JUDGMENT OF THE COURT (First Chamber)

9 December 2010 *

In Case C-421/09,

REFERENCE for a preliminary ruling under Article 234 EC from the Landesgericht für Zivilrechtssachen Wien (Austria), made by decision of 19 October 2009, received at the Court on 28 October 2009, in the proceedings

Humanplasma GmbH

v

Republik Österreich,

* Language of the case: German.

THE COURT (First Chamber),

composed of A. Tizzano, President of the Chamber, J.-J. Kasel (Rapporteur), A. Borg Barthet, M. Ilešič and M. Berger, Judges,

Advocate General: N. Jääskinen,
Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— Humanplasma GmbH, by W. Graziani-Weiss, Rechtsanwalt,

— the Austrian Government, by E. Riedl, acting as Agent,

— the German Government, by J. Möller and N. Graf Vitzthum, acting as Agents,

— the Hungarian Government, by M. Fehér, K. Szíjjártó and Z. Tóth, acting as Agents,

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

— the European Commission, by C. Cattabriga and G. Wilms, 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 Articles 28 EC and 30 EC.

2 The reference has been made in proceedings between Humanplasma GmbH ('Humanplasma'), a company established under Austrian law, and the Republik Österreich (Republic of Austria) concerning the legislative prohibition on the importation of erythrocyte concentrates provided from blood donations which were not entirely unpaid.

Legal context

European Union legislation

3 Recitals 22 and 23 in the preamble to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ 2003 L 33, p. 30), read as follows:

'(22) According to Article 152(5) of the Treaty, the provisions of this Directive cannot affect national provisions on the donations of blood. Article 152(4)(a) of the Treaty states that Member States cannot be prevented from maintaining or introducing more stringent protective measures as regards standards of quality and safety of blood and blood components.

(23) Voluntary and unpaid blood donations are a factor which can contribute to high safety standards for blood and blood components and therefore to the protection of human health. The efforts of the Council of Europe in this area should be supported and all necessary measures should be taken to encourage voluntary and unpaid donations through appropriate measures and initiatives and through ensuring that donors gain greater public recognition, thereby also increasing self-sufficiency. The definition of voluntary and unpaid donation of the Council of Europe should be taken into account.'

4 Article 4(2) of Directive 2002/98 provides:

'This Directive shall not prevent a Member State from maintaining or introducing in its territory more stringent protective measures which comply with the provisions of the Treaty.

In particular, a Member State may introduce requirements for voluntary and unpaid donations, which include the prohibition or restriction of imports of blood and blood components, to ensure a high level of health protection and to achieve the objective set out in Article 20(1), provided that the conditions of the Treaty are met.'

5 Article 20(1) of Directive 2002/98 provides:

'Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations.'

6 Article 21 of Directive 2002/98 provides:

'Blood establishments shall ensure that each donation of blood and blood components is tested in conformity with requirements listed in Annex IV.

Member States shall ensure that blood and blood components imported into the Community are tested in conformity with requirements listed in Annex IV.'

International rules

7 Under Article 2 of Recommendation No R (95) 14 of the Committee of Ministers to the Member States of the Council of Europe on the protection of health of donors and recipients in the area of blood transfusion, adopted on 12 October 1995, '[d]onation is considered voluntary and unpaid if the person gives blood, plasma or cellular components of his or her own free will and receives no payment for it, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.'

National legislation

8 Paragraph 7(1) of the Law of 2002 on medicinal imports (Arzneiwareneinfuhrgesetz 2002), in the version published in BGBl. I, 153/2005 ('the Law on medicinal imports'), provided that products covered by that law could be imported only if the authority responsible for safety in the health sector concerned had confirmed that they could be placed on the market.

9 Article 7(3) of the Law on medicinal imports laid down the precise information to be provided by, inter alia, importers of blood products at the request of the competent authorities. That information included the donor's identity, proof that the donor had been chosen in accordance with the relevant international criteria and that he was not suffering from certain viral infections.

10 Following a legislative amendment published in BGBl. I, 41/2006, a subparagraph 1a was inserted into Paragraph 7 of the Law on medicinal imports, with effect from 29 March 2006. That provision states as follows:

'When blood products are imported for direct transfusion they may in any case not be placed on the market unless the blood was donated without any payment whatsoever having been made, except in cases in which the donor was asked by the blood establishment to make an immediate donation because of an urgent need in an acute emergency. That does not apply where the importation is necessary in order to secure supplies for particularly rare blood groups.'

11 In addition, pursuant to that same amendment, a subparagraph 2a was inserted into Paragraph 7(3) of the Law on medicinal imports, which provides that the importers must in all cases establish that, with regard to 'blood products for direct transfusion, the blood was donated without any payment whatsoever having been made, or in cases in which the donor was asked by the blood establishment to make an immediate donation because of an urgent need in an acute emergency, only expenses were covered...'

12 Paragraph 8(4) of the Law of 1999 on Blood Safety (Blutsicherheitsgesetz 1999), in the version published in BGBl. I, 63/2005, provides:

'Donors of blood or of blood components or third parties may not be paid or promised payment for a donation. If the blood (whole blood) is donated for direct transfusion, it must be given without payment being made. Coverage of expenses in such cases is permitted only where a donor was asked by the blood establishment to make an immediate donation because of an urgent need in an acute emergency.'

The main proceedings and the question referred for a preliminary ruling

13 On 1 November 2005, a contract notice was published for the supply, to the Wiener Krankenanstaltenverbund (Vienna Hospital Association), of blood products, in the instant case leukocyte-depleted erythrocyte concentrates. Those erythrocyte concentrates are sold as medicines.

14 It was laid down that the period for submission of tenders would expire on 1 March 2006. The supply contract was divided into five separate lots, and tenders could be made separately for individual lots. The framework contracts put out to tender were to run for three years with the possibility of being extended once only for a further three years.

15 According to paragraph 2.2 of the contractual conditions:

'The product supplied must … comply with the Austrian Law concerning the importation of medicines (Law on medicinal imports) in the version currently applicable, … be provided from unpaid donations and be in conformity with the current state of scientific knowledge.'

16 Paragraph 6 of the special contractual provisions, headed 'Failure to supply', provides in particular:

'The contractor is obliged to guarantee supplies. Should there however be a delay in or failure to supply, the Wiener Krankenanstaltenverbund (on account of its obligation to maintain supplies) is entitled to obtain the required leukocyte-depleted erythrocyte concentrates by means not provided for under the framework contract, with the additional or consequential costs arising in that connection being borne by the contractor.'

17 Two tenderers participated in the procedure, that is to say Humanplasma and the Österreichisches Rotes Kreuz (Austrian Red Cross). It was established that Humanplasma had submitted the cheaper tender for two of the five lots.

18 In a letter accompanying its tender, Humanplasma confirmed that it had all the authorisations necessary to carry out the service in question. It therefore guaranteed that the product supplied complied with the requirements laid down in point 2.2 of the contractual conditions when it submitted its tender. It pointed out however that it could not give any warranty or guarantee with regard to the future legal position and that if, following a legislative amendment and in particular an amendment to the Law on medicinal imports, it should become impossible for it to comply with the obligation to supply the products concerned, it would not accept liability of any kind for

possible additional or consequential costs within the meaning of point 6 of the special contractual provisions.

19 According to the order for reference, since, after the end of the period for submission of tenders, the Law on medicinal imports was amended so that blood products imported for transfusion could no longer be placed on the market — subject to two special cases — unless the blood had been donated without any payment whatsoever having been made, the products offered by Humanplasma, which were not provided predominantly from such donations, were no longer in conformity with the provisions of that law.

20 When the tender was being assessed, the contracting authority requested clarification from Humanplasma whether it could nevertheless guarantee that the conditions of supply referred to in the call for tender would be met. As it could not give those guarantees, the contracting authority informed it that its tender would be excluded pursuant to the provisions of national law concerning public contracts.

21 The objection brought by Humanplasma before the Vergabekontrollsenat für Wien (Public Procurement Review Tribunal, Vienna) against the decision excluding its tender was rejected on the ground, inter alia, that, since Humanplasma could not guarantee that it could provide the services to which the conditions in the specification applied, its tender was non-compliant, for the purposes of the national provisions, and therefore could not be ruled upon. According to the Vergabekontrollsenat für Wien, the contracting authority was therefore correct to reject Humanplasma's tender.

22 In its action against that decision of the Vergabekontrollsenat für Wien, Humanplasma claimed damages from the defendant amounting to EUR 840 000, including

the refund of costs incurred, on the ground of State liability for the breach of Community law. In support of its action, it argues that Paragraph 7(1a) of the Law on medicinal imports constitutes a measure of equivalent effect to a quantitative restriction prohibited under Article 28 EC. Since it did not obtain its products predominantly from completely unpaid donations, it had been obliged to express a proviso and to assert that it might be impossible to comply with the conditions of supply. Had the Law on medicinal imports not been amended it would not have had to issue the proviso and its tender could not have been excluded from the public procurement procedure.

23 The case having been brought before it, the Landesgericht für Zivilrechtssachen Wien (Regional Civil Court, Vienna) decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Does Article 28 EC (in conjunction with Article 30 EC) preclude the application of a national provision under which the importation of erythrocyte concentrates from Germany is permitted only where the blood was donated without any payment having been made (with not even expenses being covered), that being a condition which is also applicable to the obtaining of erythrocyte concentrates within Austria?'

The question referred for a preliminary ruling

24 By its question, the referring court asks, in essence, whether Article 28 EC, read in conjunction with Article 30 EC, must be interpreted as precluding national legislation which provides that the importation of blood or blood components from another Member State is permitted only on the condition, which is also applicable to national products, that the donations of blood on which those products are based were made

without any payment being made to the donors, even in terms of the coverage of costs.

25 The free movement of goods is a fundamental principle of the EC Treaty which is expressed in the prohibition, set out in Article 28 EC, of quantitative restrictions on imports between Member States and all measures having equivalent effect (Case C-170/04 *Rosengren and Others* [2007] ECR I-4071, paragraph 31).

26 According to settled case-law, the prohibition of measures having an effect equivalent to a quantitative restriction, laid down in Article 28 EC, applies to all legislation of the Member States that is capable of hindering, directly or indirectly, actually or potentially, intra-Community trade (see, inter alia, Case 8/74 *Dassonville* [1974] ECR 837, paragraph 5; *Rosengren and Others*, paragraph 32; C-297/05 *Commission* v *Netherlands* [2007] ECR I-7467, paragraph 53; and Case C-143/06 *Ludwigs-Apotheke* [2007] ECR I-9623, paragraph 26).

27 In the present case, according to the order for reference, the national legislation at issue in the main proceedings prohibits the importation and the placing on the market, in principle, of blood and blood components obtained from donations of blood for which payment has been made, it being understood that the reimbursement of costs incurred by the donor in order to carry out the blood donation is also considered, under that legislation, as constituting payment.

28 It must be added that the prohibition of marketing in the main proceedings applies without distinction to donations of blood made on Austrian territory and blood obtained in other Member States.

29 Since, in certain other Member States, donations of blood give rise, in accordance with the provisions of Directive 2002/98, to the reimbursement of costs, blood and blood components lawfully obtained and marketed in those Member States cannot be imported and marketed in Austria.

30 Therefore, it must be held, as the Austrian Government also expressly accepts, that national legislation such as that at issue in the main proceedings is capable of hindering intra-Community trade and therefore constitutes a measure of equivalent effect to a quantitative restriction on imports within the meaning of Article 28 EC.

31 In order to determine whether that legislation constitutes a restriction which is prohibited under Article 28 EC, it must therefore also be examined whether, as inter alia the Austrian Government and the European Commission claim, it can be justified on grounds of the protection of human health.

32 In that regard, it must be noted that human health ranks foremost among the assets or interests protected by Article 30 EC and it is for the Member States, within the limits imposed by the Treaty, to decide on the degree of protection which they wish to afford to human health and on the way in which that protection is to be achieved (Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraph 103; Case C-262/02 *Commission* v *France* [2004] ECR I-6569, paragraph 24; *Rosengren and Others*, paragraph 39: and *Ludwigs-Apotheke*, paragraph 27).

33 In the present case, it is common ground that the legislation at issue in the main proceedings, which, according to the Austrian Government, has the aim, first, of

ensuring that blood and blood components marketed in Austria satisfy the criteria of high quality and safety and, second, of attaining the objective enshrined in Article 20(1) of Directive 2002/98, that is, encouraging voluntary and unpaid blood donations, addresses human health concerns such as those acknowledged in Article 30 EC. Therefore, those objectives are in principle capable of justifying a restriction on the free movement of goods.

34 However, according to the case-law, a provision 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, inter alia, Case C-14/02 *ATRAL* [2003] ECR I-4431, paragraph 64; Case C-254/05 *Commission* v *Belgium* [2007] ECR I-4269, paragraph 33; judgment of 13 March 2008 in Case C-227/06 *Commission* v *Belgium*, paragraph 61; and Case C-141/07 *Commission* v *Germany* [2008] ECR I-6935, paragraph 48).

35 With regard, first, to whether the legislation at issue in the main proceedings is appropriate, it should be noted that, according to recital 23 in the preamble to Directive 2002/98, voluntary and unpaid blood donations are a factor which can contribute to high safety standards for blood and blood components and therefore to the protection of human health.

36 In so far as legislation such as that at issue in the main proceedings precludes blood donors from obtaining any financial benefit from their donation, such legislation can meet those concerns, improve the quality and safety of blood and blood components and protect human health.

37 By contrast, it is not apparent from the observations lodged with the Court that, as claimed by the Austrian Government, legislation such as that at issue in the main proceedings, which prohibits donors from receiving any reimbursement, for example, of the travel costs incurred in attending the blood establishment nearest their home or place of work, is such as to encourage the persons concerned to donate their blood. In those circumstances, it must be held that such legislation does not make it possible to attain the second objective allegedly pursued by that national legislation.

38 With regard, second, to the assessment of whether legislation such as that at issue in the main proceedings is proportionate, it must be noted that it follows from the case-law of the Court that since Article 30 EC constitutes an exception, which is to be strictly interpreted, to the rule of the free movement of goods within the Community, it is for the national authorities to demonstrate that their rules are necessary in order to achieve the declared purpose and that that objective could not be achieved by less extensive prohibitions or restrictions, or by prohibitions or restrictions having less effect on intra-Community trade (see, to that effect, Case C-17/93 *van der Veldt* [1994] ECR I-3537, paragraph 15; Case C-189/95 *Franzén* [1997] ECR I-5909, paragraphs 75 and 76; Case C-434/04 *Ahokainen and Leppik* [2006] ECR I-9171, paragraph 31; and *Rosengren and Others*, paragraph 50).

39 Admittedly, according to the settled case-law of the Court, noted in paragraph 32 of the present judgment, when assessing whether the principle of proportionality has been observed in the field of human health, account must be taken of the fact that a Member State has the power to determine the degree of protection which it wishes to afford to human health and the way in which that degree of protection is to be achieved. Since that degree of protection may vary from one Member State to another, Member States must be allowed discretion (*Commission* v *Germany*, paragraph 51).

40 Also, the mere fact that one Member State imposes less strict rules than those applicable in another Member State does not mean that the latter's rules are incompatible with Articles 28 EC and 30 EC (see, in particular, *Commission* v *Germany*, paragraph 51).

41 However, the fact that a number of other Member States reimburse blood donors' costs may be relevant when assessing the objective justification put forward in relation to the Austrian legislation, and, particularly, concerning the assessment of its proportionality (see, in that regard, Case C-333/08 *Commission* v *France* [2010] ECR I-757, paragraph 105).

42 In that regard, it should be pointed out that, as is apparent inter alia from Article 21 of Directive 2002/98, in order to ensure the quality and safety of blood and blood components, each donation of blood must be tested in conformity with the requirements listed in Annex IV to that directive, it being understood that those requirements will evolve in line with scientific and technical progress.

43 It follows that, considered in isolation, the obligation that the blood donation must have been made without any of the costs incurred by the donor having been reimbursed is, in any case, not necessary in order to ensure the quality and safety of the blood and the blood components.

44 That conclusion is supported by the fact that, although Directive 2002/98 and Recommendation No R (95) 14, to which that directive refers, aim to improve the health of donors or recipients of blood by laying down rules and principles with which voluntary and unpaid blood donations must comply, they do not require that donations be completely unpaid but provide that small tokens, refreshments and reimbursements of travel costs connected with the donation are compatible with voluntary,

non-remunerated donation, with the result that those elements cannot be considered as liable to compromise the quality and safety of those donations or the protection of human health.

45 In the light of those considerations, it must be concluded that legislation such as that at issue in the main proceedings goes beyond what is necessary to attain the objective pursued, that is, to ensure the quality and safety of the blood and of the blood components.

46 In the light of all of the foregoing, the answer to the question referred is that Article 28 EC, read in conjunction with Article 30 EC, must be interpreted as precluding national legislation which provides that the importation of blood or blood components from another Member State is permitted only on the condition, which is also applicable to national products, that the donations of blood on which those products are based were made not only without any payment being made to the donors but also without any reimbursement of the costs incurred by them in connection with those donations.

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:

Article 28 EC, read in conjunction with Article 30 EC, must be interpreted as precluding national legislation which provides that the importation of blood or blood components from another Member State is permitted only on the condition, which is also applicable to national products, that the donations of blood on which those products are based were made not only without any payment being made to the donors but also without any reimbursement of the costs incurred by them in connection with those donations.

[Signatures]