

Case C-190/20

Request for a preliminary ruling

Date lodged:

5 May 2020

Referring court:

Bundesgerichtshof (Germany)

Date of the decision to refer:

20 February 2020

Defendant and appellant in the appeal on a point of law:

DocMorris N.V.

Applicant and respondent in the appeal on a point of law:

Apothekerkammer Nordrhein

BUNDESGERICHTSHOF (FEDERAL COURT OF JUSTICE)

ORDER

[...]

in the case of

DocMorris N.V., [...] the Netherlands,

defendant and appellant in the appeal on a point of law,

[...]

versus

Apothekerkammer Nordrhein, [...] Düsseldorf,

applicant and respondent in the appeal on a point of law,

[...] **[Or. 2]**

The First Civil Chamber of the Federal Court of Justice [...]

makes the following order:

- I. The proceedings are stayed.
- II. The following question on the interpretation 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 et seq.), last amended by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (OJ 2019 L 198, p. 241), is referred to the Court of Justice of the European Union for a preliminary ruling:

Is it compatible with the provisions of Title VIII and, in particular, with Article 87(3) of Directive 2001/83/EC if a national provision (in this case the first sentence of Paragraph 7(1) of the Gesetz über die Werbung auf dem Gebiete des Heilwesens (Law on Advertising in the Field of Medicine, ‘the HWG’)) is interpreted as prohibiting a mail-order pharmacy established in another Member State from using a prize competition to attract customers if participation in the prize competition is linked to the submission of a [Or. 3] prescription for a medicinal product for human use subject to a medical prescription, the prize offered is not a medicinal product but another object (in this case an electric bike worth EUR 2 500 and electric toothbrushes), and there is no risk that irrational and excessive use of that medicinal product is encouraged?

Grounds:

- 1 A. The applicant is the professional representative body for pharmacies in the North Rhine region. One of its tasks is monitoring compliance with the professional duties incumbent on pharmacists. The defendant is a mail-order pharmacy established in the Netherlands that supplies prescription medicines to customers in Germany.
- 2 In March 2015, the defendant carried out an advertising campaign throughout Germany using flyers for a ‘Grand Prize Draw’ in which the main prize was a voucher for an electric bicycle worth EUR 2 500 and the second to tenth prizes were electric toothbrushes. A condition for participating in the prize draw was the submission of a prescription.
- 3 The applicant considers this form of advertising to be anti-competitive. By letter from its lawyer of 1 April 2015, it issued a formal notice to the defendant without success.

distributing prescription medicinal products is consistent with the purposes of Directive 2001/83/EC on the Community code relating to medicinal products for human use and Articles 86 to 90, in particular Article 87(3), of that directive.

8 I. This Chamber takes the view that the appellate court rightly held that a right to obtain a prohibitory injunction owing to an infringement of point 13 of the first sentence of Paragraph 11(1) of the HWG does not exist. [amplification]

9 [...]

10 [...] **[Or. 6]** [...]

11 [...]

12 II. Without an answer to the question referred, it is not possible to assess conclusively whether the applicant is entitled to obtain the claimed prohibitory injunction against the defendant owing to an infringement of the first sentence of Paragraph 7(1) of the HWG.

13 1. Pursuant to the first clause of the first sentence of Paragraph 7(1) of the HWG, it is prohibited to offer, announce or grant monetary advantages and other promotional gifts (goods or services) or accept them as a healthcare professional, unless one of the exceptions laid down by law in the second clause of the first sentence of Paragraph 7(1) of the HWG is applicable. Excluded from the prohibition in the first clause of the first sentence of Paragraph 7(1) of the HWG are monetary advantages or promotional gifts which are of minor objects of low value (point 1 of the second clause of the first sentence of Paragraph 7(1) of the HWG) or which are granted as a specific sum of money or as a sum of money to be calculated in a specific way (point 2(a) of the second clause of the first sentence of Paragraph 7(1) of the HWG). However, in the case of both exceptions, monetary advantages and other promotional gifts in respect of medicinal products remain prohibited if they are granted in breach of the pricing rules applicable under the Law on medicinal products. The general prohibition on promotional gifts provided for in the first sentence of Paragraph 7(1) of the HWG is intended to counter, by minimising as far as possible advertising by means of gifts or advantages in the field of medicinal products, the abstract risk of consumers being influenced by the prospect of promotional gifts in a non-objective manner when deciding whether to use medicinal products, and, if so, which ones to use [...].

14 2. The appellate court did not err in law in assuming that the matter falls within the scope of the first sentence of Paragraph 7(1) of the HWG. [amplification] [...] **[Or. 7]** [...]

15 3. The appellate court rightly assumed that the defendant's advertising in question, which consists of the possibility of taking part in a prize draw upon the submission of a prescription, is product-related and, therefore, the provisions of the Law on the advertising of medicinal products are, in principle, applicable to that advertising.

- 16 a) Not all advertising for medicinal products within the meaning of point 1 of Paragraph 1(1) of the HWG is subject to the provisions of the Law on the advertising of medicinal products. Only product-related advertising (product and sales advertising) falls within the scope of that law, and not general corporate advertising (business and image advertising), which is used to advertise the reputation and performance of the company in general without making reference to specific medicinal products. The answer to the question that is decisive for determining the applicability of the Law on the advertising of medicinal products — whether the advertising to be assessed is sales or corporate advertising — depends crucially on whether, based on the overall appearance of the advertising, the focus is on the presentation of the company or on the promotion of certain, or at least individually identifiable, products [...]. Even advertising for a pharmacy's entire range of goods can be product-related [...]. There is no convincing reason to accept the inducement from **[Or. 8]** advertising by means of gifts or advantages, which is regarded by the legislature as being fundamentally undesirable in the advertising of medicinal products, especially where that form of advertising is used for a particularly large number of medicinal products [...].
- 17 b) The provisions of Directive 2001/83/EC do not preclude the assumption that the provisions of the Law on the advertising of medicinal products also cover advertising for a pharmacy's entire range of goods.
- 18 aa) The provisions of the Law on the advertising of medicinal products must be interpreted in accordance with EU law, in the light of the provisions of Directive 2001/83/EC. That directive completely harmonised the advertising of medicinal products (CJEU, judgment of 8 November 2007, C-374/05 [2007] ECR I-9517 = GRUR 2008, 267, paragraphs 20 to 39, *Gintec* [...]).
- 19 bb) It cannot be gathered from the provisions of Directive 2001/83/EC on advertising (Title VIII and VIIIa, Articles 86 to 100) that they only cover advertising for individual medicinal products.
- 20 (1) Pursuant to Article 86(1) of Directive 2001/83/EC, 'advertising of medicinal products' is any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. Pursuant to the first indent of Article 86(1) of Directive 2001/83/EC, the concept of 'advertising of medicinal products' covers, in particular, the advertising to the general public of medicinal products, such as that at issue here. It is apparent 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 (CJEU, **[Or. 9]** judgment of 5 May 2011, C-316/09 [2011], ECR I-3249 = GRUR 2011, 1160, paragraph 29, *MSD Sharp & Dohme*).
- 21 (2) Directive 2001/83/EC contains, in Article 88(1) to (4), rules for advertising to the general public for entire groups of medicinal products. That Directive

2001/83/EC covers only advertising to the general public of individual medicinal products does not follow from the fact that Articles 89 and 90 of Directive 2001/83/EC refer to ‘advertising to the general public of a medicinal product’; those provisions merely stipulate, for advertising relating to a particular medicinal product, what specific information must be provided in relation to that product and what information is not permitted. The other provisions — Article 86(1) and Article 88(1) to (3) of Directive 2001/83/EC — refer to ‘advertising of medicinal products’ and ‘advertising of medicinal products to the general public’. Accordingly, the directive also covers advertising for medicinal products in general and not only advertising relating to specific medicinal products [...].

22 c) The advertising in question therefore has the necessary connection with products. The promised benefit in the form of participation in the defendant’s prize draw is neither a promotion of the services of the mail-order pharmacy operated by it nor an advantage provided for other company-related reasons. According to the specific act of infringement referred to in the form of order sought by the applicant, participation in the prize draw is linked to the submission of a prescription. The advertising therefore relates to medicinal products subject to prescription, which are thus available only on prescription, and is therefore automatically product-related.

23 4. The appellate court rightly assumed that, in the present case, the opportunity offered by the defendant to participate in a prize draw constituted a promotional gift within the meaning of the first sentence of Article 7(1) of the HWG. **[Or. 10]** [amplification]

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26 5. The appellate court did not err in law in assuming that none of the exceptions laid down in the second clause of the first sentence of Paragraph 7(1) of the HWG are applicable. **[Or. 11]** [amplification]

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28 [...]

29 6. The question arises, however, as to whether the defendant’s advertising influences its customers in a non-objective manner. **[Or. 12]**

30 a) The appellate court assumed that advertising the possibility of participating in a prize draw after a prescription had been dispensed substantiated the argument that there was an abstract risk of the target group of the advertising being influenced in a non-objective manner. It could not be ruled out that a patient who needed a medicinal product subject to prescription and had obtained the prescription required for that product from his doctor could decide to have the prescription dispensed by the defendant’s mail-order pharmacy without considering whether

purchasing the medicinal product from a brick-and-mortar pharmacy would be more suited to his personal needs. Mail-order pharmacies could provide advice only by telephone and on express request. It could be important for the customer to receive unsolicited advice even when a prescription was being dispensed, for example with regard to its interaction with other medicines. The pharmacist was trained to do this. The customer's decision to use either a brick-and-mortar pharmacy or a mail-order pharmacy was therefore relevant to his health. The advertising by means of a prize draw at issue here influenced that decision in a non-objective manner.

- 31 b) The fact that participation in a prize draw involves a pecuniary advantage does not in itself justify prohibiting the defendant from using the contested advertising because it influences potential customers in a non-objective manner.
- 32 aa) It is true that in its '*Deutsche Parkinson Vereinigung*' decision (judgment of 19 October 2016, C-148/15, GRUR 2016, 1312 [...]) the Court of Justice of the European Union also assumed that traditional pharmacies are, in principle, better placed than mail-order pharmacies to provide patients with individually tailored advice given by the staff of the dispensary and to ensure a supply of medicinal products in cases of emergency, and mail-order pharmacies cannot, given the limited services that they offer, adequately replace such services. In the light of this fact, however, it also assumed that [Or. 13] price competition is capable of providing a more important factor of competition for mail-order pharmacies established in another Member State than for traditional pharmacies in Germany, since price competition lays the basis for their potential to access the German market directly and to continue to be competitive in it (CJEU, GRUR 2016, 1312, paragraph 24, *Deutsche Parkinson Vereinigung*). The Court of Justice therefore held that a system of fixed sales prices for medicinal products subject to a prescription, such as that laid down in the German legislation, constitutes a measure having equivalent effect to a quantitative restriction on imports, within the meaning of Article 34 TFEU, since that legislation has a greater impact on pharmacies established in other Member States than on pharmacies established within German territory, a fact which could impede market access for products from other Member States more than it impedes such access for domestic products (CJEU, GRUR 2016, 1312, paragraphs 26 and 27, *Deutsche Parkinson Vereinigung*). In addition, it considered that German legislation on prices for medicinal products, which provides for a system of fixed prices for the sale by pharmacies of prescription-only medicinal products for human use, cannot be justified on grounds of the protection of health and life of humans, within the meaning of that Article 36 TFEU, inasmuch as that legislation is not appropriate for attaining the objectives pursued (CJEU, GRUR 2016, 1312, paragraph 46, *Deutsche Parkinson Vereinigung*).
- 33 bb) It can be inferred from these statements made by the Court of Justice of the European Union in the '*Deutsche Parkinson Vereinigung*' judgment that mail-order pharmacies established in other Member States of the European Union cannot, in principle, be denied the possibility of compensating for the limitation

on the services that they offer — which is brought about the fact that it is impossible for them to provide patients with individually tailored advice on site — by engaging in price competition with brick-and-mortar pharmacies in the Member State concerned. There is such price competition in the present dispute. **[Or. 14]**

- 34 (1) It is true that there is no price competition for customers between pharmacies in Germany that is comparable to other product sectors due to the regulatory framework governing the supply of medicinal products subject to a prescription — irrespective of the system of fixed prices that still exists for that group of medicinal products. There is a general obligation to have sickness insurance in Germany pursuant to Paragraph 5(1) of the Fifth Book of the Sozialgesetzbuch (Social Code, ‘the SGB V’). Everyone must be covered by either statutory or private insurance. A consequence of this general obligation to have insurance is that when a medicinal product is prescribed by a doctor, it is not the patient who bears the costs of obtaining it, but the sickness insurance scheme or company with which the patient is insured. When purchasing prescription drugs, those insured under a statutory insurance scheme merely have to pay a contribution for each packet of medicinal products, referred to as a ‘prescription fee’ by the appellate court, of no more than ten euros and no less than five euros (first sentence of Paragraph 61 of the SGB V).
- 35 (2) Regarding the sale of medicinal products subject to a prescription, mail-order pharmacies established in another Member State of the European Union generally do not engage in competition for customers in Germany by offering prices for medicinal products that are lower than those of German pharmacies, but by advertising to customers using monetary advantages. These monetary advantages are intended to encourage customers in Germany to have their prescriptions dispensed not at a brick-and-mortar pharmacy but via a foreign mail-order pharmacy. For example, they may advertise using a bonus corresponding to half of the statutory contribution for people with statutory sickness insurance [...], a bonus when placing a first order [...], a bonus that depends on the price of the medicinal product and is **[Or. 15]** limited to EUR 15 [...], a monetary gift of EUR 15 as an expense allowance for participating in quality assurance [...], remuneration for the customer’s participation in a test for a medicinal product [...], or a gift for attracting a new customer [...].
- 36 (3) This is also the case in the present dispute. The defendant does not advertise to patients in Germany by means of prices for medicinal products that are lower than those of German pharmacies, but by means of a different monetary advantage granted to the patient.
- 37 c) The question arises, however, as to whether the advertising restrictions provided for in the first sentence of Paragraph 7(1) of the HWG in respect of advertising with monetary advantages are justified in the present dispute by the purposes of Directive 2001/83/EC and Articles 86 to 90 thereof, in particular Article 87(3). This is the subject matter of the question referred. The Chamber

takes the view that there is good reason to believe that advertising by offering a random chance of winning a prize in the context of selling medicinal products subject to a prescription must be regarded as influencing, in a non-objective manner, the potential customers targeted by the defendant and, for this reason, the advertising in question must be prohibited.

- 38 aa) It cannot be assumed that a prohibition on advertising by means of monetary advantages for prescription-only medicines is already justified under Article 88(1)(a) of Directive 2001/83/EC, which, in accordance with recital 44 of that directive, requires Member States to prohibit advertising of prescription-only medicinal products to the general public. **[Or. 16]**
- 39 Even if advertising to the general public which is intended — as is the case in the present dispute — to generally promote the sale of medicinal products subject to a prescription by granting monetary advantages does constitute advertising of medicinal products to the general public within the meaning of the first indent of Article 86(1), the Chamber considers that it does not constitute the generally prohibited advertising of medicinal products subject to a prescription to the general public within the meaning of Article 88(1)(a) of Directive 2001/83/EC.
- 40 The purpose of Article 88(1) of Directive 2001/83/EC is to prevent, in order to protect health, advertising to the general public from providing patients with incentives to ask their doctor to prescribe them a medicinal product subject to a prescription. On the other hand, the purpose of price-based advertising or advertising offering other monetary benefits in respect of medicinal products subject to a prescription is to encourage patients to choose a particular pharmacy when purchasing a medicinal product already prescribed for them. Price-based advertising in the distribution of medicinal products subject to a prescription is an inherent part of competition and is not covered by Article 88(1) of Directive 2001/83/EC.
- 41 bb) However, it is conceivable that advertising to the public which offers the possibility of participating in a prize draw in the context of selling medicinal products subject to a prescription is contrary to the objectives of Directive 2001/83/EC and the provisions in Articles 86 to 90 of that directive, in particular Article 87(3).
- 42 (1) Directive 2001/83/EC prohibits, in Article 94(1), the use of gifts, pecuniary advantages or benefits in kind when promoting medicinal products to persons qualified to prescribe them. Pursuant to that provision, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. Directive **[Or. 17]** 2001/83/EC does not contain a corresponding provision for the advertising of medicinal products to the general public. It is true that, pursuant to Article 87(3) of Directive 2001/83/EC, the advertising of medicinal products must encourage the rational use of the medicinal product by presenting it objectively and without exaggerating its properties and, moreover, it

must not be misleading. However, Directive 2001/83/EC does not lay down specific rules on the advertising of medicinal products by promoting the possibility of participating in prize draws.

- 43 (2) The Court of Justice has regarded the advertising of non-prescription medicinal products to the general public by means of prize draws as being difficult to accept on account of the need, pursuant to recital 45 and Article 87(3) of Directive 2001/83/EC, to prevent any excessive and ill-considered advertising which could affect public health (CJEU, GRUR 2008, 267, paragraph 55, *Gintec*). The advertising of a medicinal product by means of prize draws encourages the irrational and excessive use of that medicinal product if it is presented as a gift or a prize, thus distracting the consumer from an objective evaluation of whether he needs to take such medicine (CJEU, GRUR 2008, 267, paragraph 56, *Gintec*).
- 44 (3) Based on the Court of Justice’s decision in ‘*Gintec*’, it is not possible to provide an unequivocal answer to the question of whether a prohibition on the prize draw advertising in question is consistent with Directive 2001/83/EC, because that decision was based on a different set of facts. The advertising in the present dispute does not relate to a specific, over-the-counter medicinal product. Rather, the advertising refers to prescription-only medicinal products in a general manner. Recital 45 of Directive 2001/83/EC, on which the Court of Justice relied for its interpretation, refers only to advertising to the general public of non-prescription medicinal products. Furthermore, the prize does not consist of the medicinal product itself, unlike in the ‘*Gintec*’ case, but an electric bicycle and electric toothbrushes. According to the [Or. 18] findings of the appellate court, there is also no risk that irrational and excessive use of that medicinal product is encouraged in the present dispute.
- 45 cc) According to the findings of the appellate court, however, patients who have been prescribed a medicinal product subject to a prescription are induced by the prize draw advertising in question to dispense with the unsolicited and comprehensive advice provided in a brick-and-mortar pharmacy, which is objectively in their interest. If a doctor has prescribed a medicinal product, it is true that it can be assumed that he has provided the patient with advice on that medicinal product and has informed him, in particular, of the risks and side effects of the prescribed medicinal product. However, this does not mean that unsolicited advice from the pharmacist a second time can be dispensed with in every case. Pursuant to Paragraph 20(2) of the Verordnung über den Betrieb von Apotheken (Regulation on the operation of pharmacies, ‘the ApoBetrO’), when dispensing medicinal products to a patient, the pharmacist must determine, by making enquiries, the extent to which the patient may need further information and advice, and provide appropriate advice. Viewed objectively, it may be irrational for a patient who has been prescribed a medicinal product subject to a prescription to dispense with such an offering of advice [Or. 19] if questions remain unanswered after advice has been provided by the prescribing doctor. The Chamber takes the view that the patient’s decision to obtain a medicinal product subject to a prescription from a domestic or foreign mail-order pharmacy instead of a brick-

and-mortar pharmacy that can provide — objectively required — advice should be based on objective reasons and not be influenced by aleatory stimuli.

[...]

WORKING DOCUMENT