European Court of Justice, 8 November 2007, Ludwigs Apotheke v Juers Pharma

INTERNATIONALE APOTHEKE LUDWIGS-APOTHEKE MÜNCHEN

v

JUERS

ADVERTISING – FREE MOVEMENT – PHARMACEUTICAL LAW

Prohibition of advertising for medicinal products

- **Must be assessed in the light not of Directive 2001/83, but of Articles 28 EC and 30 EC and Articles 11 and 13 of the EEA Agreement**

A prohibition on advertising such as that laid down by Paragraph 8 of the HWG must be assessed in the light not of the provisions on advertising of Directive 2001/83, but of Articles 28 EC and 30 EC and Articles 11 and 13 of the EEA Agreement.

- **Free movement of goods precludes such a prohibition**

Article 28 EC and Article 11 of the EEA Agreement preclude such a prohibition, in so far as it applies to the distribution to pharmacists of lists of non-approved medicinal products, the importation of which from another Member State or a non-Member State which is a party to the EEA Agreement is authorised only on an exceptional basis, which contain no information other than that concerning the trade name, packaging size, dose and price of those medicinal products.

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European Court of Justice, 8 November 2007

(C.W.A. Timmermans, K. Schiemann, J. Makarczyk, J.C. Bonichot and C. Toader)

JUDGMENT OF THE COURT (Second Chamber)

8 November 2007 (*)

(Free movement of goods – Articles 28 EC and 30 EC – Articles 11 and 13 of the EEA Agreement – Imported medicinal products not authorised in the importing State – Prohibition of advertising – Directive 2001/83/EC)

In Case C-143/06,

REFERENCE for a preliminary ruling under Article 234 EC, from the Landgericht Hamburg (Germany), made by decision of 3 March 2006, received at the Court on 17 March 2006, in the proceedings

Ludwigs Apotheke München Internationale Apotheke

v

Juers Pharma Import-Export GmbH,

THE COURT (Second Chamber),

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

Advocate General: D. Ruiz-Jarabo Colomer,

Registrar: B. Fülöp, Administrator,

having regard to the written procedure and further to the hearing on 21 March 2007,

after considering the observations submitted on behalf of:

– Ludwigs-Apotheke München Internationale Apotheke, by W. Rehmann, Rechtsanwalt,

– Juers Pharma Import-Export GmbH, by A. Meisterernst, Rechtsanwalt,

– the Polish Government, by E. Ośniecka-Tamecka and T.L. Krawczyk, acting as Agents,

– the United Kingdom Government, by C. Gibbs, acting as Agent, and S. Lee, Barrister,

– the Commission of the European Communities, by B. Stromsky and B. Schima, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of the third indent of Article 86(2) 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 was made in the context of proceedings between Ludwigs-Apotheke München Internationale Apotheke ('Ludwigs-Apotheke') and Juers Pharma Import-Export GmbH ('Juers Pharma') regarding the sending of lists of medicinal products not approved in Germany by Juers Pharma to pharmacists.

Legal context

Directive 2001/83

3 Article 2(1) of Directive 2001/83 states:

'This directive is to apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.'

4 Under Article 5(1) of that directive:

'A Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.'

5 In accordance with the first subparagraph of Article 6(1) of the directive:

'No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Mem-

ber State in accordance with this Directive or an authorisation has been granted in accordance with [Council] Regulation (EEC) No 2309/93 [of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1)].'

6 Article 86 of Directive 2001/83, which appears under Title VIII, 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,

…

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,

– statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.'

7 Article 87(1) of Directive 2001/83 provides:

'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.'

German legislation

8 Paragraph 73(1) of the Law on Medicinal Products (Arzneimittelgesetz, 'the AMG') prohibits the marketing of medicinal products which require approval or registration unless they have been approved or registered.

9 By way of exception to that rule, Paragraph 73(3) of the AMG allows pharmacists to obtain in another State medicinal products not approved in Germany, but lawfully put into circulation in that other State. That exception covers only the provision of small quantities of medicinal products in response to individual orders.

10 Paragraph 8 of the Law on the advertising of medicines (Heilmittelwerbegesetz, 'the HWG') prohibits all advertising of medicinal products which can be acquired under Paragraph 73(3) of the AMG.

The main proceedings and the questions referred for a preliminary ruling

11 Ludwigs Apotheke and Juers Pharma specialise in the trade in medicinal products, the importation into Germany of which is authorised under Paragraph 73(3) of the AMG.

12 In the context of that activity, Juers Pharma sends lists of medicinal products to pharmacists, in which medicinal products not approved in Germany are identified by their trade name and are the subject of notes regarding packaging size, price and, where the medicinal product is offered in different dosages, dose. Those lists also indicate, in certain cases, the country of origin of the medicinal products, namely either a Member State of the European Union or a non Member State which is a signatory to the Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3) ('the EEA Agreement'), in which they were approved.

13 Ludwigs Apotheke brought an application for interim measures seeking an injunction to stop Juers Pharma from sending the lists, on the ground that sending them constituted advertising for medicinal products not approved in Germany which was prohibited under Paragraph 8 of the HWG, and obtained from the Landgericht (Regional Court) Hamburg (Germany) an order granting its application, dated 9 August 2004. On an objection by Juers Pharma, the Landgericht Hamburg, rehearing the case, followed Juers Pharma's argumentation and held, by order of 12 October 2004, that the lists of medicinal products at issue in those interlocutory proceedings should not be classified as advertising. That conclusion was based on the third indent of Article 86(2) of Directive 2001/83, under which factual, informative announcements and reference material relating, inter alia, to trade catalogues and price lists, provided they include no product claims, are not covered by Title VIII, on advertising, of that directive. Consequently, according to the order of 12 October 2004, the prohibition on advertising under Paragraph 8 of the HWG must not be applied to lists of medicinal products such as those at issue in those interlocutory proceedings.

14 Ludwigs Apotheke appealed against that order, and the Hanseatisches Oberlandesgericht Hamburg (Hanseatic Higher Regional Court), by judgment of 19 May 2005, reinstated the injunction granted by the Landgericht Hamburg in the first interlocutory order of 9 August 2004. According to the appeal court, in view of the wording of the third indent of Article 86(2) of Directive 2001/83, trade catalogues and price lists are excluded from the scope of Title VIII of that directive. That provision does not therefore preclude national legislation from considering such lists to be advertising and providing for their prohibition.

15 Since Juers Pharma did not accept that the injunction granted in the interlocutory proceedings was final, Ludwigs Apotheke continued the proceedings before the Landgericht Hamburg, which decided to stay the proceedings and to refer the following two questions for a preliminary ruling:

'(1) Is the rule in the third indent of Article 86(2) of Directive 2001/83 … to be interpreted as precluding a national rule prohibiting as prohibited advertising for imports of medicinal products the dispatch of price lists

for medicinal products to pharmacists if and to the extent that the medicinal products included on those lists are not approved in the relevant Member State but may be imported in isolated cases from other Member States of the European Union and other States?

(2) What is the purpose of the rule according to which the title on advertising does not cover trade catalogues and price lists provided they include no product claims, if the scope of application of national provisions on advertising of medicinal products is not thereby exhaustively defined?'

The questions referred for a preliminary ruling

The first question

16 By its first question, the national court seeks, essentially, to know whether the third indent of Article 86(2) of Directive 2001/83 must be interpreted as precluding a national provision such as Paragraph 8 of the HWG, which prohibits any advertising of medicinal products not approved in Germany which can none the less be imported, under a derogation which appears in Paragraph 73(3) of the AMG, in response to individual orders from other Member States or States which are parties to the EEA Agreement.

17 A number of interested parties who have submitted written observations to the Court have expressed doubts as to the applicability of Title VIII, on advertising, of Directive 2001/83 and, accordingly, of the third indent of Article 86(2) of that directive in circumstances such as those of the main proceedings. Thus, the Polish and United Kingdom Governments have referred to the possible relevance of Article 5(1) of Directive 2001/83 and put forward the argument that the medicinal products mentioned on the lists at issue in the main proceedings are entirely excluded from the scope of that directive by virtue of that provision. Ludwigs□Apotheke and the Commission of the European Communities have contended that the third indent of Article 86(2) of the directive excludes trade catalogues and price lists from the scope of Title VIII, on advertising, of Directive 2001/83 so that the Member States are free to regulate this area, provided that the requirements imposed by Articles 28 EC and 30 EC are respected.

18 In order to determine whether Title VIII, on advertising, of Directive 2001/83 applies in circumstances such as those of the main proceedings and to provide a useful answer to the national court, it is necessary to examine the legislative framework in which a provision such as Paragraph 8 of the HWG operates.

19 As is clear from the account of the German legislation applicable in the main proceedings which appears in the order for reference, Paragraph 73(1) of the AMG prohibits the marketing in Germany of medicinal products which require approval or registration unless they have been approved or registered. As the Court found in Case C□322/01 Deutscher Apothekerverband [2003] ECR I□14887, paragraph 52, that general prohibition corresponds to the prohibition, at Community level, on placing on the market medicinal products which have not been authorised in the Member State concerned, provided for by the first subparagraph of Article 6(1) of Directive 2001/83. According to that provision, no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that State in accordance with that directive or an authorisation has been granted in accordance with Regulation No 2309/93. Consequently, the Member States must, generally, entirely prohibit the marketing of medicinal products which are not covered by a national or Community marketing authorisation.

20 However, it is not contested that Paragraph 73(3) of the AMG allows pharmacists to obtain, in limited quantities, in another Member State or in a State which is a party to the EEA Agreement, medicinal products the placing on the market of which has not been authorised in Germany but which have been lawfully put into circulation in that other State, in order to meet an order from an individual.

21 The Court finds that, even if the power to make such a derogation is not expressly granted by Directive 2001/83, that derogation is not necessarily contrary to that directive provided that it is applied so as not to undermine the general obligation to obtain a marketing authorisation. Under recital 30 in the preamble to the directive, it must be possible for a person established in one Member State to have a reasonable quantity of medicinal products intended for his personal use sent to him from another Member State. From that point of view, Article 5(1) of Directive 2001/83 provides that a Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of that directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised practitioner and for use by an individual patient under his responsibility.

22 It must be stated that the evidence brought to the Court's attention does not give any information as to the possible intention of the German legislature to use the power granted by that provision. However, inasmuch as Paragraph 73(3) of the AMG aims to make it possible to place on the market a limited quantity of non-approved medicinal products in the context of an individual order justified by special needs, that provision may be regarded as actually implementing Article 5(1) of Directive 2001/83.

23 Therefore, the Court finds that the medicinal products covered by Paragraph 73(3) of the AMG are excluded from the scope of Directive 2001/83. Accordingly, the provisions of Title VIII, on advertising, of that directive are not applicable to them.

24 In those circumstances and in order to give a useful reply to the national court to enable it to decide the dispute before it, it is necessary to examine whether a prohibition on advertising such as that laid down by Paragraph 8 of the HWG is compatible with Community law, in the light not of Title VIII of Directive 2001/83, but of the provisions of the EC Treaty concerning the free movement of goods, more specifically Articles 28 EC and 30 EC, and, in so far as the lists at issue in the main proceedings also mention medicinal

products imported from non-Member States which are signatories to the EEA Agreement, in the light of the provisions of that agreement concerning the free movement of goods, namely Articles 11 and 13.

25 The free movement of goods is a fundamental principle of the Treaty which is expressed in the prohibition, set out in Article 28 EC, on quantitative restrictions on imports between Member States and all measures having equivalent effect.

26 That prohibition of measures having an effect equivalent to quantitative restrictions applies to all legislation of the Member States that is capable of hindering, directly or indirectly, actually or potentially, intra-Community trade (see, in particular, Case 8/74 Dassonville [1974] ECR 837, paragraph 5, and Case C-147/04 De Groot en Slot Allium and Bejo Zaden [2006] ECR I-245, paragraph 71).

27 Nevertheless, national rules which hinder the free movement of goods can be justified, as Article 30 EC provides, inter alia on grounds of protection of the health and life of humans. According to settled case-law, the health and life of humans rank foremost among the assets or interests protected by Article 30 EC and, in the absence of Community harmonisation in the area concerned, it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they wish to assure, always taking into account the requirements of the free movement of goods within the European Community (see, to that effect, Deutscher Apothekerverband, paragraph 103 and the case-law cited, and Joined Cases C-158/04 and C-159/04 Alfa Vita Vassilopoulos and Carrefour-Marinopoulos [2006] ECR I-8135, paragraph 21).

28 However, in order for such national rules to comply with the principle of proportionality, it must be ascertained not only whether the means which they employ are suitable for the purpose of attaining the desired objectives but also whether those means do not go beyond what is necessary for that purpose (see, inter alia, Alfa Vita Vassilopoulos and Carrefour-Marinopoulos, paragraph 22).

29 It is therefore necessary to examine whether national rules such as those at issue in the main proceedings constitute a restriction within the meaning of Article 28 EC and, if they do, whether they have their basis in a permissible justification under Article 30 EC, as interpreted by the Court.

30 Such an examination has already been carried out by the Court in respect of Paragraph 8 of the HWG in Case C-320/93 Ortscheit [1994] ECR I-5243. In that judgment, the Court found that the prohibition on advertising provided for by that provision constitutes a measure having equivalent effect within the meaning of Article 30 of the EEC Treaty (subsequently Article 30 of the EC Treaty, and now, after amendment, Article 28 EC). The Court stated, at paragraphs 9 and 10 of the judgment, that that measure, first, concerns only foreign medicinal products and, second, is such as to restrict the volume of imports of medicinal products not authorised in Germany, since it deprives pharmacists and doctors, whose participation is essential for the importation of those medicinal products under Paragraph 73(3) of the AMG, of a source of information on the existence and availability of such products.

31 Nevertheless, the Court considered that that prohibition was justified under Article 36 of the EEC Treaty (subsequently Article 36 of the EC Treaty, and now, after amendment, Article 30 EC) for reasons connected with the protection of the health and life of humans. It stated at paragraphs 19 and 20 of its judgment in Ortscheit that the prohibition has the purpose of ensuring that the individual importation of medicinal products which have not been authorised remains an exception, in order to prevent the general requirement of national authorisation under German law from being systematically circumvented, since, if medicinal products which were not authorised in Germany could be advertised there, there would be a danger that manufacturers would obtain authorisation for their medicinal products in a Member State imposing fewer requirements and then import them into Germany on the basis of individual orders which they would have encouraged by advertising campaigns. The Court found that the prohibition of advertising imposed by Paragraph 8 of the HWG is therefore necessary for the effectiveness of the national authorisation scheme.

32 It should be noted that at the time of the facts in Ortscheit Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use (OJ 1992 L 113, p. 13) was not applicable ratione temporis. However, as the Commission contends in its observations, that fact does not preclude the findings which the Court made in that judgment from being of continuing relevance as Community law now stands, given the harmonisation brought about in the meantime by Directive 2001/83, which repealed Directive 92/28.

33 Directive 2001/83 is based on the premiss that the marketing of a product which is classified as a medicinal product is conditional on the grant of a marketing authorisation, issued either by the competent authority of a Member State, or in the context of the centralised Community procedure under Regulation No 2309/93. That general rule, which is laid down in the first subparagraph of Article 6(1) of Directive 2001/83, allows derogations on the conditions set out in Article 5(1) of that directive. As already found at paragraphs 19 to 22 of the present judgment, it is apparent that the German legislation at issue in the main proceedings actually implements those provisions. Thus, following the example of Directive 2001/83, that national legislation aims to ensure that the possibility of importing non-approved medicinal products remains exceptional. The advertising of such medicinal products would have quite the opposite effect.

34 Distributed to pharmacists, such advertising could in fact encourage them to recommend to their customers medicinal products the placing on the market of which in Germany has not been authorised, thereby stimulating orders for such medicinal products, and could, consequently, lead to an increase in their impor-

tation. It should be noted in that regard that, in the context of the system of derogation under Paragraph 73(3) of the AMG, pharmacists are accorded only the passive role of intermediaries, since it is only in response to an order from an individual that pharmacists are entitled to take the steps necessary for the importation of the medicinal product requested from another State.

35 The Court finds that the specific function assigned to a prohibition on advertising such as that laid down in Paragraph 8 of the HWG consists in strengthening the exceptional nature of a derogating authorisation to market medicinal products which are not approved and not registered, such as that under Paragraph 73(3) of the AMG, thereby preserving the practical effect of the marketing authorisation procedure. Therefore, a restriction which follows from that prohibition may be considered to be justified by the protection of the health and life of humans, and necessary for that purpose, in accordance with Article 30 EC, inasmuch as it aims to limit the volume of imports of non-approved medicinal products.

36 It is, nevertheless, necessary to check whether such a restriction does not go beyond that which is necessary in order to attain that objective.

37 It is clear from the order for reference that Paragraph 8 of the HWG, which lays down a prohibition on the advertising of non-approved medicinal products whose sale is authorised on an exceptional basis, precludes the distribution of lists of medicinal products such as those at issue in the main proceedings, lists which do not contain substantive information on the properties or effects of the medicinal products.

38 In that regard, there is a possible parallel with the exclusion from the scope of Title VIII, on advertising, of Directive 2001/83, under the third indent of Article 86(2) of that directive, of 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.

39 Lists such as those at issue in the main proceedings, in the absence of information as to the therapeutic effects of the medicinal products not approved in the Member State concerned, cannot in themselves be regarded as permitting pharmacists to recommend to their customers the importation of such medicinal products. Thus, an increase in imports of non-approved medicinal products, as described in paragraph 34 of the present judgment, is not very plausible.

40 Consequently, it is apparent that, in such a legislative context, the distribution of lists of medicinal products, such as those at issue in the main proceedings, to pharmacists is not such as to have an impact on the volume of imports of medicinal products which are not approved in the Member State concerned and, accordingly, to compromise the exceptional nature of such imports.

41 It follows that a prohibition such as that laid down by Paragraph 8 of the HWG, taken in its legislative context, goes beyond that which is necessary to attain the objective of ensuring that the importation of non-approved medicinal products remains exceptional, in order to preserve the practical effect of the marketing authorisation procedure, in so far as that prohibition applies to the distribution to pharmacists of lists of non-approved medicinal products, such as those at issue in the main proceedings.

42 Consequently, the Court concludes that the application of a provision such as Paragraph 8 of the HWG to the distribution to pharmacists of lists of medicinal products, such as those at issue in the main proceedings, cannot be justified, under Article 30 EC, on grounds of the protection of the health and life of humans.

43 In so far as those lists also relate to medicinal products imported from non-Member States which are signatories to the EEA Agreement, it should be noted that the rules regarding restrictions on the free movement of goods set out in Articles 11 and 13 of that agreement are essentially identical to those laid down by Articles 28 EC and 30 EC. Therefore, in the light of the conclusion in the preceding paragraph of this judgment, the Court finds that, inasmuch as it precludes the distribution to pharmacists of lists of medicinal products, such as those at issue in the main proceedings, the prohibition on advertising laid down by a provision such as Paragraph 8 of the HWG cannot be justified under Article 13 of the EEA Agreement.

44 In view of the foregoing considerations, the answer to the first question referred for a preliminary ruling must be that a prohibition on advertising such as that laid down by Paragraph 8 of the HWG must be assessed in the light not of the provisions on advertising of Directive 2001/83, but of Articles 28 EC and 30 EC and Articles 11 and 13 of the EEA Agreement. Article 28 EC and Article 11 of the EEA Agreement preclude such a prohibition, in so far as it applies to the distribution to pharmacists of lists of non-approved medicinal products, the importation of which from another Member State or a non-Member State which is a party to the EEA Agreement is authorised only on an exceptional basis, which contain no information other than that concerning the trade name, packaging size, dose and price of those medicinal products.

The second question

45 Having regard to the answer given to the first question, it is not necessary to answer the second question referred for a preliminary ruling by the national court.

Costs

46 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:

A prohibition on advertising such as that laid down by Paragraph 8 of the Law on the advertising of medicines (Heilmittelwerbegesetz) must be assessed in the light not of the provisions on advertising 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, but of Articles 28 EC and 30 EC and Articles 11 and 13 of the Agreement on the European Economic Area of 2 May 1992. Article 28 EC and Article 11 of the Agreement on the European Economic Area preclude such a prohibition, in so far as it applies to the distribution to pharmacists of lists of non-approved medicinal products, the importation of which from another Member State or a non Member State which is a party to the Agreement on the European Economic Area is authorised only on an exceptional basis, which contain no information other than that concerning the trade name, packaging size, dose and price of those medicinal products.