Reports of Cases

JUDGMENT OF THE COURT (First Chamber)

19 October 2016*

(Reference for a preliminary ruling — Articles 34 TFEU and 36 TFEU — Free movement of goods — National legislation — Prescription-only medicinal products for human use — Sale by pharmacies — Setting of fixed prices — Quantitative restriction on imports — Measure having equivalent effect — Justification — Protection of the health and life of humans)

In Case C-148/15,

REQUEST for a preliminary ruling under Article 267 TFEU from the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf, Germany), made by decision of 24 March 2015, received at the Court on 30 March 2015, in the proceedings

Deutsche Parkinson Vereinigung eV

v

Zentrale zur Bekämpfung unlauteren Wettbewerbs eV,

THE COURT (First Chamber),

composed of R. Silva de Lapuerta, President of the Chamber, E. Regan (Rapporteur), A. Arabadjiev, C.G. Fernlund and S. Rodin, Judges,

Advocate General: M. Szpunar,

Registrar: K. Malacek, Administrator,

having regard to the written procedure and further to the hearing on 17 March 2016,

after considering the observations submitted on behalf of:

— Deutsche Parkinson Vereinigung eV, by T. Diekmann, Rechtsanwalt, K. Nordlander, advokat, M. Meulenbelt, advocaat, and D. Costesec, Solicitor,

— Zentrale zur Bekämpfung unlauteren Wettbewerbs eV, by C. Dechamps, Rechtsanwalt, and J. Schwarze,

— the German Government, by T. Henze and A. Lippstreu, acting as Agents,

— the Italian Government, by G. Palmieri, acting as Agent, assisted by M. Russo, avvocato dello Stato,

— the Netherlands Government, by M. Bulterman and M. de Ree, acting as Agents,

* Language of the case: German.

— the Swedish Government, by A. Falk, C. Meyer-Seitz, U. Persson, N. Otte Widgren, E. Karlsson and L. Swedenborg, acting as Agents,

— the European Commission, by E. Manhaeve, J. Herkommer and A. Sipos, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 2 June 2016,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Articles 34 TFEU and 36 TFEU.

2 The request has been made in proceedings between Deutsche Parkinson Vereinigung eV ('DPV') and the Zentrale zur Bekämpfung unlauteren Wettbewerbs eV (Association for Protection Against Unfair Competition, 'the ZBUW') concerning the setting, in German law, of fixed prices for the sale by pharmacies of prescription-only medicinal products for human use.

German law

Law on medicinal products

3 The first sentence of Paragraph 78(1) of the Gesetz über den Verkehr mit Arzneimitteln (Arzneimittelgesetz) (Law on medicinal products) provides:

'The Federal Minister for Economics and Technology shall be authorised … to establish

1. price margins for medicinal products which are supplied for re-sale by wholesalers, pharmacies or veterinary surgeons.'

4 By the Law of 19 October 2012 (BGBl. I, p. 2192), the following sentence was added to Paragraph 78(1) of the Law on medicinal products:

'The Regulation on the pricing of medicinal products, adopted on the basis of the first sentence, shall also apply to medicinal products brought within the scope of the present Law pursuant to point 1a of the first sentence of Paragraph 73(1).'

5 Point 1a of the first sentence of Paragraph 73(1) of the Law on medicinal products, to which Paragraph 78(1) of that law refers, concerns the sale, by mail order, of medicinal products supplied in Germany to end consumers by pharmacies established in another Member State of the European Union. The Joint Chamber of the Superior Federal Courts in Germany ruled, by order of 22 August 2012, that, in the same way as the amended version of the Law on medicinal products, it was appropriate to interpret the previous wording of that law to the effect that the Arzneimittelpreisverordnung (Regulation on the pricing of medicinal products) also applies to such sales.

6 Paragraph 78(2) of the Law on medicinal products provides:

'Prices and price margins shall take account of the legitimate interests of consumers of medicinal products, veterinary surgeons, pharmacies and wholesale traders. A uniform pharmacy retail price shall be guaranteed for medicinal products that may not be sold other than through pharmacies …'

Regulation on the pricing of medicinal products

7 Paragraph 1 of the Regulation on the pricing of medicinal products provides that the manufacturer must establish a price for its medicinal product to which, under Paragraph 2 of that regulation, wholesaler additions and, under Paragraph 3 thereof, pharmacy additions must be added. That regulation does not apply to medicinal products which do not require a prescription.

Law on the advertising of medicinal products

8 It is apparent from the documents before the Court that Paragraph 7(1)(2) of the Heilmittelwerbegesetz (Law on the advertising of medicinal products) prohibits monetary advantages, such as discounts and bonuses, and promotional gifts for prescription-only medicinal products.

The facts in the main proceedings and the questions referred for a preliminary ruling

9 DPV is a self-help organisation which has as its objective to improve the lives of patients suffering from Parkinson's disease and those of their families. By letter of July 2009, promoting a cooperative venture between DPV and the Dutch mail-order pharmacy DocMorris, DPV informed its members of a bonus system under which various bonuses would be provided to members of DPV when purchasing from DocMorris prescription-only medicinal products for Parkinson's disease available only from pharmacies ('the bonus system').

10 The ZBUW takes the view, inter alia, that the bonus system infringes German legislation which provides for a system of fixed prices for the supply by pharmacies of prescription-only medicinal products.

11 According to the documents in the case file submitted to the Court, the Landgericht Düsseldorf (Regional Court, Düsseldorf, Germany) upheld the application for an injunction brought by the ZBUW and ordered DPV not to recommend the bonus system in any manner similar to that of the letter sent in July 2009. DPV appealed against the judgment of the Landgericht Düsseldorf (Regional Court, Düsseldorf) to the referring court.

12 The referring court takes the view that the bonus system infringes the relevant national legislation not only in the case where a pharmacist supplies a medicinal product at a price differing from that which must be charged under the Regulation on the pricing of medicinal products, but also in the case where, in parallel to the purchase of a medicinal product at the fixed price, the customer is afforded a benefit which makes the purchase appear more economically advantageous to him.

13 The referring court is unsure whether, in a situation such as that at issue in the present case, Paragraph 78(1) of the Law on medicinal products, in its original version and also following amendment, constitutes a restriction prohibited under Article 34 TFEU.

14 In the event that the conditions laid down by that article are satisfied, the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf, Germany) asks whether a system of fixed prices may be justified on the basis of Article 36 TFEU in order to protect the health and life of humans. According to that court, in assessing whether there is justification, the issue arises, in particular, as to whether the recent possibility for the rural population to obtain medicinal products through mail order could at least qualify the case-law of the Court in the light, inter alia, most recently, of the judgment of 13 February 2014, *Sokoll-Seebacher* (C-367/12, EU:C:2014:68).

15 The referring court takes the view that the assessment as to whether a system of fixed prices for prescription-only medicinal products alone can ensure a uniform supply to the population of prescription-only medicinal products across all parts of the country will, in all probability, be decisive in resolving the case at issue in the main proceedings. That court notes that, up to the present, the ZBUW has not made submissions addressing that issue in detail or presented evidence supporting such a line of argument. The explanatory memorandum to the national legislation at issue in the main proceedings also merely refers to the alleged risks that the fixed-price system at issue in the main proceedings seeks to counteract.

16 In that regard, the referring court also harbours doubts as to whether, as regards the possibility of a mail-order supply, it would be appropriate, where relevant, to tolerate potential threats to traditional pharmacies, particularly in rural areas.

17 To the extent that the explanatory memorandum to the Law of 19 October 2012 sets out further arguments, the referring court considers these to be insufficient, from the outset, to justify a restriction on the free movement of goods.

18 In those circumstances, the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

‘(1) Must Article 34 TFEU be interpreted as meaning that a system of fixed prices for prescription-only medicinal products laid down by national law constitutes a measure having equivalent effect within the meaning of Article 34 TFEU?

(2) If the Court answers the first question in the affirmative: is the system of fixed prices for prescription-only medicinal products justified under Article 36 TFEU on grounds of the protection of health and life of humans if that system is the only means of ensuring a consistent supply of medicinal products to the population across all parts of the country, in particular in rural areas?

(3) If the Court also answers the second question in the affirmative: what is the degree of judicial scrutiny required when determining whether the condition mentioned in the second question is in fact satisfied?’

Consideration of the questions referred

The first question

19 By its first question, the referring court asks, in essence, whether Article 34 TFEU must be interpreted as meaning that national legislation, such as that at issue in the main proceedings, which provides for a system of fixed prices for the sale by pharmacies of prescription-only medicinal products for human use, constitutes a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 34 TFEU.

20 As a preliminary matter, it should be pointed out that the free movement of goods is a fundamental principle of the FEU Treaty which is expressed in the prohibition, set out in Article 34 TFEU, of quantitative restrictions on imports between Member States and all measures having equivalent effect (judgment of 5 June 2007, *Rosengren and Others*, C-170/04, EU:C:2007:313, paragraph 31).

21 In the case in the main proceedings, it is common ground that the system of fixed prices applies both to pharmacies established in Germany and to those established in other Member States. It is thus necessary to consider whether that system may be characterised as 'a measure having equivalent effect to a quantitative restriction' for the purposes of Article 34 TFEU.

22 In that regard, it must be borne in mind that the Court has consistently held that the prohibition, laid down in Article 34 TFEU, of measures having equivalent effect to quantitative restrictions covers any measure of the Member States that is capable of hindering, directly or indirectly, actually or potentially, imports between Member States (see judgment of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraph 28 and the case-law cited).

23 The Court has also held, in relation to a prohibition under German law of mail-order sales of medicinal products the sale of which is, in the Member State concerned, restricted to pharmacies, that such a prohibition is more of an obstacle to pharmacies outside Germany than to those within Germany. Although there is little doubt that, as a result of the prohibition, pharmacies in Germany cannot use an extra or alternative method of gaining access to the German market consisting of end consumers of medicinal products, they are nonetheless able to sell the products in their dispensaries. By contrast, for pharmacies not established in Germany, the internet provides a more significant way by which to gain direct access to the German market. A prohibition which has a greater impact on pharmacies established outside German territory could impede access to the market for products from other Member States more than it impedes access for domestic products, and therefore constitutes a measure having equivalent effect to a quantitative restriction within the meaning of Article 34 TFEU (see, to that effect, judgment of 11 December 2003, *Deutscher Apothekerverband*, C-322/01, EU:C:2003:664, paragraphs 74 to 76).

24 In the present case, it must be found that, as the ZBUW and the German and Swedish Governments have each noted, 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. In so far as mail-order pharmacies cannot, given the limited services that they offer, adequately replace such services, it must be held that price competition is capable of providing a more important factor of competition for mail-order pharmacies than for traditional pharmacies, since price competition lays the basis for their potential to access the German market directly and to continue to be competitive in it.

25 Consequently, and in so far as sales by mail order constitute a more important means of accessing the German market directly for pharmacies established in Member States other than Germany, if not, given the particular characteristics of the German market evidenced in the documents in the case file submitted to the Court, potentially the only means of accessing that market directly, the national legislation at issue in the main proceedings does not affect the sale of national medicinal products in the same way as it affects the sale of medicinal products originating in other Member States.

26 In the light of the foregoing, it must be held that a system of fixed sales prices, such as that laid down in the German legislation, has a greater impact on pharmacies established in a Member State other than the Federal Republic of Germany than on those which are 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.

27 Consequently, the answer to the first question is that Article 34 TFEU must be interpreted as meaning that national legislation, such as that at issue in the main proceedings, which provides for a system of fixed prices for the sale by pharmacies of prescription-only medicinal products for human use, constitutes a measure having equivalent effect to a quantitative restriction on imports, within the meaning of that article, since that legislation has a greater impact on the sale of prescription-only medicinal products by pharmacies established in other Member States than on the sale of the same medicinal products by pharmacies established within the national territory.

The second and third questions

28 By its second and third questions, which it is appropriate to examine together, the referring court asks, in essence, whether Article 36 TFEU must be interpreted as meaning that national legislation, such as that at issue in the main proceedings, which provides for a system of fixed prices for the sale by pharmacies of prescription-only medicinal products for human use, may be justified on grounds of the protection of health and life of humans within the meaning of that article.

29 As a preliminary matter, it is appropriate to recall the settled case-law of the Court according to which Article 36 TFEU, as an exception to the rule of the free movement of goods within the European Union, must be strictly interpreted (see, to that effect, judgments of 10 January 1985, *Association des Centres distributeurs Leclerc and Thouars Distribution*, 229/83, EU:C:1985:1, paragraph 30; of 11 September 2008, *Commission* v *Germany*, C-141/07, EU:C:2008:492, paragraph 50, and of 9 December 2010, *Humanplasma*, C-421/09, EU:C:2010:760, paragraph 38).

30 As regards a national measure coming within the field of public health, the Court has on numerous occasions held that the health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved. Since that level may vary from one Member State to another, Member States should be allowed a measure of discretion (see judgment of 12 November 2015, *Visnapuu*, C-198/14, EU:C:2015:751, paragraph 118 and the case-law cited).

31 In particular, the need to ensure that the country has reliable supplies for essential medical purposes may, so far as Article 36 TFEU is concerned, justify a barrier to trade between Member States if that objective is one of protecting the health and life of humans (see judgment of 28 March 1995, *Evans Medical and Macfarlan Smith*, C-324/93, EU:C:1995:84, paragraph 37).

32 Although it is common ground, in the case in the main proceedings, that the sale by mail order of prescription-only medicinal products is no longer prohibited in Germany, the ZBUW and the German and Swedish Governments argue that a system of fixed prices which applies to the sale of such medicinal products is justified in order to ensure a safe and high-quality supply of medicinal products to the German population.

33 In particular, according to the German Government, that system seeks to ensure that mail-order pharmacies do not engage in ruinous price competition which would result in the closure of traditional pharmacies, especially in rural or underpopulated areas which are less attractive areas for traditional pharmacies to set up business. The German Government insists that such pharmacies alone are capable of ensuring safe and high-quality supplies, especially in cases of emergency, tailored advice and effective checks on the medicinal products supplied.

34 Although the objective of ensuring a safe and high-quality supply of medicinal products throughout a Member State comes, in principle, within the ambit of Article 36 TFEU, the fact remains that legislation which is capable of restricting a fundamental freedom guaranteed by the Treaty, such as the free movement of goods, can be properly justified only if it is appropriate for securing the attainment of that objective and does not go beyond what is necessary in order to attain it (see, to that effect, judgments of 9 December 2010, *Humanplasma*, C-421/09, EU:C:2010:760, paragraph 34, and of 23 December 2015, *Scotch Whisky Association and Others*, C-333/14, EU:C:2015:845, paragraph 33).

35 As the Court has previously held, it is, in each case, for the national authorities to provide the necessary evidence to that effect. The reasons which may be invoked by a Member State by way of justification must thus be accompanied by an analysis of the appropriateness and proportionality of

the measure adopted by that State, and by specific evidence substantiating its arguments (see, to that effect, judgment of 23 December 2015, *The Scotch Whisky Association and Others*, C-333/14, EU:C:2015:845, paragraph 54 and the case-law cited).

36 It follows that, where a national court examines national legislation in the light of the justification relating to protection of the health and life of humans under Article 36 TFEU, that court must examine objectively, through statistical or ad hoc data or by other means, whether it may reasonably be concluded from the evidence submitted by the Member State concerned that the means chosen are appropriate for the attainment of the objectives pursued and whether it is possible to attain those objectives by measures that are less restrictive of the free movement of goods (see, to that effect, judgment of 23 December 2015, *The Scotch Whisky Association and Others*, C-333/14, EU:C:2015:845, paragraph 59).

37 As to whether the national legislation at issue in the main proceedings is appropriate for attaining the objectives invoked, it must be stated that there is no evidence to substantiate the contention that it is necessary to ensure a uniform supply of prescription-only medicinal products for essential medical purposes throughout Germany that satisfies the conditions set out in paragraph 35 above. In particular, by the general nature of the contentions made in the present case in that regard, it has not been demonstrated, as the Advocate General has, in essence, noted in point 51 of his Opinion, how setting fixed prices for such medicinal products allows for a better geographical allocation of traditional pharmacies in Germany.

38 Quite to the contrary, certain factors on which the Commission relies tend to suggest that increased price competition between pharmacies would be conducive to a uniform supply of medicinal products by encouraging the establishment of pharmacies in regions where the scarcity of dispensaries allows for higher prices to be charged.

39 As regards the argument based on a high-quality supply of prescription-only medicinal products, it must be found that, contrary to what the German Government claims, no factor has been laid before the Court that is capable of establishing that, in the absence of a system such as that at issue in the main proceedings, mail-order pharmacies would be able to compete in terms of price in such a way that essential services, such as emergency care, could no longer be ensured in Germany due to a consequential fall in the number of dispensing pharmacies. In that regard, it must be reiterated that competition factors other than price, such as those set out in paragraph 24 above, could potentially allow traditional pharmacies, faced with competition from mail-order sales, to remain competitive in the German market.

40 Similarly, the elements laid before the Court in the present case do not suffice to show that price competition for prescription-only medicinal products would adversely affect traditional pharmacies in performing certain activities in the general interest, such as producing prescription medicinal products or maintaining a given stock and selection of medicinal products. On the contrary, as the Advocate General stated, in essence, in point 47 in his Opinion, it may be that, faced with price competition from mail-order pharmacies, traditional pharmacies will be encouraged to improve such activities.

41 Nor has the alleged relationship between the fixed sales price in the case in the main proceedings and a consequential reduction of the risk that patients might attempt to pressurise doctors in order to obtain prescriptions of convenience been established in compliance with the conditions cited in paragraph 35 above.

42 As regards the argument put forward by the ZBUW and the German Government that a patient in poor health ought not to be required to carry out a market analysis in order to determine which pharmacy offers the medicinal product sought at the most attractive price, it should be noted that the existence of a genuine risk to human health must be measured, not according to the yardstick of general conjecture, but on the basis of relevant scientific research (see, to that effect, judgment of

14 July 1994, *van der Veldt*, C-17/93, EU:C:1994:299, paragraph 17). Such general conjecture made in that regard does not in any way suffice to prove that the possibility for the consumer to seek to acquire prescription-only medicinal products at lower prices poses an actual risk to public health.

43 Moreover, the Court notes, as did DPV and the Netherlands Government, that, in the present case, price competition could be capable of benefiting the patient in so far as it would allow, where relevant, for prescription-only medicinal products to be offered in Germany at more attractive prices than those currently imposed by that Member State. As the Court has previously held, the effective protection of health and life of humans demands, inter alia, that medicinal products be sold at reasonable prices (see judgment of 20 May 1976, *de Peijper*, 104/75, EU:C:1976:67, paragraph 25).

44 Finally, it should be added that the fact that there are other national measures, such as the rule excluding non-pharmacists from the right to own and operate pharmacies, which have the objective, according to the documents before the Court, of supplying safe and high-quality prescription-only medicinal products in Germany, does not affect the Court's assessment of the fixed-price system at issue in the case in the main proceedings.

45 Having regard to all of the foregoing considerations, it must be found that a restriction such as that resulting from the legislation at issue in the main proceedings has not been shown to be an appropriate means of attaining the objectives relied on and cannot therefore be regarded as justified by the attainment of those objectives.

46 Consequently, the answer to the second and third questions referred is that Article 36 TFEU must be interpreted as meaning that national legislation, such as that at issue in the main proceedings, 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, inasmuch as that legislation is not appropriate for attaining the objectives pursued.

Costs

47 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 (First Chamber) hereby rules:

1. **Article 34 TFEU must be interpreted as meaning that national legislation, such as that at issue in the main proceedings, which provides for a system of fixed prices for the sale by pharmacies of prescription-only medicinal products for human use, constitutes a measure having equivalent effect to a quantitative restriction on imports, within the meaning of that article, since that legislation has a greater impact on the sale of prescription-only medicinal products by pharmacies established in other Member States than on the sale of the same medicinal products by pharmacies established within the national territory.**

2. **Article 36 TFEU must be interpreted as meaning that national legislation, such as that at issue in the main proceedings, 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, inasmuch as that legislation is not appropriate for attaining the objectives pursued.**

[Signatures]