Reports of Cases

OPINION OF ADVOCATE GENERAL
BOBEK
delivered on 6 February 2020 [1]

Case C-581/18

RB
v
TÜV Rheinland LGA Products GmbH,
Allianz IARD SA

(Request for a preliminary ruling from the Oberlandesgericht Frankfurt am Main (Higher Regional Court, Frankfurt am Main, Germany))

(Reference for a preliminary ruling — Medical devices — Defective breast implants — Insurance against civil liability for the use of medical devices — Territorial limitation — Purely internal situations — Article 18 TFEU — Applicability of EU law)

I. Introduction

1. A German patient received, in Germany, defective breast implants manufactured by Poly Implant Prothèse SA ('PIP'), a French undertaking that is now insolvent. The patient seeks compensation before the German courts from Allianz IARD SA, the French insurer of PIP. In France, manufacturers of medical devices are under a statutory obligation to be insured against civil liability for harm suffered by third parties arising from their activities. That obligation led PIP to conclude an insurance contract with Allianz, which contained a territorial clause limiting the cover to damage caused on French territory only. Thus, PIP medical devices that were exported to another Member State and used there were not covered by the insurance contract.

2. In this context, the Oberlandesgericht Frankfurt am Main (Higher Regional Court, Frankfurt am Main, Germany) enquires whether the fact that PIP was insured by Allianz for damage caused by its medical devices on French territory only, to the exclusion of that potentially caused in other Member States, is compatible with Article 18 TFEU and the principle of non-discrimination on grounds of nationality contained therein.

1 Original language: English.

II. Legal framework

A. EU law

3. Article 18, first paragraph, TFEU provides that:

'Within the scope of application of the Treaties, and without prejudice to any special provisions contained therein, any discrimination on grounds of nationality shall be prohibited.'

4. Pursuant to Article 34 TFEU:

'Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.'

5. According to Article 35 TFEU:

'Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States.'

6. Article 56, first paragraph, TFEU reads as follows:

'Within the framework of the provisions set out below, restrictions on freedom to provide services within the Union shall be prohibited in respect of nationals of Member States who are established in a Member State other than that of the person for whom the services are intended.'

B. French law

7. Article L.1142-2 of the Code de la santé publique (Public Health Code)[2] provides that:

'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 required 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 as a whole.

The Minister responsible for health may, by decree, grant a derogation from the insurance obligation laid down in the first paragraph to public health establishments which have available financial resources sufficient to enable them to compensate for harm in a manner equivalent to that resulting from an insurance contract.

The insurance contracts taken out in accordance with the first paragraph may provide that their guarantees are capped …

…

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.'

2 As amended by Law No 2002-1577 of 30 December 2002.

8. Pursuant to Article L.252-1 of the Code des assurances (Insurance Code):[3]

'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; 'the BCT')], the establishment criteria and operating rules of which shall be laid down by decree adopted in the Conseil d'État [(Council of State)].

The Central Pricing Office shall have the exclusive role of setting the amount of the premium at which the insurance company concerned is bound to guarantee 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 Central Pricing Office 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 Central Pricing Office shall be null and void.'

III. Facts, procedure and the questions referred

9. PIP was a manufacturer of breast implants established in France. The Dutch undertaking Rofil Medical Nederland BV ('Rofil') marketed those implants. It packaged them and provided them with a package insert. TÜV Rheinland LGA Products GmbH ('TÜV Rheinland'), in its capacity as a 'notified body' within the meaning of Directive 93/42/EEC,[4] had been commissioned by PIP since October 1997 to carry out the conformity assessment in accordance with German, European and other international standards. To that end, TÜV Rheinland performed several supervisory audits of PIP between 1997 and 2010.

10. In autumn 2006, the appellant in the main proceedings underwent surgery in Germany, during which she received breast implants marketed by Rofil. It was subsequently confirmed that instead of the 'NuSil' material described in the product documents and specified and approved in the scope of the marketing authorisation, those implants were filled with unauthorised industrial silicone.

11. In March 2010, the French health authorities first discovered, during an inspection, that PIP was unlawfully using industrial silicone. In April 2010, the German authorities recommended that doctors who had used PIP silicone implants should inform the patients concerned and discontinue use of those breast implants. In 2012, the complete removal of those implants was recommended.

12. PIP became insolvent and was liquidated in 2011. In December 2013, the founder of the undertaking was sentenced to four years' imprisonment by a French court for manufacturing and selling products that were dangerous to health.

13. The appellant brought an action before the German courts against the doctor who performed the surgery, against TÜV Rheinland, and against Allianz.

3 Created by Law No 2002-303 of 4 March 2002.

4 Council Directive of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1).

14. She argued that she had a direct claim against Allianz under French law. According to Article L.1142-2 of the Public Health Code, manufacturers of medical devices are under an obligation to conclude an insurance contract with an insurance company ('the insurance obligation'). That insurance against civil liability grants a direct claim (Direktanspruch) against the insurance company to third parties who have suffered harm.

15. Pursuant to Article L.252-1 of the Insurance Code, any person subject to the insurance obligation 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 the BCT. The BCT shall then set the amount of the premium at which the insurance company concerned is bound to guarantee the risk proposed to it.

16. In 2005, the BCT obliged AGF IARD, the predecessor of Allianz, to provide PIP with insurance cover. The BCT set the amount of the insurance premium in the light of PIP's turnover on French territory. In the special contractual terms of the insurance contract, under the heading 'Geographic scope', it was agreed that the cover exclusively applies to cases of damage occurring in metropolitan France and the French Overseas Territories ('the territorial limitation'). The BCT did not object to the territorial limitation. It was furthermore provided that, in the event of serial damages, the maximum cover amount per case of damage is EUR 3 000 000 and the maximum cover amount per insurance year is EUR 10 000 000.

17. The appellant's action was rejected by the first-instance court. She filed an appeal against that judgment before the Oberlandesgericht Frankfurt am Main (Higher Regional Court, Frankfurt am Main), the referring court, with regard to the findings in the first-instance judgment concerning TÜV Rheinland and Allianz, but not as far as the liability of the doctor who performed the operation is concerned. Before the referring court, the appellant seeks the annulment of the judgment in respect of TÜV Rheinland and Allianz. She also requests that TÜV Rheinland and Allianz be ordered to pay her damages.

18. According to the appellant, the first-instance court erred in law in holding that the territorial limitation of insurance cover to the French territory was lawful and by ruling out any infringement of the free movement of goods.

19. The questions posed by the referring court to this Court concern only the potential liability of Allianz. The referring court questions the compatibility of the territorial limitation at issue with Article 18 TFEU. According to that court, there is a cross-border aspect to the territorial limitation that materialises when harm occurs outside France. Article 18, first paragraph, TFEU is applicable because the specific prohibitions of discrimination laid down in other provisions of the TFEU do not apply to the case at hand. The territorial limitation is indirectly discriminatory on grounds of nationality because it usually affects foreign patients, as much as a residence condition would. In addition, Article 18, first paragraph, TFEU can be relied on in disputes between private parties. The BCT could also be reproached for its failure to object to the territorial limitation.

20. It is within this factual and legal context that the Oberlandesgericht Frankfurt am Main (Higher Regional Court, Frankfurt am Main) decided to stay the proceedings and refer the following questions to the Court of Justice for a preliminary ruling:

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

(2) If the first question should be answered in the negative and [Article 18, first paragraph, TFEU] is not applicable to relations between private parties: Is [Article 18, first paragraph, 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 corresponding clause, even though that clause is contrary to [Article 18, first paragraph, TFEU] because it involves indirect discrimination on the basis of nationality?

(3) If the first question should be answered in the affirmative: Under what conditions can indirect discrimination be justified in cases of third-party effect? In particular: Can territorial restriction of insurance cover to cases of damage occurring within a certain EU Member State be justified with the argument of restriction of the liability obligation of the insurance company and the premium level if the relevant insurance policies at the same time provide that, in the event of serial damages, the cover per case of damage and the cover per insurance year are limited in terms of amount?

(4) If the first question is to be answered in the affirmative: Is [Article 18, first paragraph, TFEU] to be interpreted as meaning that if, contrary to [Article 18, first paragraph, TFEU], the insurer has only settled 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 amount was already reached, if the case of damage occurred outside of those territories?'

21. Written submissions were lodged by Allianz ('the respondent'), the Danish and Finnish Governments and the European Commission. The respondent, the French Government and the Commission participated at the hearing that took place on 8 October 2019.

IV. Assessment

22. The referring court asks four questions focused on the legal *consequences* that would flow from an infringement of Article 18 TFEU in the circumstances of the present case. By Questions 1 and 2, the referring court seeks to know whether Article 18 TFEU can be directly relied on *horizontally* by the appellant against Allianz or *vertically* (or, rather, diagonally) against the French Republic, inasmuch as the BCT, as an emanation of the State, did not oppose the territorial limitation of the insurance cover. Questions 3 and 4 concern the precise reach of Article 18 TFEU in a case such as the present one, where the contract at issue provides, in addition to the territorial limitation, for the capping of the maximum cover (per case of damage and per insurance year).

23. All four questions share an unspoken assumption, namely that the territorial limitation at issue is not only within the scope of EU law, but also discriminatory on grounds of nationality and contrary to Article 18 TFEU.

24. However, before engaging in a discussion of the consequences of an infringement, it is necessary to take a step back, or rather two steps back, in the reasoning process, and to ascertain whether there was in fact an infringement in the first place. What specific obligation or provision of EU law was infringed by allowing for such a territorial limitation of insurance cover for potentially defective medical devices? To address that question, it is first necessary to examine (i) whether the case falls within the scope of EU law, that is, whether the Court has jurisdiction to answer the referring court's questions, and, in the affirmative, (ii) what provision of EU law could lead to a finding of (in)compatibility in relation to the territorial limitation at issue.

25. I acknowledge that (i) and (ii) tend not to be examined separately in the case-law of the Court. That is understandable in view of the fact that, once a concrete obligation under EU law has been identified under (ii), it follows that (i) is satisfied, without it needing to be specifically addressed. The present case is, however, somewhat unusual. While, in the light of the traditionally rather generous case-law on fundamental freedoms, the case at hand appears to fall within the scope of EU law (A), there is a distinct difficulty in identifying a provision of EU law that would preclude the territorial limitation of the insurance obligation (B).

A. Within the scope of EU law?

26. The respondent and the French Government consider that the case at hand is outside the scope of EU law. According to the respondent, from the point of view of a German patient who underwent surgery in Germany, the present case is a purely internal situation. The Commission seems to come to the same conclusion regarding the applicability of Article 18 TFEU in particular. By contrast, the Finnish Government is of the view that, although the insurance at issue in the present case is not specifically governed by EU law, the situation at hand falls within the scope of EU law. That is because the situation is linked to the cross-border movement of goods and provision of services and because EU secondary law regulates both medical devices and liability for defective products.

27. I largely share the position of the Finnish Government. In my view, despite the uncertainty regarding the applicability *in concreto* of Article 18 TFEU — or any other provision of EU law — it is simply impossible, in view of the established case-law of this Court, to state that the situation in the present case falls outside the scope of EU law for the purposes of the Court's jurisdiction.

28. For the jurisdiction of the Court to be triggered, there needs to be a sufficiently clear and direct link between the case at hand and one of the fundamental freedoms (free movement of goods, persons, services or capital) (1) and/or there must be a potentially applicable provision of (secondary) EU law in need of interpretation for the case at hand (2).

(1) Fundamental freedoms and free movement

29. Within the context of the fundamental freedoms, the applicability of EU law depends on the concrete factual circumstances of the dispute: an actual cross-border element is necessary to trigger the application of EU law. Otherwise, the situation is normally deemed 'purely internal'.[5] EU law on the fundamental freedoms should not apply to a situation that is confined in all respects within a single Member State.[6] Legislation of a Member State, which applies without distinction to nationals of that State and to nationals of other Member States, 'may generally fall within the scope of the provisions on the fundamental freedoms established by the Treaty only to the extent that it applies to *situations related to intra-[EU] trade*'.[7]

30. It is true that over the years the case-law on the provisions on the fundamental freedoms further expanded their scope of application. The case-law began to cover not only real (in the sense of already materialised) obstacles, but also *dissuasion* or the rendering of the exercise of the freedoms less attractive.[8] Equally, mere cross-border *potentiality* is sufficient, which does not necessarily have to be

5 See, for example, the early judgment of 28 March 1979, *Saunders* (175/78, EU:C:1979:88, paragraph 11).

6 See, for example, judgment of 30 June 2016, *Admiral Casinos & Entertainment* (C-464/15, EU:C:2016:500, paragraph 21).

7 See, for example, judgments of 11 September 2003, *Anomar and Others* (C-6/01, EU:C:2003:446, paragraph 39 and the case-law cited); of 19 July 2012, *Garkalns* (C-470/11, EU:C:2012:505, paragraph 21); and of 11 June 2015, *Berlington Hungary and Others* (C-98/14, EU:C:2015:386, paragraph 24). My emphasis.

8 See, for example, judgment of 30 November 1995, *Gebhard* (C-55/94, EU:C:1995:411, paragraph 37 and the case-law cited).

established in the individual case.[9] Cross-border potentiality remains at the level of a reasonably conceivable hypothesis: thus, in the context of services, the fact that, for example, some recipients of a service are likely to come from another Member State is enough to engage the rules of the Treaty on services.[10]

31. Those types of cases naturally raise the issue of how far the logic of potentiality can be stretched, so that any and all issues relating, for example, to goods or persons might ultimately be covered by EU law. For goods, the answer was given in the judgment in *Keck*.[11] For the other freedoms, the answer is perhaps still outstanding,[12] but one thing is clear: the discussion is normally focused on evaluating the (in)compatibility of Member State measures with EU law, that is, within the jurisdiction of the Court. It does not often happen that the Court finds that it lacks jurisdiction if there is a reasonably conceivable (and not entirely hypothetical)[13] cross-border element to the case concerning any of the four freedoms.

32. Recently, in *Ullens de Schooten*,[14] the Court consolidated its case-law on the absence of a cross-border situation (a purely internal situation), which results in the case not coming within the scope of EU law. That judgment restated that, irrespective of any *actual* cross-border element, a given situation falls within the scope of EU law, first, when 'it [is] not inconceivable that nationals established in other Member States had been or were interested in making use of those freedoms for carrying on activities in the territory of the Member State that had enacted the national legislation in question'; second, when 'the decision of the referring court that will be adopted following the Court's preliminary ruling will also have effects on the nationals of other Member States'; third, 'where national law requires the referring court to grant the same rights to a national of its own Member State as those which a national of another Member State in the same situation would derive from EU law'; and fourth, when 'the provisions of EU law have been made applicable by national legislation, which, in dealing with situations confined in all respects within a single Member State, follows the same approach as that provided for by EU law'.[15]

33. It is nonetheless clear that the scenarios captured by *Ullens de Schooten* do not exhaust all the situations that can come within the scope of EU law.[16] That case was only concerned with allegations of cross-border potentiality for the purposes of invoking the free movement rules of the Treaty in the context of a claim of State liability for an infringement of EU law. Thus, the Court provided a reply with regard to the Treaty provisions invoked.

34. The other situation that typically comes within the scope of EU law is where, even in the absence of any cross-border element, a provision of EU law regulates the area in question.

9 See, for example, to that effect, judgments of 10 May 1995, *Alpine Investments* (C-384/93, EU:C:1995:126, paragraphs 23 to 28); of 15 December 1995, *Bosman* (C-415/93, EU:C:1995:463, paragraphs 88 to 91); of 9 September 2004, *Carbonati Apuani* (C-72/03, EU:C:2004:506, paragraphs 22 to 26); and of 10 February 2009, *Commission* v *Italy* (C-110/05, EU:C:2009:66, paragraph 58).

10 See, for example, judgment of 11 June 2015, *Berlington Hungary and Others* (C-98/14, EU:C:2015:386, paragraph 27); or, for a similar logic in the context of free movement of workers, see recently, for example, judgment of 10 October 2019, *Krah* (C-703/17, EU:C:2019:850, paragraphs 42 to 54).

11 Judgment of 24 November 1993, *Keck and Mithouard* (C-267/91 and C-268/91, EU:C:1993:905).

12 For a critical view, see, in the context of workers, my Opinion in *Krah* (C-703/17, EU:C:2019:450) and, for establishment, that in *Hornbach-Baumarkt* (C-382/16, EU:C:2017:974).

13 See, to that effect, in the context of services, order of 4 June 2019, *Pólus Vegas* (C-665/18, not published, EU:C:2019:477, paragraphs 16 to 24).

14 Judgment of 15 November 2016 (C-268/15, EU:C:2016:874).

15 Ibid., paragraphs 50 to 53 (with the references to the various strands of case-law that the judgment brought together).

16 See, for critical views on *Ullens de Schooten* and, more broadly, the category of 'purely internal situations', for example, Dubout, É., 'Voyage en eaux troubles: vers une épuration des situations "purement" internes? CJUE, gde ch., 15 novembre 2016, Ullens de Schooten, aff. C-268/15, ECLI:EU:C:2016:874', *Revue des affaires européennes*, 4, 2016, p. 679; and Iglesias Sánchez, S., 'Purely Internal Situations and the Limits of EU Law: A Consolidated Case-Law or a Notion to be Abandoned?', *European Constitutional Law Review*, Vol. 14, 2018, Issue 1, p. 7.

(2) An EU (secondary) law (harmonising) measure?

35. Is there a provision of EU law (typically a harmonising provision of secondary law) that might be applicable to the case at hand and that might require interpretation? Does the provision of EU law cover the legal area within which the dispute in the main proceedings is unfolding? Is there a legal rule in that provision that could be construed as relating to the situation in the main proceedings? If so, then the case is likely to fall within the scope of EU law for the purposes of the interpretation of that provision.

36. That scenario is largely independent of the existence of any cross-border element. A number of harmonising measures of secondary EU law are applicable to purely internal situations, despite their Treaty basis being provisions relating to free movement and the establishment of the internal market.[17] It is therefore immaterial, for the purposes of the jurisdiction of the Court, whether the situation is *factuall*y purely internal, that is, if all the facts are confined within a single Member State.

37. In the absence of any actual or potential cross-border element, a connecting factor sufficient to trigger EU law is the existence of relevant, *potentially applicable* legal rules laid down in (secondary) EU law that do not make any distinction between activities having a foreign aspect and activities that have no such aspect.[18] Thus, unless the scope of the measure is expressly limited to situations having a cross-border dimension, the existence of harmonising measures and the need to interpret them in relation to the case at hand may constitute a sufficient link to trigger the application of EU law.[19]

38. In my view, for a matter to fall within the scope of EU law, it is sufficient that there are rules of secondary EU law governing *generally* the subject matter or issues in question. It is therefore not necessary, at the stage of ascertaining the Court's jurisdiction, to have clearly and unequivocally identified a *specific* rule or obligation under EU law that applies to the case.

39. A recent example coming from a different area of EU law might illustrate the point. The judgment in *Moro*[20] concerned the question whether EU law opposes a provision of Italian law providing that it is not possible to apply for a negotiated penalty following a confession of the culprit made once the trial proceedings had begun. That question arose as a matter of interpretation of Directive 2012/13/EU, on the right to information in criminal proceedings,[21] in particular Article 6 (right to information about the accusation). There was little doubt that, in general, the directive could apply *ratione materiae* to that type of situation. Whether that directive created any *specific* obligations for the Member States in the *specific* context of the main proceedings was then a matter for the discussion of the merits of the case, as opposed to admissibility or the jurisdiction of the Court.[22]

40. In my Opinion in *Moro*,[23] I also sought to highlight the somewhat peculiar consequence which would follow from not clearly distinguishing between the scope of EU law (and the jurisdiction of the Court) and the discussion on the identification of a specific obligation flowing from its provisions (the assessment of an issue on the merits) in similar types of cases. If those two issues were allowed to collapse into one, then all of the discussion of the merits of the case would take place during the assessment of the Court's jurisdiction.

17 See, for example, judgment of 20 May 2003, *Österreichischer Rundfunk and Others* (C-465/00, C-138/01 and C-139/01, EU:C:2003:294, paragraph 41 and the case-law cited), as well as judgment of 6 November 2003, *Lindqvist* (C-101/01, EU:C:2003:596, paragraphs 40 and 41).

18 See, for example, to that effect, judgment of 30 January 2018, *X and Visser* (C-360/15 and C-31/16, EU:C:2018:44, paragraphs 98 to 110).

19 See, to that effect, judgment of 13 June 2019, *Moro* (C-646/17, EU:C:2019:489, paragraphs 29 to 37).

20 Judgment of 13 June 2019 (C-646/17, EU:C:2019:489).

21 Directive of the European Parliament and of the Council (OJ 2012 L 142, p. 1).

22 Judgment of 13 June 2019, *Moro* (C-646/17, EU:C:2019:489, paragraphs 29 to 37).

23 C-646/17, EU:C:2019:95, points 29 and 76 to 81, including footnote 29.

41. To sum up, the Court declines jurisdiction where the situation at issue is, in all respects, confined within a single Member State,[24] or where it is obvious that no provision of EU law, especially those referred to the Court for interpretation, is capable of applying.[25] Although those two situations might sometimes overlap in an individual case (for example, where there is an EU secondary law instrument regulating a cross-border situation), it is worth noting, in conclusion, that the logic underpinning them differs. The existence of a cross-border element (and the absence of a purely internal situation) is a *circumstantial* assessment relating to the facts of each case. By contrast, the (non-)existence of an EU harmonising measure is a *normative* assessment of a given legal area: are there EU law measures that are potentially applicable to the case at hand?

(3) The present case

42. Assessed in the light of the considerations just outlined, the present case finds itself within the scope of EU law on at least three accounts: (i) a cross-border element in the context of free movement of goods and its consequence in terms of liability; (ii) the potentiality with regard to freedom to receive (insurance) services from another Member State; and, (iii) the normative subject matter of the case, namely manufacturers' liability for defective products and medical devices as goods in the internal market, which are both partially harmonised by secondary EU law.

43. First, the medical devices that allegedly caused harm to the appellant had been put on the market across the European Union: they were produced in France, and then marketed in the Netherlands by a Dutch undertaking, which eventually sold them in Germany. Certainly, the questions posed by the referring court relate, in one way or another, to *subsequent* damage that those apparently defective goods have caused within one Member State to a resident of that Member State. However, it can hardly be denied that the damage was, in a way, a consequence of intra-Union trade in goods. Equally, the questions posed by the referring court specifically enquire about the scope of the liability of a manufacturer resident in another Member State and the involvement of public authorities in the liability and compulsory insurance regime.

44. Second, just as there was undeniably free movement between the Member States upstream (since the goods that caused the damage have been moved), there is also the alleged potential cross-border element downstream. If the territorial clause were indeed considered incompatible with EU law, the appellant located in Germany could, hypothetically, seek compensation from the respondent located in France, thus seeking access to cross-border insurance as the injured party.[26] Although I must admit that I consider this connecting factor, in contrast to the first one, rather tenuous, it is also fair to say that in its previous free movement case-law, the Court took a rather generous approach to the inclusion of remote scenarios within the scope of the four freedoms.

24 See, by analogy, judgment of 1 April 2008, *Government of the French Community and Walloon Government* (C-212/06, EU:C:2008:178, paragraph 33 and the case-law cited).

25 See, to that effect, judgment of 30 June 2016, *Admiral Casinos & Entertainment* (C-464/15, EU:C:2016:500, paragraphs 19 to 22 and the case-law cited).

26 In the written submissions and at the oral hearing, there was some discussion about the fact that the appellant is neither the insurer nor the insured, thus not really a party to the insurance contract and therefore not involved in any insurance services. I think that this argument is not entirely convincing, since insurance matters, whatever their dogmatic construction, always concern by definition more parties than just the insurer and the insured, such as (or in particular) the injured party or the beneficiary or policyholder (if different persons) — see, by analogy, for example, Article 13 of Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (OJ 2012 L 351, p. 1).

45. Third, the subject matter of the present case touches upon matters that have been the object of some harmonisation, including liability for defective goods or medical devices. Directive 85/374/EEC [27] established the principle of liability without fault on the part of the producers of defective products. For its part, Directive 93/42 harmonised national provisions on the safety and health protection of patients and users of medical devices. That directive governs the placing on the market of those devices and sets standards to protect against the risks associated with the design, manufacture and packaging of medical devices.

46. Do any of the provisions of those secondary law instruments cover (or could they, read alone or together, be interpreted as covering) the issue of insurance against civil liability for the use of medical devices by patients? It might be recalled that the assessment, *for the purposes of the assessment of the Court's jurisdiction*, concerns the subject matter covered by the instruments in question, in particular their scope of application *ratione materiae*, when compared with the subject matter of the dispute. In contrast, the existence or absence of specific obligations is a matter for the interpretation of those instruments. [28]

47. As a consequence, it must be concluded that the Court has jurisdiction to address the present request for a preliminary ruling.

48. That conclusion remains unaffected by the fact, repeatedly stressed by the respondent and by the French Government, that the appellant, who seeks the benefit of the insurance attached to the breast implants at issue in France, has not herself exercised free movement. She is a German national who received breast implants in Germany. There was therefore neither free movement *of persons* (the appellant has not moved), nor free movement *of (medical) services* (the operation was carried out in Germany on a German resident).

49. Far from rebutting the jurisdiction of the Court already established on the account of the three elements listed above, those arguments are symptomatic of a different problem present in this case. In its order for reference, the referring court relies solely on Article 18 TFEU, without explicitly identifying which other provision of EU primary or secondary law might have been infringed by the territorial restriction of the insurance. Thus, in a way, it is left to the imagination as to which of the specific freedoms (goods, services or persons) could potentially apply, and in which specific constellation, with different parties in fact presenting arguments relating to different fundamental freedoms. That in turn prompts the real question of this case: does any specific provision of EU law in fact preclude such a territorial restriction? If not, can Article 18 TFEU, in and of itself, represent such a provision?

B. Which specific provision of EU law?

50. By its questions, the referring court invokes only Article 18 TFEU. Under that provision, 'within the scope of application of the Treaties, and without prejudice to any special provisions contained therein, any discrimination on grounds of nationality shall be prohibited'. According to settled case-law, Article 18 TFEU, which enshrines the general principle of non-discrimination on grounds of nationality, is intended 'to apply independently *only* to situations governed by EU law in respect of which the Treaty lays down no specific prohibition of discrimination'. [29]

27 Council Directive 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).

28 Above, points 35 to 40.

29 See, for example, judgments of 18 July 2017, *Erzberger* (C-566/15, EU:C:2017:562, paragraph 25 and the case-law cited); of 26 October 2017, *I* (C-195/16, EU:C:2017:815, paragraph 70); and of 18 June 2019, *Austria* v *Germany* (C-591/17, EU:C:2019:504, paragraph 39). My emphasis.

51. Thus, the role of Article 18 TFEU is a residual one. As Advocate General Jacobs once put it, the function of that provision is 'to close any gaps left by the more specific provisions of the Treaty'.[30] Article 18 TFEU applies only when no specific provision (*lex specialis*) prohibiting discrimination on grounds of nationality is applicable.

52. Beyond such a gap-closing, residual function, is there an independent role for Article 18 TFEU? Since Article 18 TFEU is defined *in relation* to other provisions ('without prejudice to any special provisions contained [in the Treaties]'), it is necessary to look into other potentially relevant EU law provisions that contain specific prohibitions of discrimination on grounds of nationality, even without the referring court having explicitly raised them,[31] before turning to Article 18 TFEU.[32] When selecting the potentially relevant fundamental freedoms, the Court does not make a decision in the abstract, but in view of the case before it.[33]

53. Therefore, before turning to the scope of Article 18 TFEU as a free-standing provision (4), I shall first explore whether there are any specific provisions of secondary law that are relevant (1), the implications and reach of the free movement of goods rules in the present case (2), and the possibility of patients who suffered harm in other Member States receiving insurance services (3).

1. Secondary law: product liability and medical devices

54. Under Article 1 of Directive 85/374 on product liability, 'the producer shall be liable for damage caused by a defect in his product'. Where a defective product causes damage to a consumer, the producer may be liable even without negligence or fault. Although Directive 85/374 establishes a strict (or objective) regime of liability for producers, it is silent on compulsory insurance. Thus, as has already been confirmed with regard to other matters that could potentially flow from that directive, but are not explicitly provided for therein, the directive does not seek to harmonise the sphere of liability for defective products beyond the matters expressly regulated by it.[34]

55. As far as the provisions of Directive 93/42 on medical devices are concerned, Section 6 of Annex XI to that directive only requires notified bodies to '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'. That provision was interpreted by the Court in *Schmitt*,[35] where the Court held that under EU law as it currently stands, it is for the Member States to set out the conditions under which culpable failure on the part of a notified body to fulfil its obligations under the procedure relating to the EC declaration of conformity laid down by Directive 93/42 may give rise to liability on its part vis-à-vis the end users of medical devices.

30 Opinion of Advocate General Jacobs in Joined Cases *Phil Collins and Others* (C-92/92 and C-326/92, EU:C:1993:276, point 12).

31 Which, even irrespective of the special context of the construction of Article 18 TFEU, would not in fact be an issue — see, for example, judgment of 29 October 2015, *Nagy* (C-583/14, EU:C:2015:737, paragraph 20).

32 See, to that effect, judgment of 14 July 1994, *Peralta* (C-379/92, EU:C:1994:296, paragraph 18).

33 See to that effect, for example, judgments of 22 June 1999, *ED* (C-412/97, EU:C:1999:324, paragraphs 13 to 14), and of 21 June 2016, *New Valmar* (C-15/15, EU:C:2016:464, paragraph 31).

34 Judgments of 20 November 2014, *Novo Nordisk Pharma* (C-310/13, EU:C:2014:2385, paragraph 24 and the case-law cited), and of 21 June 2017, *W and Others* (C-621/15, EU:C:2017:484, paragraph 21).

35 Judgment of 16 February 2017 (C-219/15, EU:C:2017:128, paragraphs 56 and 59).

56. That position has apparently not changed much with the recent legislation in the form of Regulation (EU) 2017/745 on medical devices.[36] Although of course not applicable *ratione temporis* to the case at hand, it might still be worth noting that, even though it was adopted in the wake of the PIP scandal,[37] the further requirements in that regulation concern the notified body's liability only.[38] It remains silent on the insurance obligations of manufacturers. Under Article 10(16) of Regulation 2017/745, manufacturers are only required 'to have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law'. That provision further states that 'natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law'.

57. Although Article 10(16) could perhaps be interpreted, at a stretch, as potentially also including insurance against civil liability, there are other means of making sure that the manufacturer has available 'sufficient financial coverage in respect of their potential liability' than an insurance obligation. Moreover, the reference in Article 10(16) to national law makes clear that the EU legislature did not intend to provide for one harmonised solution in that regard, such as compulsory insurance against civil liability to be taken out by all manufacturers of medical devices.

58. Thus, none of those directives contain specific provisions regarding insurance against civil liability for harm caused to end users of medical devices, which is the specific issue raised by the present case. Unlike, for instance, in the motor insurance sector,[39] where an insurance obligation for vehicles covering the entire territory of the European Union was laid down, it was manifestly not the intention of the EU legislature to harmonise the Member States' legislation regarding insurance against civil liability arising out of the use of medical devices. Therefore, since that issue was intentionally left unregulated by secondary EU law, the case at hand is to be examined in the light of *primary* EU law.[40]

2. Free movement of goods

59. In the free movement case-law, the Court has not hesitated to characterise national measures as restrictions to free movement falling within the scope of Article 34 TFEU[41] (or Article 35 TFEU). However, even with that expansionist approach towards identifying rules that might impede the free flow of goods between the Member States (1), I still find it impossible to qualify a national rule of the Member State of origin, or *home* Member State (in this case France), that does not concern the movement of goods in any conventional sense but the *conditions of subsequent use*, as a measure impeding the free movement of those goods (2).

36 Regulation of the European Parliament and of the Council of 5 April 2017, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42 (OJ 2017 L 117, p. 1).

37 See the Commission proposal for a Regulation on medical devices (COM(2012) 0542 final). See also the European Parliament resolution of 14 June 2012 on defective silicone gel breast implants made by French company PIP (2012/2621(RSP)).

38 Point 1.4.2. of Annex VII to Regulation 2017/745 reads: 'The scope and overall financial value of the liability insurance shall correspond to the level and geographic scope of activities of the notified body and be commensurate with the risk profile of the devices certified by the notified body.'

39 Articles 3 and 6 of 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 civil liability (OJ 2009 L 263, p. 11).

40 See to that effect, for example, judgments of 11 July 2002, *Carpenter* (C-60/00, EU:C:2002:434, paragraph 36); of 10 July 2014, *Commission* v *Belgium* (C-421/12, EU:C:2014:2064, paragraph 63 and the case-law cited); and of 14 July 2016, *Promoimpresa and Others* (C-458/14 and C-67/15, EU:C:2016:558, paragraphs 59 to 62).

41 Beginning with the sweeping scope of 'all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade …'. Judgment of 11 July 1974, *Dassonville* (8/74, EU:C:1974:82, paragraph 5).

(1) Exit, entry and access: the free flow of goods in the European Union

60. With regard to *barriers to exit*, which will typically concern *home* Member State rules, according to the Court, a national measure applicable to all traders active in the national territory whose actual effect is greater on goods leaving the market of the exporting Member State than on the marketing of goods in the domestic market of that Member State is covered by the prohibition laid down by Article 35 TFEU. [42]

61. As far as *barriers to entry* are concerned, which are typically erected by the rules of the *host* Member State, Article 34 TFEU catches a wide range of measures ranging from discriminatory obstacles, [43] to physical barriers to trade [44] and product requirements (such as those relating to designation, form, size, weight, composition, presentation, labelling or packaging), even if those requirements apply to all products alike and are not intended to regulate trade in goods between Member States. [45]

62. The most recent restatement of the latter line of case-law came in *Commission* v *Italy* and *Mickelsson and Roos*, [46] with regard to national measures on the use of products in the host Member State. The Court stated that apart from measures having the object or effect of treating products coming from other Member States less favourably, any other measures that hinder access of products originating in other Member States to the market of a Member State are also covered by Article 34 TFEU, since 'the restriction which they impose on the use of a product in the territory of a Member State may, depending on its scope, have a considerable influence on the behaviour of consumers, which may, in turn, affect the access of that product to the market of that Member State'. [47]

63. Identifying the common thread in the Court's rich free movement of goods case-law is no easy task. [48] However, for the purpose of the present case, three elements are worth highlighting.

64. First, the free movement of goods concerns cross-border flows and rules that prevent exit or entry. It is the mobility or the free flow of goods that is thus at issue, typically as regards the ability of the goods to penetrate the market of the host Member State. Articles 34 and 35 TFEU catch national provisions that hinder the *entry* or the *exit* of a product.

65. However, the free movement rules are not there to regulate the *subsequent use* or consumption of the goods in the host Member State. Thus, once goods have exited one Member State and entered another, 'cross-border movement' has occurred. While those goods are moving freely on the territory of the host Member State, they must comply with the rules of that Member State within the exercise of its regulatory autonomy.

42 See for example, to that effect, judgments of 16 December 2008, *Gysbrechts and Santurel Inter* (C-205/07, EU:C:2008:730, paragraphs 40 to 43), and of 21 June 2016, *New Valmar* (C-15/15, EU:C:2016:464, paragraph 36).

43 See, for example, judgment of 24 November 1982, *Commission* v *Ireland* (249/81, EU:C:1982:402, paragraphs 28 to 29).

44 For example, the requirement for a certificate of authenticity issued by the exporting Member State, as early as the judgment of 11 July 1974, *Dassonville* (8/74, EU:C:1974:82).

45 See, for example, judgment of 14 February 2008, *Dynamic Medien* (C-244/06, EU:C:2008:85, paragraph 27 and the case-law cited).

46 Judgment of 10 February 2009, *Commission* v *Italy* (C-110/05, EU:C:2009:66), which concerned a prohibition on using a motorcycle and a trailer together in Italy; and judgment of 4 June 2009, *Mickelsson and Roos* (C-142/05, EU:C:2009:336), which concerned Swedish legislation limiting the use of personal watercraft in Sweden.

47 Judgment of 10 February 2009, *Commission* v *Italy* (C-110/05, EU:C:2009:66, paragraphs 37 and 56), and judgment of 4 June 2009, *Mickelsson and Roos* (C-142/05, EU:C:2009:336, paragraphs 24 and 26).

48 See, for example, Barnard, C., 'Fitting the Remaining Pieces into the Goods and Persons Jigsaw?' *European Law Review*, Vol. 26, 2001, p. 35; Snell, J., 'The Notion of Market Access: A Concept or A Slogan?', *Common Market Law Review* Vol. 47, 2010, p. 437; Ritleng, D., 'L'accès au marché est-il *le* critère de l'entrave aux libertés de circulation?', in Dubout, É., Maitrot de la Motte, A., (eds), *L'unité des libertés de circulation. In varietate concordia*, Coll. Droit de l'Union européenne, Bruylant, Brussels, 2013, pp. 159-183; Nic Shuibhne, N., *The Coherence of EU Free Movement Law*, Studies in European Law, Oxford University Press, Oxford, 2013, pp. 210-256.

66. Second, it is fair to admit that although the rules on the free movement of goods are not designed to regulate subsequent use in the host Member State, there is a degree of overreach. The free movement of goods case-law clearly touches on certain conditions of use, consumption, or other applicable national rules of the *host* Member State. But I would still suggest that those instances of overreach should only and properly concern either total bans on certain activities or practices that (almost) entirely prevent the use and commercialisation of certain products or their effective access to the market. [49]

67. Third, precisely in order to limit such undesirable overreach, there was the judgment in *Keck*, [50] as well as the limitation of the reach of Articles 34 and 35 TFEU by the requirement of proximity.

68. On the one hand, the Court limited the reach of Article 34 TFEU by excluding certain selling arrangements from its scope. Under the *Keck* line of case-law, [51] national provisions restricting or prohibiting selling arrangements are *not* liable to hinder intra-EU trade, so long as they apply to all relevant traders operating within the national territory *and* so long as they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States.

69. On the other hand, the Court limits the reach of Articles 34 and 35 TFEU with a test of remoteness. It is settled case-law that those articles do not cover a measure that applies without distinction and whose purpose is not to regulate trade in goods with other Member States, and the restrictive effects of which on the free movement of goods are too uncertain and indirect for the obligation which it lays down to be regarded as being of a nature to hinder trade between Member States. [52]

70. Although presented under different headings, *Keck* and the requirement of proximity (or the absence of remoteness) share the same logic: they exclude from the reach of Article 34 TFEU in particular all national rules that do not concern either the movement of goods or immediately subsequent or correlating steps having a clear impact on access, thus hindering access itself.

(2) Absence of insurance cover and 'considerable influence on the behaviour of consumers'

71. With that analytical framework in mind, it appears that the rules on the free movement of goods do not provide a basis for attempting to compensate for the absence of rules in the *host* Member State on compulsory insurance against civil liability of manufacturers of medical devices by, in effect, importing such rules that exist in the *home* Member State from which the goods have moved.

72. That conclusion is further underlined by two particular features of the present case.

49 Well-known examples in this category being a total ban on advertising of alcoholic beverages, judgment of 8 March 2001, *Gourmet International Products* (C-405/98, EU:C:2001:135, paragraphs 21 and 25), or the prohibition on the sale of contact lenses other than in shops specialised in medical devices, in particular via the internet, judgment of 2 December 2010, *Ker-Optika* (C-108/09, EU:C:2010:725, paragraphs 54 and 55). See also judgment of 14 February 2008, *Dynamic Medien* (C-244/06, EU:C:2008:85, paragraphs 31 to 34).

50 Judgment of 24 November 1993, *Keck and Mithouard* (C-267/91 and C-268/91, EU:C:1993:905).

51 Judgment of 24 November 1993, *Keck and Mithouard* (C-267/91 and C-268/91, EU:C:1993:905, paragraph 16). See also judgments of 15 December 1993, *Hünermund and Others* (C-292/92, EU:C:1993:932, paragraph 21); of 28 September 2006, *Ahokainen and Leppik* (C-434/04, EU:C:2006:609, paragraph 19); and of 14 February 2008, *Dynamic Medien* (C-244/06, EU:C:2008:85, paragraph 29).

52 See, for example, judgments of 7 March 1990, *Krantz* (C-69/88, EU:C:1990:97, paragraph 11); of 13 October 1993, *CMC Motorradcenter* (C-93/92, EU:C:1993:838, paragraph 12); and of 14 July 1994, *Peralta* (C-379/92, EU:C:1994:296, paragraph 24). But see judgment of 21 June 2016, *New Valmar* (C-15/15, EU:C:2016:464, paragraphs 45 to 46).

73. First, the present case has not been brought by a person who would normally be a claimant in such type of disputes: a manufacturer of the goods in question, an importer or a trader. No manufacturer of medical devices has argued that the insurance obligation in question would constitute a barrier to exit (for French manufacturers) or to entry (for foreign manufacturers).[53] Nor, of course, is that the argument of the appellant. She does not claim that the rules at issue would impede the exit of medical devices produced in France, thereby having an impact on (German) users of those products. Instead, the product, once transported from France, across the Netherlands and into Germany, caused harm to the appellant as a patient, that is, as the *end user* of the product.

74. Second, the referring court in the present case is a court of the *host* Member State (Germany) that enquires into the legislation of the *home* Member State (France), which is unusual in the context of free movement rules.[54] Normally, in that context, irrespective of whether alleged barriers to entry or to exit are at issue, home State measures (that allegedly impede exit) are challenged before the home State courts, while host State measures (that allegedly impede entry) are challenged before host State courts. Accordingly, if the present case were a 'normal' free movement case, either the referring court would be a French court called upon to assess whether the French rules amount to a barrier to exit, or the (German) referring court would refer questions regarding the compatibility with EU law of German law.

75. That said, in the case at hand, a German court nonetheless seeks guidance from the Court on a matter regarding French rules, in a case brought by the end user of the goods. According to the logic of the rules on free movement of goods, the question is then, in essence, whether the fact that the compulsory insurance attached to medical devices that are manufactured in France does not 'travel' with those goods constitutes a barrier to free movement from the perspective of an end user based in another Member State.

76. To that question, my answer would be a clear 'no'. The fact that the insurance does not 'travel' with the goods, even if it is compulsory in the home Member State for subsequent use of those goods in that Member State, is not an issue that is covered by either Article 34 or Article 35 TFEU.

77. I acknowledge that a fairly long chain of hypothetical causality could be conjured up in order to render such national rules (or, rather, the absence of any such rules) problematic from the perspective of the free movement of goods. Relying, for example, on *Mickelsson and Roos*, it could be suggested that the fact that insurance is limited to the territory of the home Member State only, could have 'a considerable influence on the behaviour of consumers' in the host Member State, and thus operate as an obstacle to market access.[55] Naturally, medical devices are not ordinary goods. Consumers are likely to carry out detailed research before purchasing a medical device and having it implanted into their body. Thus, it could be suggested that a German consumer might become aware that the manufacturer of those specific medical devices is insured against civil liability only on the French territory, and she would therefore know that *if* the medical devices were defective and *if* the manufacturer went bankrupt, she could not recover any damages because there is a territorial limitation clause in the contract that the French manufacturer has with its insurer in France. In such a scenario of perfect knowledge, bordering on providence, a German consumer might therefore potentially be dissuaded from purchasing such a product from France, and the cross-border flow of goods could indeed be affected.

53 For example, if a trader were to challenge a rule of the host Member State making the importation of goods subject to compulsory insurance, that would be a very different case, likely to fall squarely under Article 34 TFEU.

54 See, to that effect, judgment of 16 December 1981, *Foglia* (244/80, EU:C:1981:302, paragraph 30), where the Court held that 'the Court … must display special vigilance when, in the course of proceedings between individuals, a question is referred to it with a view to permitting the national court to decide whether the legislation of another Member State is in accordance with [EU] law'. See also judgment of 21 January 2003, *Bacardi-Martini and Cellier des Dauphins* (C-318/00, EU:C:2003:41).

55 Above, point 62 of this Opinion.

78. However, the number of 'ifs' in those propositions illustrates why such a scenario is too remote and hypothetical to have anything to do with the rules on the free movement of goods. If that logic were to be embraced, *quod non*, any national rule of the home Member State — at least those more favourable than the ones of the host Member State — could potentially be brought into play.

79. In a way, the present situation is even more remote and hypothetical in terms of access to a market of the host Member State (or even exit from the home market) than the (in)famous line of cases concerning the issue of 'Sunday trading',[56] which gave rise to the judgment in *Keck*. In the Sunday trading cases, a generally applicable ban on shops opening on Sundays had a clear impact on the overall volume of sales, including the sales of goods from other Member States. In the present case, the chain of 'ifs' is considerably longer.

80. It follows that the Treaty rules on free movement of goods are not applicable to the conditions concerning the subsequent use of goods in the host Member State, provided that those conditions do not directly and immediately hinder access to the market of that Member State. From the point of view of the end user, an obligation on a manufacturer to take out insurance against civil liability for defective products, or the absence of any such obligation, exclusively concerns the conditions of subsequent use of the goods on the territory of the host Member State and does not directly and immediately concern either exit of the goods from the home Member State or access to the market of the host Member State.

3. Freedom to receive (insurance) services from another Member State

81. The freedom to *provide* services does not appear to be relevant in the present case. First, it is not factually at issue in the main proceedings since the appellant is the end user of a medical device and not a provider of services. Second, the rules at issue do not affect the freedom to provide services, whether medical or insurance services. As far as the freedom to provide insurance services is concerned, as stated by the French Government, the territorial limitation of the insurance obligation at issue does not prevent insurance companies from covering medical devices produced in France but used in another Member State. Manufacturers and insurance companies can indeed decide, within the exercise of their contractual freedom, on the territorial scope of the insurance contract, beyond the legal minimum required by French law, namely cover on French territory.

82. However, according to the Court, freedom to provide services includes the freedom for *recipients* to go to another Member State in order to receive a service. The appellant could hypothetically be in receipt of two types of services: medical and insurance services. The Court has already confirmed that persons receiving medical treatment can be considered as recipients of services.[57]

83. However, the appellant received medical services in Germany, not in France. Thus, unless the case-law on service recipients were to be redefined to include 'travelling without moving', there was simply no cross-border element.

84. The only remaining scenario would be to understand the position of the appellant as that of a *potential recipient of insurance services*. Such services would indeed have a cross-border character in the sense that a German resident would be claiming compensation as an injured party in France, against a French insurer. The existence of the territorial limitation would thus present an obstacle to freely receiving insurance services from abroad.

56 See notably judgment of 16 December 1992, *B & Q* (C-169/91, EU:C:1992:519, paragraphs 9 to 10). See, more recently, judgment of 23 February 2006, *A-Punkt Schmuckhandel* (C-441/04, EU:C:2006:141, paragraph 21), where the Court did not consider the prohibition of doorstep selling a measure having equivalent effect, even if it is likely to limit the total volume of sales of the relevant products in the Member State concerned and may, consequently, affect the volume of sales of those products from other Member States.

57 See judgment of 31 January 1984, *Luisi and Carbone* (286/82 and 26/83, EU:C:1984:35, paragraph 16), where the Court explicitly included persons receiving medical treatment as recipients of services.

85. There are a number of problems with such a construction. Taken together, those problems would push the freedom to receive services beyond its logical limits.

86. Admittedly, there is the judgment in *Cowan*.[58] That case concerned a British citizen seeking compensation from the French State for injury resulting from an assault suffered by him, as a tourist, during a stay in Paris. The French legislation limited compensation to French nationals and foreign nationals residing in France. The Court held that, 'when Community law guarantees a natural person the freedom to go to another Member State the protection of that person from harm in the Member State in question, on the same basis as that of nationals and persons residing there, is a corollary of that freedom of movement. It follows that the prohibition of discrimination is applicable to recipients of services within the meaning of the Treaty as regards protection against the risk of assault and the right to obtain financial compensation provided for by national law when that risk materialises'.[59]

87. But there are crucial differences. First, Mr Cowan had in fact exercised free movement (from the United Kingdom to France), albeit as a mere tourist. The Court explicitly stated that it was as a 'corollary' of that movement that Mr Cowan was entitled to receive services in the Member State hosting him. He therefore successfully challenged the legislation of the *host* Member State, before a court of that *host* Member State. Second, the logic underpinning the *Cowan* judgment was, at a time when Union citizenship did not exist,[60] to ensure that a 'travelling consumer' could enjoy the same benefits and services in the *host* Member State as a national or resident of that State.

88. The present situation is different. First, the appellant has not moved. Second, she is not challenging the legislation of her Member State (Germany), but (indirectly) that of France, before the court of another Member State.

89. Moreover, the intellectual difficulty with any such construction is again its remote and hypothetical relationship to any clear rule of EU law. The free movement of services perspective throws the true problem of this case into sharp relief: the absence of any clear rule of EU law preventing the territorial limitation in question, which leads to a series of hypotheses and conjectures as to how to create such a rule after the fact. That this argument puts the cart before the horse is even more apparent with regard to the *potential* provision of services: *because* the appellant could potentially claim damages from the respondent *if* the territorial limitation clause were removed from the insurance contract, and could therefore be in receipt of insurance services as the injured party, the territorial limitation of the insurance cover must be incompatible with EU law. Following that line of argument, the (desired) outcome would be allowed to steer the analysis, even in the absence of an applicable rule of EU law.

90. In my view, it is not possible to take such an approach. It must therefore be concluded that, in the circumstances of the present case, the appellant cannot rely on the freedom to provide services.

4. Article 18 TFEU

91. I thought it essential, in the previous parts of this Opinion, to canvass in quite some detail all the other substantive provisions of the Treaty or of secondary law that could potentially contain a prohibition that would apply in the present case. But there appears to be no other provision of EU law, certainly not one brought to the attention of this Court in the course of these proceedings, that might preclude a territorial limitation in an insurance contract concluded by a manufacturer of medical devices if invoked by a patient who suffered harm in another Member State.

58 Judgment of 2 February 1989 (186/87, EU:C:1989:47).

59 Ibid., paragraph 17.

60 Nowadays, *Cowan*-type scenarios would more naturally fall under Union citizenship. See, for example, judgment of 26 October 2017, *I* (C-195/16, EU:C:2017:815, paragraphs 69 to 72). See also my Opinion in that case (EU:C:2017:374, points 64 to 75).

92. That detailed discussion of other potentially applicable EU rules, in particular those on free movement, was not only mandated by the relational, subsidiary nature of Article 18 TFEU;[61] it was also necessary for the purpose of fully grasping how far Article 18 TFEU might reach, if interpreted as establishing in and of itself a general, free-standing prohibition of discrimination within the scope of application of the Treaties.

93. In this closing section, I shall first explain why the Court, in (most of) its recent case-law, has not given such a far-reaching interpretation to Article 18 TFEU (1). I will then set out the way in which Article 18 TFEU could indeed, in the context of the present case, be conceived of and applied as a free-standing provision, producing enforceable obligations irrespective of other provisions of EU law (2). I will close by explaining why, despite having a great deal of moral sympathy for the case of the appellant, I consider that construing Article 18 TFEU in this way would be highly problematic in structural terms. It would turn Article 18 TFEU into a limitless harmonising provision, with the consequence of upsetting the division of competences between the European Union and the Member States and creating problematic conflicts between legal regimes within the internal market (3).

(1) Article 18 TFEU and the case of an EU citizen who exercises free movement

94. Article 18 TFEU can be relied on 'in all situations falling within the scope *ratione materiae* of EU law'. Among such 'situations falling within the scope *ratione materiae* of EU law', the Court has admitted in particular that 'the situation of an EU citizen who *has made use of his right to move freely* comes within the scope of Article 18 TFEU, which lays down the principle of non-discrimination on grounds of nationality'.[62]

95. It is true that, in the context of applying Article 18 TFEU, the Court is not very strict when it comes to assessing the actual existence of movement. There are strands of case-law, in particular the more recent ones involving Union citizenship, in which the actual exercise of free movement by the party in question is not readily apparent.[63] However, in general, *some* movement by a Union citizen or, in a number of such cases, by *persons closely related* to a Union citizen, remains a condition. Merely residing in a Member State is not sufficient to trigger Article 18 TFEU.[64] Only those persons who *actually moved* can avail themselves of that provision.[65]

61 Outlined above in points 50 to 52 of this Opinion.

62 See, for example, judgments of 24 November 1998, *Bickel and Franz* (C-274/96, EU:C:1998:563, paragraph 26); of 10 April 2018, *Pisciotti* (C-191/16, EU:C:2018:222, paragraph 34); 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). My emphasis.

63 See for example, to that effect, judgments of 2 October 2003, *Garcia Avello* (C-148/02, EU:C:2003:539); of 19 October 2004, *Zhu and Chen* (C-200/02, EU:C:2004:639); and of 2 March 2010, *Rottmann* (C-135/08, EU:C:2010:104), where Article 18 TFEU is triggered even when the movement is that of another family member, such as the parents when the EU citizens are children.

64 For a critical view, see, for example, Opinion of Advocate General Sharpston in *Ruiz Zambrano* (C-34/09, EU:C:2010:560, points 77 to 90).

65 The same holds for Article 45 TFEU, which is 'not applicable to workers who have never exercised their freedom to move within the Union and who do not intend to do so'. Judgment of 18 July 2017, *Erzberger* (C-566/15, EU:C:2017:562, paragraph 28).

96. Apart from Union citizenship, in the context of which Article 18 TFEU tends to be invoked most often, the Court has also acknowledged, in a few cases, that Article 18 TFEU can be triggered when the situation at hand concerns a national measure transposing an instrument of secondary EU law;[66] or in view of the effects of the subject matter on intra-EU trade in goods and services when commercial freedom is at issue;[67] or where the situation is specifically governed by EU harmonisation measures, as for example in *International Jet Management*.[68]

97. The latter judgment, according to which Article 18 TFEU is triggered by the existence of EU harmonising measures, is, however, to be put in perspective. In contrast to the loose and broadly defined subject matter assessment of secondary EU law for the purposes of establishing the Court's jurisdiction,[69] for Article 18 TFEU to be applicable as a substantive and enforceable obligation, the question at issue (or the subject matter in the narrow sense) must have been *specifically* harmonised, so that it is considered as falling within the material scope of EU law and thus triggering the applicability of Article 18 TFEU.

(2) Article 18 TFEU as independently creating a substantive obligation

98. Article 18, first paragraph, TFEU sets out three conditions of its application in a given case: (i) the situation must fall within the scope of application of the Treaties, (ii) it must be without prejudice to any special provisions contained therein, and (iii) there must be discrimination on the grounds of nationality.

99. As regards the first condition, having regard to the generous approach to free movement in the case-law, the case at hand must be considered to fall within the scope of EU law.[70] However, it could also be suggested that if, having examined EU primary and secondary law in detail, it emerges that there is in fact *no specific* provision of EU law requiring the compulsory insurance of manufacturers of medical devices against civil liability and that, in the context of the present case, no such obligation can be inferred from any of the fundamental freedoms either, then the case falls entirely back outside the scope of EU law and the jurisdiction of the Court. I have doubts about the intellectual honesty of such a construction,[71] but it could also have intriguing repercussions for the applicability of Article 18 TFEU itself.

100. As regards the second condition, there are no special provisions on the specific subject of the insurance obligation and its scope, either in the Treaties or in secondary legislation.

101. As for the third condition, the existence of more favourable conditions for manufacturers' liability in some Member States and not in others might appear, at a cursory glance, to be a textbook scenario of indirect discrimination on grounds of nationality. Of course, the discrimination in question does not concern access to medical services: as repeatedly and correctly stated by the French Government, if German women were to undergo the medical treatment in France, they would also be covered by the compulsory insurance.

66 See, for example, judgment of 5 September 2012, *Lopes Da Silva Jorge* (C-42/11, EU:C:2012:517, paragraph 39).

67 Judgment of 20 October 1993, *Phil Collins and Others* (C-92/92 and C-326/92, EU:C:1993:847, paragraph 24). It would appear that in paragraphs 17 to 28 of that judgment, the Court was ready to base the triggering of the then Article 7 EEC on an abstract hypothesis, being satisfied by a list of Treaty provisions under which the issue of the protection of literary and artistic property, while not harmonised by EEC law, *could* come into question.

68 See, for example, judgment of 18 March 2014 (C-628/11, EU:C:2014:171, paragraphs 34 to 62), where the Court held in particular that 'air transport services provided between a third country and a Member State by an air carrier holding an operating licence issued by another Member State are regulated by secondary legislation'.

69 Discussed above, in points 35 to 41.

70 Above, points 28 to 49.

71 Above, point 40.

102. Access to medical services is not the issue in the present case. The discrimination would instead be said to lie in the difference of treatment in accessing compensation under the insurance policy. Despite the fact that the harm was caused by the same defective goods moving freely in the European Union, access to compensation differs depending on where the patient in question underwent the surgery. There is no doubt that most French citizens are likely to undergo such surgery in France, and most Germans in Germany. Thus, German patients are far less likely ever to receive any compensation from the insurance cover.

103. In addition, through indirect discrimination on the basis of nationality, France could also be accused of indirectly promoting the provision of medical services on its territory, by making it more difficult for nationals from other Member States to receive the benefit of the insurance since, for that purpose, they would have to travel to France to undergo surgery. By contrast, French women could obtain compensation from the insurance policy more easily than foreign women, since they are more likely to have surgery on the French territory.[72]

104. Thus, one could potentially argue that all three conditions triggering Article 18 TFEU appear to be present. There are three additional arguments that could perhaps be said to support the triggering of Article 18 TFEU in the case like the present one.

105. First, if EU law provides for and enforces free movement of goods, it could be argued that it must also provide for and enforce equal responsibility and liability for cases in which those goods prove to be defective. Goods often carry risks, and free trade allows those risks to circulate and potentially create harm anywhere. It seems only fair that all patients, anywhere in the European Union, who suffer adverse consequences from defective products produced in a Member State, should have the chance to obtain adequate compensation.

106. Second, and partially connected to the first point, consumer protection has been at the forefront of EU policy-making in recent years. Article 12 TFEU made consumer protection requirements transversally applicable, to be taken into account in defining and implementing other EU policies. Thus, free movement must reflect and strive for a high level of consumer protection, as enshrined in Article 38 of the Charter of Fundamental Rights of the European Union ('the Charter').

107. Third, there is Union citizenship to consider. In a way, the older case-law on Article 18 TFEU, certainly that relating to the free movement of persons,[73] could be seen as a precursor to Union citizenship. However, the advent of Union citizenship, which is necessarily tied to equal dignity under EU law (Articles 1 and 20 of the Charter), makes nitpicking about who exactly moved, where and for how long, or who might be dependent on whom, redundant.

108. All those arguments considered together, in conjunction with the undeniably dreadful consequences that the defective products in question had for the appellant, could lead to the suggestion that the imperative of equal protection of all European citizen-consumers precludes a national rule that, in effect, limits insurance cover to persons who undergo surgery on the territory of the Member State, thus indirectly limiting the cover to citizens of that Member State.

72 See for example, to that effect, judgment of 1 April 2008, *Government of the French Community and Walloon Government* (C-212/06, EU:C:2008:178, paragraphs 49 to 50 and the case-law cited), in relation to conditions of residence.

73 Judgment of 2 February 1989, *Cowan* (186/87, EU:C:1989:47).

(3) Respecting the regulatory logic of the internal market

109. Although such a suggestion could be entirely understandable in moral terms in the specific context of this individual case, it would, however, be entirely wrong in structural terms. It would turn Article 18 TFEU into a limitless provision, by virtue of which any issue, however remotely connected to a provision of EU law, could be harmonised by judicial means. It would furthermore turn regulatory competence within the internal market on its head, generating irreconcilable future conflicts of competence between the Member States.

110. The starting principle for the regulation of the internal market is respect for regulatory diversity in matters not explicitly harmonised by EU law. Implicit harmonisation might indeed sometimes reach into that realm. Certain rules of the Member States not previously harmonised by legislation might be declared incompatible with any of the four freedoms.

111. What clearly emerges from the discussion of the free movement of goods [74] and services [75] is that the scope of those freedoms is already considerable. But it is also clear from the discussion of the present case that if Article 18 TFEU were allowed to operate as a free-standing, substantive obligation in the way implied by the referring court in its questions, its reach would go beyond anything that the free movement case-law ever contemplated, including the case-law on goods pre-*Keck*. Interpreted in that way, there would be no limit to the scope of Article 18 TFEU: that provision would be turned into a *Dassonville* formula on steroids. In today's interconnected world, sooner or later, there is inevitably some sort of interaction with goods, services or persons from other Member States. 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.

112. To take just one example: [76] imagine that, while drafting this Opinion, I am injured — hopefully not too seriously — because the computer I am typing on explodes. The various parts of the computer are likely to have been produced in a Member State other than Luxembourg, more likely even, in the age of integrated supply chains, in several Member States, if not also third countries. Absent any specific contractual terms concerning applicable law and jurisdiction between the producer of that computer and myself, therefore assuming normal rules on tort (delict) were to apply, the applicable law governing any damages claim is likely to be Luxembourg law, as the law of the State in which the accident occurred. Should I then, if I were to find Luxembourg law unsatisfactory for my damages case, have the possibility of relying on Article 18 TFEU in order to invoke the law of the place of production of the computer, or perhaps even the place of production of any of the components of the computer, and have my claim enforced before a Luxembourg court?

113. That scenario underlines the common theme already emerging from the discussion of potential free movement of goods and services: the rules on free movement, as well as Article 18 TFEU, logically only cover the free flow of goods or services across borders, including exit and entry. Unless expressly harmonised by the EU legislature, the rules on their *subsequent use* are a matter for the Member States where they are used. That also includes potential liability issues, including matters of compulsory insurance, again where not already expressly harmonised. [77]

74 Above, points 59 to 80.

75 Above, points 81 to 90.

76 Naturally purely fictitious and simplified, with no intention of entering into the issues of applicable law under Article 5 of Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II) (OJ 2007 L 199, p. 40).

77 Above, points 54 to 58.

114. In other words, 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 logic were to be embraced, by a questionable interpretation of Article 18 TFEU, the movement of goods in Europe would become (once again) reminiscent of medieval legal particularism,[78] whereby each product would, like a person, carry its own laws with it. Goods would be like snails, carrying their homes with them in the form of the legislation of their country of origin, to be applicable to them from their production to their destruction.

115. Such a consequence would not only displace any (normal) territoriality in the application of laws, but would also generate *conflicts of regulatory regimes* between the Member States. Indeed, such 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.[79]

116. In that context, it is useful to recall another particularity of the present case, namely that whereas the State of origin of the goods, or *home* Member State (France), has adopted rules concerning their subsequent use on its territory (compulsory insurance for surgeries carried out on its territory), the State in which the goods were used, the *host* Member State (Germany), does not appear to have adopted any rules in that regard.[80]

117. But what if rules on the matter had been adopted in Germany? In such a case, it is fair to assume that no one would have doubted that the German rules apply, fully and exclusively, to potential harm occurring on German territory. It is unlikely that anyone would seek to substitute the potentially more favourable French rules for the German rules on the matter, which, at that stage, has no connection with French law.

118. That again underlines why Article 18 TFEU cannot be interpreted as precluding the limitation to the domestic territory of the obligation to insure against civil liability for the use of medical devices. A fortiori, that provision cannot be interpreted as obliging the respondent or the French Republic to grant compensation to the appellant on the basis of direct effect.

119. In sum, Article 18 TFEU cannot be construed as creating, in and of itself, a free-standing, independent substantive obligation not already contained in any of the four freedoms or specifically provided for in any other EU law measure. In particular, that provision certainly should not be applied in a way that reaches even further than the already rather comprehensive reach of the four freedoms of movement.

120. By way of conclusion, I note that the present case is the consequence of the fact that EU law has not harmonised the issue of insurance against civil liability for the use of medical devices and that, apparently, German law did not contain any provisions to that effect either. It might be recalled that in a not entirely dissimilar context, the Court already held in *Schmitt* that it is for national law to

78 It was the modern law that only gradually asserted territorial exclusivity over medieval legal particularism — see, for example, Lesaffer, R., *European Legal History: A Cultural and Political Perspective*, Cambridge University Press, Cambridge, 2009, pp. 168–9, 269 et seq., and 277 et seq., or Romano, S., *L'Ordre juridique*, Dalloz, 1975, p. 77 et seq.

79 Thus adding another layer of complexity and (un)foreseeability to a regime which, as far as the choice of the applicable law and forum for the consumer is concerned, is not straightforward or clear as it is — for a recent review see, for example, Risso, G., 'Product liability and protection of EU consumers: is it time for a serious reassessment?' *Journal of Private International Law*, Vol. 15, 2019, Issue 1, p. 210.

80 Or at least they have not been brought to the attention of this Court, since the referring court is silent on that matter and the German Government did not submit any observations in the present case.

decide on the conditions of liability of notified bodies vis-à-vis end users of medical devices.[81] It is also for the Member States, as EU law currently stands, to regulate insurance policies applicable to medical devices used on their territory, even when those devices are imported from another Member State.

121. In this respect, Member States are certainly free, in the absence of harmonisation, to decide to introduce a higher level of protection of patients and users of medical devices through more favourable insurance policies applying on *their* territory.[82] Thus, the territorial limitation at issue in the present case was a legitimate legislative choice of France.[83] That fact can hardly then be turned around or, rather, against that Member State, by suggesting that that legislative choice must then be extended to the territory of any other Member State that failed to enact similar rules.

V. Conclusion

122. I propose that the Court answer the questions posed by the Oberlandesgericht Frankfurt am Main (Higher Regional Court, Frankfurt am Main, Germany) as follows:

– Article 18 TFEU does not, in and of itself, preclude the limitation to the territory of a Member State of an obligation to insure against civil liability for the use of medical devices.

81 Judgment of 16 February 2017 (C-219/15, EU:C:2017:128).

82 See, to that effect, judgments of 13 February 1969, *Wilhelm and Others* (14/68, EU:C:1969:4, paragraph 13); of 14 July 1981, *Oebel* (C-155/80, EU:C:1981:177, paragraph 9); and of 14 July 1994, *Peralta* (C-379/92, EU:C:1994:296, paragraphs 48 and 52).

83 See, by analogy, judgment of 18 July 2017, *Erzberger* (C-566/15, EU:C:2017:562, paragraphs 36 and 40), concerning a limitation to the German territory of the German legislation regarding the right to vote and to stand as a candidate for election as the workers' representatives in the supervisory body of a company.