001/83, but concerns above all the validity of that provision, in so far as a rule of law prohibiting the online publication of information on medicinal products, which has been checked by the competent authorities and which is useful to patients, cannot be compatible with the funda-

mental rights of the European Union, in particular the freedom of information, the right to decide freely how to care for one's own health, freedom of expression and freedom of enterprise. Also arguing that the referring court expressly doubts the proportionality of that provision, MSD invites the Court to give a ruling on its validity.

21 According to the Court's case-law, it is for the referring court alone to determine the subject-matter of the questions it intends to refer. It is solely for the national courts before which actions are brought, and which must bear the responsibility for the subsequent judicial decision, to determine in the light of the special features of each case both the need for a preliminary ruling in order to enable them to deliver judgment and the relevance of the questions which they submit to the Court (see Joined Cases C-376/05 and C-377/05 Brünsteiner and Autohaus Hilgert [2006] ECR I-11383, paragraph 26).

22 It must be held in that connection that the question referred for a preliminary ruling clearly seeks the interpretation of Article 88(1)(a) of Directive 2001/83. It is apparent from the order for reference that the referring court asks essentially if the definition of advertising of medicinal products for the purposes of European Union law covers a specific situation, described in detail in that decision, in which the referring court envisages the possibility of a restrictive interpretation taking account of fundamental rights. However, that does not mean that the validity of the legislation of the European Union concerned is itself called into question. The referring court does not express doubts as to the validity of Article 88(1)(a) of that directive, or that such a question was raised in the main proceedings.

23 In accordance with settled case-law, Article 267 TFEU does not make available a means of redress to the parties to a case pending before a national court, so that the Court cannot be compelled to evaluate the validity of European Union law on the sole ground that that question has been put before it by one of the parties in its written observations (Brünsteiner and Autohaus Hilgert, paragraph 28 and the case-law cited).

24 It follows that there is no need to give a ruling on the validity of Article 88(1)(a) of Directive 2001/83.

The interpretation of Article 88(1)(a) Directive 2001/83

25 Article 88(1)(a) of Directive 2001/83 prohibits without exception any advertising to the general public of medicinal products which are available only on medical prescription. Therefore, in order to answer the question from the referring court, it is necessary to examine whether the activity at issue in the main proceedings concerns medicinal products which are available only on medical prescription in accordance with Title VI of that directive, whether it constitutes advertising within the meaning of that provision and, finally, whether it is directed at the general public.

26 In that connection, it is common ground that the activity at issue in the main proceedings concerns medicinal products which are available only on medical prescription in accordance with Title VI of Directive 2001/83.

27 In order to interpret the concept of 'advertising' within the meaning of Article 88(1)(a) of Directive 2001/83 it is appropriate to examine the wording of the provision of that directive which defines it as well as the general scheme and purpose of the provision in the context of that directive.

28 As regards the concept of 'advertising of medicinal products', Article 86(1) of Directive 2001/83 defines that concept as 'any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products'.

29 It is apparent from the outset from the wording of that provision, in particular from the expression 'any form', that the concept of advertising of medicinal products adopted by the European Union legislature is very broad. As is clear from recital 44 in the preamble to Directive 2001/83, that concept may include the dissemination on the internet of information relating to medicinal products (see, to that effect, **Case C-421/07 Damgaard [2009] ECR I-2629, paragraph 28**).

30 As regards, in particular, medicinal products which, like those at issue in the main proceedings, are available only on prescription, that broad conception of advertising is supported by the essential aim of Directive 2001/83, which is to safeguard public health (see **Damgaard, paragraph 22**) and which, in light of the serious consequences for health which may arise from improper use or overconsumption of such medicinal products, justifies a broad interpretation of the prohibition on advertising those products.

31 It is also clear from the wording of Article 86(1) of Directive 2001/83 that the purpose of the message constitutes the fundamental defining characteristic of advertising, and the decisive factor for distinguishing advertising from mere information.

32 Consequently, the definition in Article 86(1) of Directive 2001/83 does not, in principle, preclude publications or dissemination which include only objective information from being regarded as advertising. If the message is designed to promote the prescription, supply, sale or consumption of medicinal products, it is advertising for the purposes of that directive. However, material which is purely informative, without promotional intent, is not covered by the provisions of that directive relating to advertising of medicinal products.

33 The question whether a dissemination of information has a promotional objective must be determined by undertaking a detailed examination of all the relevant circumstances of the case, which is for the national court (see, to that effect, **Damgaard, paragraph 23**).

34 As regards the identity of the person disseminating information relating to a medicinal product, although it is undeniable that the manufacturer of that medicinal product has a financial interest in marketing its product, the fact that the manufacturer disseminates such information itself cannot, as such, lead to the conclusion that it has an advertising purpose. It is also necessary, for such a fact to be a conclusive factor in favour of the

classification of that dissemination as advertising, that the conduct, action and approaches of the manufacturer disclose its intention to promote, via such dissemination, the prescription, supply, sale or consumption of that medicinal product (see, by analogy, Case C-219/91 Ter Voort [1992] ECR I-5485, paragraph 26).

35 However, it is conceivable that, in certain circumstances, the publication by a manufacturer of information relating to its medicinal products forms part of the general communication policy of the undertaking, in order to provide objectively accurate information to the patients concerned and to avoid as far as possible the risks to health from self-medication without consulting the package leaflet. Such may be the case of patients who have lost the package leaflet for the medicinal product used. Furthermore, the intention to take account of the public desire to be informed or to highlight the transparency of the undertaking might also lead a pharmaceutical undertaking to publish information about its medicinal products.

36 As regards the purpose of the communication, it must be observed that, as a general rule, the requirement for a medical prescription for medicinal products such as those at issue in the main proceedings is to ensure that any interest aroused by the objective information relating to the medicinal products mentioned on the manufacturer's website cannot lead directly to a decision to purchase and that the final decision as to the medicinal product to be taken by the patient remains with his doctor.

37 It is admittedly possible that, because of a request by an informed patient, the doctor is led to prescribe a medicinal product other than that which he initially preferred and that, consequently, the factual information contributes, even marginally, to increasing sales. However, such a possibility is not sufficient to show promotional intent on the part of the manufacturer of the medicinal product. Furthermore, in principle it does not represent a specific danger to the health of the patient if the doctor takes the view that the prescription of one or other of the medicinal products may be envisaged and cannot compromise the objectivity with which, as noted in recital 50 in the preamble to Directive 2001/83, a doctor must act when issuing a prescription for a given patient. A prescribing doctor is required, from the point of view of professional conduct, not to prescribe a given medicinal product if it is not fitting for the therapeutic treatment of his patient (see, to that effect, Case C-62/09 Association of the British Pharmaceutical Industry [2010] ECR I-0000, paragraphs 39 and 40).

38 Furthermore, the possibility for the patient to access in advance, before a medical examination, objective information from reliable sources could, in some circumstances, contribute to the prescription of appropriate treatment, in so far as there may be a more fruitful dialogue between the doctor and the informed patient.

39 In the same way, the dissemination on the internet of the packaging and the package leaflet of the medicinal product could, in certain circumstances, avoid uninformed self-medication by a patient who has lost that leaflet.

40 As regards the contents of the communication, it is apparent from the order for reference that the presentation by MSD of its products on its website consists in reproducing the packaging of the medicinal products at issue and the therapeutic indications and the instructions in the package leaflet.

41 In that connection, it should be observed that Article 61 of Directive 2001/83 provides that all the information appearing on the packaging and the package leaflet of a medicinal product must have been submitted to the competent authorities when the marketing authorisation was requested and approved by them. Thus, this is information which is not only objective, and without any danger a priori to the consumer, but also approved, and the appearance of which on the packaging and the package leaflet is even obligatory in accordance with Articles 54 and 59 of that directive.

42 Furthermore, according to Article 62 of Directive 2001/83, the outer packaging and the package leaflet may not include any element of a promotional nature.

43 It follows that, if the dissemination of information relating to medicinal products, which are available only on medical prescription, on the manufacturer's website consists solely in the faithful reproduction of the packaging of the medicinal product, in accordance with Article 62 of Directive 2001/83, and in a literal and complete reproduction of the package leaflet or the summary of the product's characteristics approved by the authorities with competence in relation to medicinal products, and if it is not accompanied by any additional element which supports its classification as advertising, the objective of protecting health pursued by the prohibition on advertising of such medicinal products does not appear to lead to such a dissemination being classified as prohibited advertising for the purposes of Article 88(1)(a) of Directive 2001/83.

44 A different classification must, however, be adopted where the information relating to the medicinal product is selected or rewritten by the manufacturer, since such manipulation of information can be explained only by an advertising purpose.

45 Among the other relevant factors for determining whether the communication at issue in the main proceedings must be classified as advertising are, in the present case, the group of addressees and the technical characteristics of the media used in order to disseminate the information.

46 In that connection, it should be observed that, admittedly, according to the information provided by the order for reference, the information at issue in the main proceedings is accessible to everyone, since MSD did not decide to reserve access to it to certain groups of persons such as healthcare professionals

47 However, that information is simply available on the manufacturer's website, according to the system of 'pull' services, so that consulting it requires active research steps by the internet user and a person who is not interested in the medicinal product concerned will not be unwillingly confronted with that information.

That means of communicating information with the assistance of a passive presentation platform is not, in principle, intrusive and does not impose itself unexpectedly on the general public, such a situation thus distinguishing itself from that of 'push' services, in which an internet user is confronted, without searching for it, with that kind of content by means of intrusive windows called 'pop-ups', which appear spontaneously on the screen, from which situation a strong presumption of advertising must, by contrast, be inferred.

48 Having regard to all of the foregoing, the answer to the question referred is that Article 88(1)(a) of Directive 2001/83 must be interpreted as meaning that it does not prohibit the dissemination on a website, by a pharmaceutical undertaking, of information relating to medicinal products available only on medical prescription, where that information is accessible on the website only to someone who seeks to obtain it and that dissemination consists solely in the faithful reproduction of the packaging of the medicinal product, in accordance with Article 62 of that directive, and in the literal and complete reproduction of the package leaflet or the summary of the product's characteristics, which have been approved by the authorities with competence in relation to medicinal products. On the other hand, the dissemination, on such a website, of information relating to a medicinal product which has been selected or rewritten by the manufacturer, which can be explained only by an advertising purpose, is prohibited. It is for the referring court to determine whether and to what extent the activities at issue in the main proceedings constitute advertising within the meaning of that directive.

Costs

49 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 (Third Chamber) hereby rules:

Article 88(1)(a) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, must be interpreted as meaning that it does not prohibit the dissemination on a website, by a pharmaceutical undertaking, of information relating to medicinal products available on medical prescription only, where that information is accessible on the website only to someone who seeks to obtain it and that dissemination consists solely in the faithful reproduction of the packaging of the medicinal product, in accordance with Article 62 of Directive 2001/83, as amended by Directive 2004/27, and in the literal and complete reproduction of the package leaflet or the summary of the product's characteristics, which have been approved by the authorities with competence in relation to medicinal products. On the other hand, the dissemination, on such a website, of information relating to a medicinal product which has been selected or rewritten by the manufacturer, which can be explained only by an advertising purpose, is prohibited. It is for the referring court to determine whether and to what extent the activities at issue in the main proceedings constitute advertising within the meaning of Directive 2001/83, as amended by Directive 2004/27.