Court of Justice of the European Union
PRESS RELEASE No 69/20
Luxembourg,11 June 2020

Press and Information

Judgment in Case C-581/18
RB v TÜV Rheinland LGA Products GmbH and Allianz IARD SA

The general prohibition of discrimination on grounds of nationality cannot be the basis for challenging a clause, contained in a contract concluded between a manufacturer of medical devices and an insurance company, that places a territorial limit on civil liability insurance coverage

In the judgment TÜV Rheinland LGA Products and Allianz IARD (C-581/18), delivered on 11 June 2020, the Grand Chamber of the Court held that the general prohibition of discrimination on grounds of nationality[1] is not applicable to a clause, stipulated in a contract 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.

In 2006 a German citizen had inserted in Germany, where she is resident, breast implants manufactured by Poly Implant Prothèses SA ('PIP'), a company established in France. Since 1997 PIP had commissioned TÜV Rheinland LGA Products GmbH ('TÜV Rheinland'), in accordance with Directive 93/42 concerning medical devices[2] to undertake an assessment of the quality system put in place for the design, manufacture and final inspection of the breast implants that PIP was producing. Following a number of inspections at the premises of PIP, TÜV Rheinland had approved the quality system and renewed the CE examination certification guaranteeing the conformity of those implants with the requirements of that directive.

Further, PIP had taken out with the company AGF IARD SA, the predecessor of Allianz IARD SA ('Allianz'), an insurance contract covering its civil liability arising from the manufacture of those implants. That contract included a clause limiting the geographical extent of the insurance coverage to harm that occurred in metropolitan France or in the French overseas territories.

In 2010 the Agence française de sécurité sanitaire des produits de santé (the French agency for the safety of healthcare products) found that the breast implants manufactured by PIP were filled with unauthorised industrial silicone. PIP was liquidated in 2011. Further, in 2012 the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for medicinal products and medical devices, Germany) advised the patients concerned to take steps, as a precaution, to remove the implants manufactured by PIP, because of the risk of their premature rupture and the inflammatory effects of the silicone used.

The patient concerned brought, before the German court with jurisdiction, an action for damages imputing joint and several liability to the doctor who had inserted the defective breast implants, TÜV Rheinland and Allianz. She claimed, inter alia, 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 France, since that clause is contrary to EU law. The action at first instance having been dismissed, she brought an appeal before the Oberlandesgericht Frankfurt am Main (Higher Regional Court of Frankfurt am Main, Germany); that court is uncertain

[1] Laid down in the first paragraph of Article 18 TFEU.
[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1).

as to the compatibility of that clause with the prohibition of any discrimination on grounds of nationality, laid down in the first paragraph of Article 18 TFEU, and has referred to the Court a number of questions for a preliminary ruling on that point.

The Court examined, first, whether the first paragraph of Article 18 TFEU is applicable to the present case. The Court stated, in that regard, that, in accordance with settled case-law, the application of that provision is subject to two cumulative conditions being satisfied: (i) the situation that has given rise to the discrimination claimed must fall within the scope of application of EU law and (ii) there must be no specific rule laid down by the Treaties prohibiting discrimination on grounds of nationality that is applicable to that situation.

In order to determine whether the first condition was satisfied in this instance, the Court examined, in the first place, whether the situation in the main proceedings has been the subject of regulation under EU law. The Court observed that there is not, in EU secondary law (including Directives 93/42 and 85/374[3]), 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 such insurance. The Court concluded 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.

In the second place, the Court determined whether the situation at issue falls within the scope of a fundamental freedom laid down by the FEU Treaty, by reason of the existence of a specific connecting factor linking that situation and such a freedom, a link which would bring that situation within the scope of application of the Treaties, within the meaning of the first paragraph of Article 18 TFEU.

As regards, first, the free movement of EU citizens, the Court observed that the patient concerned did not make use of her freedom of movement, since she seeks payment of insurance compensation for harm caused by the insertion of breast implants in Germany, the Member State in which she resides, so that there is no specific connecting factor linking the situation at issue in the main proceedings and that freedom. Second, as regards the freedom to provide services, the Court noted that the situation at issue again has no specific connecting factor linking it to that freedom, since, in the first place, the patient concerned received medical treatment in the Member State where she resides and, in the second place, the insurance contract concerned was concluded between two companies established in one and the same Member State, in this instance France. Last, as regards the free movement of goods, the Court observed that the dispute in the main proceedings relates not to the cross-border movement of goods in itself, since the cross-border movement of the breast implants concerned was not affected by any discriminatory obstacle, but to the harm caused by the goods so moved. Consequently, the situation at issue again has no specific connecting factor linking it to free movement of goods.

The Court accordingly concluded 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, and consequently that provision must be held not to apply to the present case.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

Press contact: Jacques René Zammit ☎ (+352) 4303 3355

[3] 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).