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Press and Information

Advocate General's Opinion in Case C-581/18
RB v TÜV Rheinland LGA Products and Allianz IARD

Advocate General Bobek: The civil liability insurance of breast implant producer PIP could validly be limited to women who underwent surgery in France

EU law as it currently stands does not oppose the limitation to the French territory of insurance against civil liability for the use of medical devices

In 2006, a German patient received defective breast implants in Germany that were manufactured by Poly Implant Prothèse SA ('PIP'), a French undertaking that is now insolvent. Instead of medical silicone, the implants were filled with unauthorised industrial silicone. The patient seeks compensation before the German courts from the French insurance company Allianz IARD, with whom PIP had taken out civil liability insurance, which is compulsory in France. However, the insurance contract contains a territorial clause limiting the cover to damage caused in France only.[1] Thus, PIP implants that were exported to another Member State and used there are not covered by the insurance contract.

In that context, the Oberlandesgericht Frankfurt am Main (Higher Regional Court, Frankfurt am Main, Germany) enquires whether the fact that PIP was only insured by Allianz for harm caused by its implants in France is compatible with the principle of non-discrimination on grounds of nationality (Article 18 TFEU).

In today's opinion, Advocate General Michal Bobek acknowledges that **the present case falls within the scope of EU law**. In particular, the medical devices that allegedly caused harm to the patient in question had been put on the market across the EU. Thus, the damage was, in a way, a consequence of intra-Union trade in goods. The fact that the patient had not exercised free movement is immaterial for the purposes of determining the scope of EU law.

Advocate General Bobek begins by examining which provisions of EU law might apply to the case. He notes that **EU secondary legislation does not contain specific provisions regarding insurance against civil liability for harm caused to end users of medical devices**. Although Directive 85/374 on product liability[2] establishes a strict regime of liability for producers, it is silent on compulsory insurance. For its part, Directive 93/42 on medical devices[3] only requires notified bodies to take out civil liability insurance. That obligation does not apply to manufacturers.

According to the Advocate General, **the free movement rules** catch national provisions that hinder the entry or exit of goods to or from a given Member State. However, they **do not regulate the subsequent use or consumption of goods once they have moved to a different Member State.** While such goods are moving freely on the territory of another Member State, they must comply with the rules of that Member State within the exercise of its regulatory autonomy. The fact that, in this case, the insurance does not 'travel' to Germany with the goods, even if it is compulsory in France for subsequent use of those goods in France, is not covered by the free movement of goods provisions.

[1] The contract further provided that, in the event of serial damage, the maximum cover amount per case of damage is €3 000 000 and the maximum cover amount per insurance year is €10 000 000.
[2] Council Directive 85/374/ECC 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).
[3] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1).

Turning to **Article 18 TFEU**, Advocate General Bobek explains why that article **cannot be construed as a free-standing provision, producing enforceable obligations not already contained in any of the four freedoms or specifically provided for in any other EU law measure.** In particular, such a construction would turn Article 18 TFEU into a limitless harmonising provision, with the consequence of upsetting the division of competences between the EU and the Member States. The starting principle for the regulation of the internal market is respect for **regulatory diversity in matters not explicitly harmonised by EU law**.

According to the Advocate General, in today's interconnected world, sooner or later, there is inevitably some sort of interaction with goods, services or persons from other Member States. The fact that goods once came from another Member State is not a sufficient reason to suggest that any matter later concerning those goods is covered by EU law. If that were enough to trigger the independent applicability of Article 18 TFEU, every single rule in a Member State would be caught by that provision.

Such a consequence would not only displace any territoriality in the application of laws, but would also generate conflicts of regulatory regimes between the Member States. An expansionist interpretation of Article 18 TFEU could make the legislation of any of the Member States potentially applicable on the same territory without any clear and objective criteria as to which legislation should prevail in a given dispute, with the victim being able to choose the most favourable legislation.

Thus, **in the absence of harmonisation, it is for the Member States to regulate insurance policies applicable to medical devices used on their territory, even when those devices are imported from another Member State**.[4] **France could legitimately choose to introduce a higher level of protection of patients and users of medical devices through more favourable insurance policies applying on its territory.**

NOTE: The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.

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.

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[4] The Advocate General recalls in this context the *Schmitt* case, which concerned liability of notified bodies vis-à-vis patients who had received defective breast implants. The Court held that it is for national law to decide on the conditions of such liability (Judgment of 16 February 2017, C-219/15 Schmitt; see also press release No 14/17).