ECLI:EU:C:2020:453

Provisional text

JUDGMENT OF THE COURT (Grand Chamber)

11 June 2020(*)

(Reference for a preliminary ruling — EU law — General principles — Article 18 TFEU — Prohibition of discrimination on grounds of nationality — Applicability of EU law — Defective breast implants — Insurance against civil liability arising from the production of medical devices — Insurance contract prescribing a geographical limitation on insurance coverage)

In Case C-581/18,

REQUEST for a preliminary ruling under Article 267 TFEU from the Oberlandesgericht Frankfurt am Main (Higher Regional Court of Frankfurt am Main, Germany), made by decision of 11 September 2018, received at the Court on 19 September 2018, in the proceedings

RB

v

TÜV Rheinland LGA Products GmbH,

Allianz IARD SA,

THE COURT (Grand Chamber),

composed of K. Lenaerts, President, R. Silva de Lapuerta, Vice-President, A. Arabadjiev, A. Prechal, M. Vilaras, M. Safjan, P.G. Xuereb and L.S. Rossi (Rapporteur), Presidents of Chambers, L. Bay Larsen, T. von Danwitz, C. Toader, F. Biltgen, K. Jürimäe, C. Lycourgos and N. Piçarra, Judges,

Advocate General: M. Bobek,

Registrar: M. Krausenböck, administrator,

having regard to the written procedure and further to the hearing on 8 October 2019,

after considering the observations submitted on behalf of:

– Allianz IARD SA, by R.-T. Wittmann, F. Witzke and D. Strotkemper, Rechtsanwälte, and by J.-M. Coste-Floret and B. Esquelisse, avocats,

– the Danish Government, by J. Nymann-Lindegren, M. Wolff and P.Z.L. Ngo, acting as Agents,

– the French Government, by R. Coesme and A. Daly, acting as Agents,

– the Finnish Government, by J. Heliskoski and S. Hartikainen, acting as Agents,

– the European Commission, by F. Erlbacher, L. Malferrari and A.C. Becker, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 6 February 2020,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of the first paragraph of Article 18 TFEU.

2 The request has been made in proceedings between, on the one hand RB, a German citizen, and, on the other, TÜV Rheinland LGA Products GmbH ('TÜV Rheinland') and the insurance company Allianz IARD SA ('Allianz'), the successor of AGF IARD SA, concerning an action seeking compensation for harm caused to the applicant in the main proceedings by the insertion of defective breast implants.

Legal context

European Union law

3 The 2nd and 18th recitals of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ 1985 L 210, p. 29) are worded as follows:

'… liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production;

…

… the harmonization resulting from this cannot be total at the present stage, but opens the way towards greater harmonization …'

4 Article 1 of Directive 85/374 provides:

'The producer shall be liable for damage caused by a defect in his product.'

5 The 3rd, 6th and 12th recitals of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1), are worded as follows:

‘… the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonized in order to guarantee the free movement of such devices within the internal market;

…

… certain medical devices are intended to administer medicinal products …; in such cases, the placing on the market of the medical devices as a general rule is governed by the present directive …

…

… in order to demonstrate conformity with the essential requirements and to enable conformity to be verified, it is desirable to have harmonized European standards to protect against the risks associated with the design, manufacture and packaging of medical devices …’

6 The first subparagraph of Article 16(1) of that directive provides:

‘The Member States shall notify the Commission and other Member States of the bodies which they have designated for carrying out the tasks pertaining to the procedures referred to in Article 11 and the specific tasks for which the bodies have been designated. The Commission shall assign identification numbers to these bodies, hereinafter referred to as “notified bodies”.’

7 Point 6 of Annex XI to that directive provides:

‘The body must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.’

8 Article 2(2)(b) of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ 2006 L 376, p. 36) provides:

‘This Directive shall not apply to the following activities:

…

(b) financial services, such as banking, credit, insurance and re-insurance, occupational or personal pensions, securities, investment funds, payment and investment advice, including the services listed in Annex I to Directive 2006/48/EC’.

French law

9 The code de la santé publique, tel que modifié par la loi n° 2002-1577 du 30 décembre 2002 relative à la responsabilité civile médicale (the Public Health Code, as amended by the Law No 2002-1577 of 30 December 2002 on medical civil liability) (JORF of 31 December 2002), contains provisions relating to compensation for the consequences of health risks incurred by individuals through the operation of the health system. In that regard, Article L. 1142-2 of that code provides:

‘Health professionals in private practice, health establishments, health services and bodies referred to in Article L. 1142-1 and all other legal entities, other than the State, carrying out preventive, diagnostic or healthcare activities, as well as the producers, operators and suppliers of healthcare

products, in their finished state, referred to in Article L. 5311-1 with the exception of point 5°, subject to the provisions of Article L. 1222-9 and of points 11°, 14° and 15°, used in those activities, shall be obliged to hold insurance intended to cover them for their third-party or administrative liability which may be incurred as a result of harm suffered by third parties arising from personal injury occurring in the context of that activity.

…

The insurance contracts taken out in accordance with the first paragraph may provide that their cover is capped. The conditions governing how the amount of cover may be capped for health professionals in private practice shall be fixed by Decree adopted in the Conseil d'État [(Council of State)].

The insurance of establishments, services and bodies mentioned in the first paragraph shall cover their employees while performing the tasks conferred on them, even if those employees have autonomy in the practice of medicine.

…

In the event of failure to comply with the insurance obligation laid down in the present article, the competent disciplinary body may order disciplinary sanctions.'

10 Article L. 252-1 of the code des assurances, tel que modifié par la loi n° 2002-303, du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé (the Insurance Code, as amended by Law No 2002-303 of 4 March 2002 on the rights of patients and the quality of the health system) (JORF of 5 March 2002), provides:

'Any person subject to the insurance obligation laid down in Article L. 1142-2 of the Public Health Code who, having attempted to take out an insurance contract with an insurance company in France covering the third-party risks referred to in that article, has twice been refused cover, may bring a claim before a bureau central de tarification [(Central Pricing Office; 'BCT')], the establishment criteria and operating rules of which shall be laid down by decree adopted in the [(Council of State].

The [BCT] shall have the exclusive role of setting the amount of the premium at which the insurance company concerned is bound to insure the risk proposed to it. It may, on conditions laid down by decree of the Council of State, determine the amount of the excess which shall fall to be paid by the insured party.

The [BCT] shall advise the State representative of the department when a person subject to the insurance obligation under Article L. 1142-2 of the Public Health Code constitutes an abnormally high insurance risk. It shall inform the professional involved thereof. In that case, it shall set the amount of the premium for a contract the duration of which may not exceed six months.

Any reinsurance contract clause which seeks to exclude certain risks of the reinsurance guarantee as a result of the amount of the premium set by the [BCT] shall be null and void.'

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

11 On 30 October 2006, in Germany, the applicant in the main proceedings had breast implants inserted which were manufactured by Poly Implant Prothèses SA ('PIP'), a company established in France, and marketed by the Dutch undertaking Rofil Medical Netherlands BV.

12 As from October 1997 PIP commissioned TÜV Rheinland , as a ‘notified body’, within the meaning of Directive 93/42, to undertake the assessment, in accordance with Annex II to that directive, of the quality system put in place for the design, manufacture and final inspection of the breast implants that it was producing and the examination of the design dossier of those implants. Between 1997 and 2010 TÜV Rheinland carried out a number of inspections at the premises of PIP, all announced in advance. Following those inspections, TÜV Rheinland approved the quality system and renewed the CE examination certification, provided for in Annex II to that directive, guaranteeing the conformity of those implants with the requirements of that directive.

13 PIP had taken out an insurance contract with the company AGF IARD, the predecessor of Allianz, that contract covering its civil liability arising from the manufacture of those products. The conclusion of that insurance contract had been imposed in 2005 by the Bureau central de tarification (France) (‘the BCT’), the competent national authority in this area. Following rejection by various insurance companies approached by PIP, the BCT had ordered AGF IARD, by decision of 28 June 2005, to issue to PIP an insurance policy for a duration of one year, that term being extended several times.

14 It is apparent from the information available to the Court that that insurance contract had been concluded on the basis of a proposal made to the BCT by AGF IARD and that it included a clause limiting the geographical extent of the insurance coverage to harm that occurred in metropolitan France or in the ‘départements et territoires français d’outre-mer’ (‘French overseas territories’). In accordance with French law, that contract granted to the injured parties a direct right of action against the insurer.

15 In March 2010 the Agence française de sécurité sanitaire des produits de santé (the French agency for the safety of healthcare products) found, in the course of an inspection, that the breast implants manufactured by PIP were filled with unauthorised industrial silicone. Accordingly, on 1 April 2010 the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for medicinal products and medical devices, Germany) recommended to doctors who had inserted such implants that they should (i) notify the patients concerned and (ii) no longer use those implants.

16 PIP was declared insolvent in 2010. That company was then liquidated in 2011.

17 On 6 January 2012, because of the risk of the premature rupture of the implants manufactured by PIP and the inflammatory effects of the silicone used, the Federal Institute for medicinal products and medical devices advised the patients concerned to take steps, as a precaution, to remove those implants.

18 In 2012 the applicant in the main proceedings accordingly had the implants at issue replaced by new implants.

19 In December 2013 the head of PIP was convicted and sentenced by a French court to four years imprisonment for the manufacture and distribution of products that were dangerous to health.

20 The applicant in the main proceedings brought before the Landgericht Frankfurt am Main (Regional of Frankfurt am Main, Germany) an action for damages imputing joint and several liability to the doctor who had inserted her defective breast implants, TÜV Rheinland and Allianz.

21 In that action, the applicant in the main proceedings claimed, first, that the doctor had not given her sufficient information on the risks entailed by the procedure itself and by the nature of the implants to be inserted. Second, she claimed that TÜV Rheinland had not properly carried out the

necessary checks or annual inspections. She considered, in particular, that TÜV Rheinland should have made unannounced visits to the premises of PIP in order to check the latter's stocks, which would have made it possible to identify significant differences between the quantity of industrial silicone improperly used, on the one hand, and the quantity of silicone required for the manufacture of breast implants, on the other. Third, she claimed that she has, under French law, a direct right of action against Allianz, even though the insurance contract contains a clause limiting the insurance coverage to harm that has occurred in metropolitan France or in the French overseas territories, since that clause is contrary to EU law.

22 TÜV Rheinland contended that it was not obliged to make unannounced visits. It argued that, because of the organised system of deception and concealment established by PIP, it could not have suspected the fraud committed. For its part, Allianz maintained that it could not be required to be a party to proceedings, since the insurance contracts linking it to PIP covered exclusively harm that occurred in French territory.

23 The action at first instance having been dismissed by a judgment of 21 December 2016, the applicant in the main proceedings brought an appeal before the Oberlandesgericht Frankfurt am Main (Higher Regional Court of Frankfurt am Main, Germany).

24 That court is uncertain, in essence, whether the clause limiting insurance cover to harm that occurred in metropolitan France or in the French overseas territories, as stipulated in the insurance contract entered into by PIP and Allianz, is compatible with the prohibition of any discrimination on grounds of nationality, laid down in the first paragraph of Article 18 TFEU. The referring court states, however, that the Court has not yet given an explicit ruling on whether that provision has direct horizontal effect, in the sense that it could be relied upon in a dispute between individuals. In that regard, the referring court considers that, in the light of the relevant case-law of the Court, that question may be answered in the affirmative.

25 Further, if it is the case that the first paragraph of Article 18 TFEU is not applicable to relationships between individuals, the referring court is uncertain whether that provision precludes a clause limiting insurance coverage to harm that has occurred in metropolitan France or in the French overseas territories, having regard, in particular, to the fact that the BCT clearly did not challenge the clause concerned.

26 Last, if the opposite is true, the referring court wonders on what conditions the indirect discrimination which stems, in its view, from that clause can be justified, and wonders whether the insurer can dispute the claim of the applicant in the main proceedings on the ground that the maximum insurance cover has already been reached with respect to coverage of claims made in metropolitan France or in the French overseas territories.

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

'(1) Is the prohibition of discrimination under the first paragraph of Article 18 TFEU directed not only at the EU Member States and the Union institutions, but also at private parties (direct third-party effect of the first paragraph of Article 18 TFEU?

(2) If the first question is answered in the negative and the first paragraph of Article 18 TFEU is not applicable to relations between private parties: is the first paragraph of Article 18 TFEU to be interpreted as meaning that this provision precludes restricting cover to cases of damage occurring

in metropolitan France and the French overseas territories because the competent French authority, the [BCT], did not object to the clause concerned, even though that clause is contrary to the first paragraph of Article 18 TFEU because it involves indirect discrimination on the basis of nationality?

(3) If the first question is answered in the affirmative: under what conditions can indirect discrimination be justified in cases of relations between individuals? In particular: can a territorial restriction of insurance cover to cases of damage occurring within a certain EU Member State be justified by the argument that the insurance company took on an indemnity obligation of a limited scope for a set premium if the relevant insurance contracts at issue moreover provide, in the event of multiple claims, for a monetary cover limit per damage claim and for a monetary cover limit per insurance year?

(4) If the first question is answered in the affirmative: is the first paragraph of Article 18 TFEU to be interpreted as meaning that if, contrary to the first paragraph of Article 18 TFEU, the insurer has only met claims in cases of damage occurring in metropolitan France and the French overseas territories, it is prohibited from objecting that payment could not take place because the maximum cover limit was already reached, where the damage occurred outside of those territories?'

Consideration of the questions referred

The first question

28 By its first question, the referring court seeks, in essence, to ascertain whether the prohibition of discrimination on grounds of nationality, laid down in the first paragraph of Article 18 TFEU, has direct horizontal effects, so that that provision can be relied upon in the case of relations between individuals.

29 It must, first, be determined whether the first paragraph of Article 18 TFEU is applicable to the main proceedings.

30 The first paragraph of Article 18 TFEU states that within the scope of application of the Treaties, and without prejudice to any special provisions contained therein, any discrimination on grounds of nationality is to be prohibited.

31 In accordance with settled case-law, that provision is intended to apply independently only to situations governed by EU law in respect of which the Treaties lay down no specific rules on non-discrimination (judgment of 18 June 2019, *Austria* v *Germany*, C-591/17, EU:C:2019:504, paragraph 39 and the case-law cited). The application of the first paragraph of Article 18 TFEU is accordingly subject to two cumulative conditions being satisfied.

32 Under the first condition, the situation that has given rise to the discrimination claimed must fall within the scope of application of EU law.

33 Under the second condition, there must be no specific rule laid down by the Treaties prohibiting discrimination on grounds of nationality that is applicable to that situation. As the Court has stated, national measures can be examined having regard to the first paragraph of Article 18 TFEU only to the extent that they apply to situations which do not fall within the scope of specific rules on non-discrimination laid down by the FEU Treaty (see judgment of 18 June 2019, *Austria* v *Germany*, C-591/17, EU:C:2019:504, paragraph 41).

34 In this instance, it must be stated that the dispute in the main proceedings concerns an insurance contract, entered into by Allianz and the manufacturer of breast implants, PIP, which contained a clause limiting the geographical extent of the insurance coverage against civil liability, arising from the manufacture of those implants, to harm that occurred in metropolitan France or in French overseas territories. The referring court is uncertain, in that context, as to the compatibility of that clause with the first paragraph of Article 18 TFEU, in that, since that clause fails to provide that that insurance coverage extends to harm that has occurred throughout the European Union, that would amount to indirect discrimination on grounds of nationality, which is prohibited, as a general rule, by that provision.

35 In the light of the considerations set out in paragraphs 30 to 34 of the present judgment, the first paragraph of Article 18 TFEU can apply to that dispute only where (i) that dispute relates to a situation which falls within the scope of application of EU law and (ii) that situation does not fall within the scope of a specific rule on non-discrimination laid down by the FEU Treaty.

36 In order to determine whether the first condition is satisfied in this instance, it is necessary to examine, in the first place, whether that situation has been the subject of regulation under EU law.

37 In that regard, it is clear that there is not, in EU secondary law, any provision which imposes an obligation on the manufacturer of medical devices to take out civil liability insurance designed to cover risks linked to those devices or which regulates, in one way or another, such insurance.

38 In particular, Directive 93/42, the aim of which, in accordance with its third recital, is to harmonise the national provisions for the safety and health protection of patients and users of medical devices in order to guarantee the free movement of those devices within the internal market, contains no provision of the kind mentioned in the preceding paragraph.

39 That directive, as is apparent from its 6th and 12th recitals, regulates the marketing of medical devices and establishes harmonised European standards to protect against risks associated with the design, manufacture and packaging of medical devices.

40 Within that framework, point 6 of Annex XI to that directive imposes an obligation solely on the ‘notified body’, within the meaning of the first subparagraph of Article 16(1) of that directive, which is responsible for carrying out inspections in relation to the design and manufacture of medical devices, to take out civil liability insurance, unless that liability is assumed by the State under domestic legislation or the inspections required of notified bodies, under that directive, are carried out by the Member State itself. However, no obligation to take out insurance is imposed on the manufacturer of such devices.

41 Likewise, Directive 85/374, which establishes the principle that a producer is liable without fault on his part for damage caused by the defectiveness of his products, does not impose any obligation on the manufacturer of such products to take out civil liability insurance against any harm that may be linked to those products, and it does not regulate that insurance in any other way.

42 Directive 85/374, as follows from its 18th recital, does not seek exhaustively to harmonise the sphere of liability for defective products beyond the matters regulated by that directive (judgment of 21 June 2017, *W and Others*, C-621/15, EU:C:2017:484, paragraph 21 and the case-law cited).

43 It must be added that, under Article 2(2)(b) of Directive 2006/123, that directive does not apply to financial services such as insurance. Consequently, that directive cannot be applicable in a case such as that in the main proceedings.

44 It follows that, as EU law currently stands, insurance covering the civil liability of manufacturers of medical devices with respect to harm linked to those devices is not the subject of regulation by EU law, unlike, for example, the area of civil liability insurance in respect of the use of motor vehicles, which is regulated by Directive 2009/103/EC of the European Parliament and of the Council of 16 September 2009 relating to insurance against civil liability in respect of the use of motor vehicles, and the enforcement of the obligation to insure against such liability (OJ 2009 L 263, p. 11), which imposes an obligation on each Member State to take the appropriate measures to ensure that an insurance contract also covers harm caused on the territory of other Member States.

45 That said, it is necessary, in the second place, to determine whether the situation giving rise to the discrimination claimed in the present case falls within the scope of a fundamental freedom laid down by the FEU Treaty.

46 According to the Court's case-law, it is the exercise of one of those freedoms that brings the situation in which that freedom is exercised within the scope of the Treaties, within the meaning of the first paragraph of Article 18 TFEU. It is also necessary that there be a specific connecting factor linking the person, service or goods concerned and the alleged discrimination. Such a connection is particularly evident when the person who has suffered the alleged discrimination is a person who has moved within the European Union (see, to that effect, judgments of 2 February 1989, *Cowan*, 186/87, EU:C:1989:47, paragraph 20, and of 13 June 2019, *TopFit and Biffi*, C-22/18, EU:C:2019:497, paragraphs 29 and 30) or where discrimination is the direct result of the national rules applicable to goods from other Member States (see, to that effect, judgment of 20 October 1993, *Phil Collins and Others*, C-92/92 and C-326/92, EU:C:1993:847, paragraphs 22, 23 and 27).

47 In this case, it is accordingly necessary to examine whether there is a particular connecting factor linking the specific situation that gives rise to the alleged discrimination and the provisions of the FEU treaty on the various freedoms of movement, particularly those relating to the free movement of persons, the free movement of goods or the freedom to provide services.

48 As regards, first, the free movement of Union citizens, the Court has held that the situation of a Union citizen who has made use of his or her freedom of movement falls within the scope of Article 18 TFEU (judgments of 13 November 2018 *Raugevicius*, C-247/17, EU:C:2018:898, paragraph 27, and of 13 June 2019, *TopFit and Biffi*, C-22/18, EU:C:2019:497, paragraph 29).

49 However, it is clear that the applicant in the main proceedings, a German citizen who seeks the payment of insurance compensation for harm caused by the insertion of breast implants in Germany, the Member State in which she resides, has not made use of her freedom of movement. Consequently, there is no specific connecting factor linking the situation at issue in the main proceedings and the freedom of movement of Union citizens.

50 Further, as regards the freedom to provide services, laid down in Article 56 TFEU, it must be recalled, first, that, as stated by the Advocate General in point 82 of his Opinion, that freedom also includes the freedom of recipients of services to travel to another Member State in order to receive a service there and that persons receiving medical treatment can be regarded as recipients of services (judgment of 31 January 1984, *Luisi and Carbone*, 286/82 and 26/83, EU:C:1984:35, paragraph 16). However, it is undisputed that the applicant in the main proceedings received medical treatment in Germany, that is, in her Member State of residence, and not in another Member State.

51 Second, the freedom to provide insurance services corresponds to the freedom of insurers to offer their services to buyers of insurance established in other Member States and, conversely, the freedom of persons seeking an insurance contract to contact an insurer established in another Member State (see, to that effect, judgments of 28 April 1998, *Safir*, C-118/96, EU:C:1998:170, paragraphs 22, 26 and 30; of 3 October 2002, *Danner*, C-136/00, EU:C:2002:558, paragraph 31; and of 26 June 2003, *Skandia and Ramstedt*, C-422/01, EU:C:2003:380, paragraphs 27 and 28).

52 However, the insurance contract at issue in the main proceedings, which is intended to cover the civil liability of the manufacturer of the breast implants concerned with respect to the harm associated with those implants, was entered into by PIP, a manufacturer of prostheses established in France, on the one hand, and the insurance company AGF IARD, also established in France, on the other. The conclusion of that contract does not therefore fall within the scope of the exercise of the freedom to provide services.

53 As regards the fact that the applicant in the main proceedings resides in Germany, it must be noted that she is not a party to that contract. That fact alone cannot therefore permit a finding that the situation at issue in the main proceedings falls within the scope of the freedom to provide insurance services.

54 In those circumstances, the situation at issue in the main proceedings is not linked by any specific connecting factor to the freedom to provide services laid down in Article 56 TFEU.

55 Last, as regards the free movement of goods, laid down in Article 34 TFEU, it is not disputed that the cross-border movement of the breast implants at issue in the main proceedings was not affected by any discriminatory obstacle. On the contrary, those products, which were manufactured in France, were subsequently marketed in the Netherlands by a Dutch company which thereafter sold them in Germany.

56 In that context, the dispute in the main proceedings relates not to the cross-border movement of goods in itself, but to the harm caused by the goods that have been so moved. That dispute concerns the issue whether it is possible, for a person such as the applicant in the main proceedings, to obtain, due to the harm resulting from the insertion of defective breast implants, compensation from an insurance company that entered into a contract with the manufacturer of those implants covering the risks associated with the use of those implants in metropolitan France or in the French overseas territories. It must be added that civil liability insurance taken out in those terms does not affect the marketing in another Member State of the products the risks from which that insurance is intended to cover, or their movement within the European Union. Since there is no effect on trade in goods and services within the European Union, the situation at issue in the main proceedings is not, therefore, comparable to the situation at issue in the case that gave rise to the judgment of 20 October 1993, *Phil Collins and Others* (C-92/92 and C-326/92, EU:C:1993:847, paragraphs 22 and 23).

57 Consequently, the situation at issue in the main proceedings is not linked by any specific connecting factor to the provisions of the FEU Treaty on the free movement of goods.

58 It follows from paragraphs 36 to 57 of the present judgment that that situation does not fall within the scope of application of EU law, within the meaning of the first paragraph of Article 18 TFEU.

59 The first condition laid down in the first paragraph of Article 18 TFEU is therefore not satisfied in this instance, and consequently, taking into consideration the circumstances of the main

proceedings, that provision must be held not to apply to those proceedings, there being no need to examine whether there is a specific rule on non-discrimination laid down by the FEU Treaty applicable to those proceedings and whether that provision can be relied on in relations between individuals.

60 Consequently, the answer to the first question is that the first paragraph of Article 18 TFEU must be interpreted as meaning that it is not applicable to a clause, stipulated in a contract concluded between an insurance company and a manufacturer of medical devices, limiting the geographical extent of the insurance coverage against civil liability arising from those devices to harm that has occurred in the territory of a single Member State, since such a situation does not fall, as EU law currently stands, within the scope of application of EU law.

The second, third and fourth questions

61 In view of the answer given to the first question, there is no need to examine the other questions.

Costs

62 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 (Grand Chamber) hereby rules:

The first paragraph of Article 18 TFEU must be interpreted as meaning that it is not applicable to a clause, stipulated in a contract concluded between an insurance company and a manufacturer of medical devices, limiting the geographical extent of the insurance coverage against civil liability arising from those devices to harm that has occurred in the territory of a single Member State, since such a situation does not fall, as EU law currently stands, within the scope of application of EU law.

[Signatures]

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* Language of the case: German.