The scope of application of the free movement provisions and the role of Article 18 TFEU: *Allianz*

Case C-581/18, *RB v TÜV Rheinland LGA Products GmbH and Allianz IARD SA*, Judgment of the Court (Grand Chamber) of 11 June 2020, EU:C:2020:453

1. Introduction

The PIP breast implants scandal is one of the most serious health scandals that the EU has experienced in the last decade.[1] For many years, the French manufacturer PIP, one of the largest manufacturers of breast implants in the world, used sub-standard industrial silicone gel instead of the required medical gel. This fraud remained unnoticed by the certification body that was responsible for verifying that the implants complied with the relevant EU legislation. When the fraud was finally discovered in 2010, millions of women across the world had received sub-standard and potentially dangerous breast implants. Although research on the potential health risks of the use of industrial gel remains ambivalent, it is clear that PIP breast implants have a significantly higher chance of leaking.[2] As a result, many women had their breast implants replaced. Although the costs of the replacement were covered by some national healthcare systems, in other countries victims remained responsible for the costs.

Against this background, it is unsurprising that many victims have been looking for legal avenues to obtain compensation for the harm they suffered. Under EU law, the most likely avenue is to bring a case against the manufacturer under the Product Liability Directive.[3] However, this avenue was blocked by the liquidation of PIP. As a result, victims started procedures against several parties, such as the certification body that was responsible for verifying that PIP breast implants complied with the relevant European standards (TÜV Rheinland), the insurer of PIP (Allianz), public supervisory agencies at the national level, the medical doctors who operated on the women and the clinics where the implants were placed.[4] Most cases were brought in France, Germany and the Netherlands. In many of these cases, the fundamental question was whether and to what extent the potential liability of the defendant was regulated by EU law.

The present case, *Allianz*,[5] is the second case on PIP breast implants that has made it to the Court. Both cases were preliminary references made by German courts. In 2017, in *Schmitt*,[6] the Court held that the Medical Devices Directive,[7] which lays down the conditions under which breast implants can be placed on the market, did not regulate the conditions under which a notified body could be held liable for its potential failure to carry out the inspections of the manufacturer with sufficient skill and care. This was a matter for national law – subject to the principles of equivalence and effectiveness.[8] When the case returned to Germany, the *Bundesgerichtshof* held that TÜV

[1] For the background, see B. van Leeuwen, "PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies" (2014) 5 *European Journal of Risk Regulation* 338.
[2] European Commission, 2014 Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Opinion on the Safety of Poly Implant Prothèse (PIP) Silicone Breast Implants – Update of the Opinion of February 2012: https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_043.pdf.
[3] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [1985] OJ L 210.
[4] For an overview, see P. Verbruggen and B. van Leeuwen, "The Liability of Notified Bodies under the EU's New Approach: The Implications of the PIP Breast Implants Case" (2018) 43 *EL Rev* 394.
[5] Case C-581/18, *RB v TÜV Rheinland and Allianz*, EU:C:2020:543.
[6] Case C-219/15, *Schmitt v TÜV Rheinland LGA Products GmbH,* EU:C:2017:128.
[7] Council Directive 93/42/EC of 14 June 1993 concerning medical devices [1993] OJ L 169/1.
[8] See Verbruggen and Van Leeuwen, *supra* n 4, and A. Wallerman, "Pie in the sky when you die? Civil liability of notified bodies under the Medical Devices Directive: *Schmitt*" (2018) 55 *CML Rev* 265.

Rheinland was not liable because it had not breached its duty of care towards the women who had received PIP implants.[9] The fraud had been very elaborate and, under the EU legislation in force at the time, TÜV Rheinland could not have been expected to have done more or to have acted more pro-actively. The focus in *Schmitt* was essentially on the extent to which the New Approach, the EU's regulatory approach to placing goods on the internal market, had an impact on liability issues in private law at the national level.[10] The same question was central to *Allianz*. However, where *Schmitt* focussed on the impact of secondary EU law on national private law, *Allianz* focussed on the impact of primary EU law – in particular, of Article 18 TFEU.

2. Factual and legal background

Ms RB ("RB") received breast implants in Germany in 2006. These implants had been produced by PIP and had been placed on the market by a Dutch company, Rofil Medical.[11] Breast implants are covered by the Medical Devices Directive. As a result, they have to comply with the requirements laid down in European standards. Before they can be placed on the market, a certification body – a so-called "notified body" – has to carry out a conformity assessment procedure to verify that the breast implants comply with the relevant European standards. Between 1997 and 2010, TÜV Rheinland carried out several (announced) inspections of PIP's factory. It never discovered the fraud. In 2010, the French supervisory agency discovered that PIP had been using sub-standard industrial silicone gel to fill the implants. PIP breast implants were immediately taken off the market. The company went into liquidation in 2010 and its management were sentenced to imprisonment for fraud.[12]

Under French law, manufacturers of medical devices have to take out compulsory liability insurance.[13] PIP had approached a number of insurance companies, all of which refused to conclude an insurance policy. In those circumstances, a public authority, the *Bureau central de tarification* ("BCT"), had the power to order an insurance company to agree a policy with PIP. In 2005, Allianz was ordered to conclude an insurance policy with PIP. The policy included a clause that restricted its cover to harm that occurred in France. This clause was proposed by Allianz and was not objected to by the BCT. The contract provided that injured parties could bring a direct claim against the insurer.[14]

RB brought an action before the German courts against three parties: the doctor who had implanted the breast implants, TÜV Rheinland and Allianz. It was not in dispute that the liability of the doctor was regulated exclusively by national law. After the Court's judgment in *Schmitt*, and the subsequent judgment of the *Bundesgerichtshof*, it was unlikely that RB would be able to hold TÜV Rheinland liable. As a result, RB's case focussed on the potential liability of Allianz. Allianz argued that the territorial restriction clause in the insurance policy was valid and that it was under no

[9] Judgment of the *Bundesgerichtshof* of 22nd June 2017, VII ZR 36/14.
[10] Under the New Approach, the EU adopts legislation which lays down the "essential requirements" with which goods have to comply before they can be placed on the market. The precise "technical specifications" are laid down in European standards, which are developed by the European standardisation organisations. Goods which comply with the relevant European standard(s) are also presumed to comply with the applicable EU legislation. For a more detailed explanation of the New Approach, see B. van Leeuwen, *European Standardisation of Services and its Impact on Private Law* (Hart Publishing, 2017), 40-47.
[11] *Allianz, supra* n 5, para 11.
[12] Ibid., para 19.
[13] Article L. 1142-1 of the Public Health Code, as amended by the Law No 2002-1577 of 30 December 2002 on medical civil liability (*Code de la santé publique, tel que modifié par la loi nº 2002-1577 du 30 décembre 2002 relative à la responsabilité civile médicale*).
[14] *Allianz, supra* n 5, para 14.

obligation to compensate RB for damage that had occurred in Germany.[15] At first instance, RB's claims were dismissed. On appeal, the *Oberlandesgericht Frankfurt am Main* submitted a number of questions about Article 18 TFEU to the Court. It was clear that the territorial restriction clause discriminated indirectly against non-French nationals, because they were more likely to suffer harm outside France. The first two questions asked whether Article 18 TFEU was applicable in a dispute between two private parties through horizontal direct effect, or through a form of indirect effect based on the relationship between Allianz and the BCT. The second set of questions focussed on the potential justification for the indirect discrimination.[16] All questions were based on the assumption that Article 18 TFEU was applicable to RB's case.[17]

3. Opinion of the Advocate General

At the start of his Opinion, Advocate General ("AG") Bobek took a step back and started with the fundamental question of whether Article 18 TFEU was applicable to this case.[18] He developed his analysis in three steps. First, he analysed whether the Court had jurisdiction to provide a ruling on the questions submitted by the *Oberlandesgericht*. Second, he investigated whether any other specific provision of EU law was applicable to this case. Finally, he focussed on the role of Article 18 TFEU as a free-standing provision in free movement law. His conclusion was that making Article 18 TFEU a free-standing prohibition of discrimination within the scope of application of the Treaties would go against the "regulatory logic" of the internal market by harmonising aspects of national law that were beyond the proper reach of free movement law.[19]

First, AG Bobek had to deal with the submission that RB's case was a purely internal situation and that, as a result, the preliminary reference was not admissible. He found that the case did come within the scope of application of EU law in two different ways. First, there was a sufficiently clear and direct link to the free movement of goods, since goods had moved from France to Germany.[20] There was also the possibility of a German patient seeking compensation from a French insurer, which created a link to the free movement of services. Again, this was sufficient to find a cross-border element.[21] Second, although there was no obligation to take out compulsory liability insurance for manufacturers in secondary EU law, there was a close connection to the Product Liability Directive, which established the strict liability of manufacturers for defective products, and the Medical Devices Directive, which regulated the conditions under which breast implants could be placed on the market.[22] For these reasons, AG Bobek concluded that the Court had jurisdiction to give a preliminary ruling.

His next step was to analyse whether any specific provisions of EU law were applicable. Article 18 TFEU expressly provides that it is only applicable if there is no specific provision of (primary or secondary) EU law that regulates the issue. The answer was straightforward when it came to EU secondary law: neither the Product Liability Directive nor the Medical Devices Directive contained a provision imposing compulsory liability insurance on manufacturers.[23] The assessment of the potential application of the free movement provisions was more complicated. AG Bobek focussed

[15] Ibid., para 22.
[16] Ibid., para 27.
[17] Ibid.
[18] Opinion of Advocate General Bobek in *Allianz, supra* n 5, EU:C:2020:77.
[19] Ibid., para 109.
[20] Ibid., para 43.
[21] Ibid., para 44.
[22] Ibid., para 45.
[23] Ibid., paras 54-58.

on the free movement of goods and services. For goods, he argued that a national rule that regulated the conditions for the subsequent use of the product *after* it had been placed on the market should not be regarded as a restriction on free movement.[24] The French legislation did not have an impact on the exit or entry of breast implants. The Court had developed the remoteness and *Keck*[25] tests to demarcate the boundaries of Article 34 TFEU. After *Commission v Italy (Italian Trailers)*[26] and *Mickelsson and Roos*,[27] restrictions on use could be caught by Article 34 TFEU, but only if they prevented or greatly restricted the use of a product. Furthermore, it was important that the present case was not brought by a manufacturer or importer of breast implants. AG Bobek acknowledged that the impact of national rules on the behaviour of consumers played an important role in the Court's judgment in *Mickelsson and Roos*.[28] However, in RB's case, it was unlikely that women would be discouraged from buying breast implants in Germany if they found out that the compulsory French liability insurance had not "travelled" with the breast implants to Germany. AG Bobek found this link to the free movement of goods too hypothetical. Therefore, the case did not come within the scope of Article 34 TFEU.[29]

Similarly, he argued that Article 56 TFEU was not applicable either.[30] The freedom to receive medical services was not applicable, because RB had received the breast implants in her home Member State. AG Bobek also rejected the possibility that RB could be seen as seeking access to insurance services in France. He distinguished the present case from *Cowan*,[31] in which Mr Cowan had moved to another Member State and challenged the legislation of the host Member State before the courts of the host Member State. RB had not moved to another Member State and was seeking to challenge French legislation before the courts of her home Member State. AG Bobek concluded that this was too remote to bring the case within the scope of Article 56 TFEU.

Since no specific provision of EU law was applicable, AG Bobek finally turned to Article 18 TFEU. He identified three conditions for its application. First, the situation must come within the scope of application of the Treaties. Second, there must not be any specific provisions regulating the issue. Third, there must be discrimination on the ground of nationality. AG Bobek did not conduct a separate analysis of whether the case came within the scope of EU law – he simply followed his earlier analysis when he had established that the Court had jurisdiction to give a preliminary ruling. Although there was no specific provision of EU law applicable to this case, it still fell within the scope of EU law.[32] He had already concluded that there were no specific provisions of EU law applicable and it was clear that the French rule discriminated indirectly against nationals from other Member States. As such, all three conditions for the application of Article 18 TFEU were satisfied.

AG Bobek then identified three arguments in favour of applying Article 18 TFEU to the present case.[33] The first was that, if EU law creates an elaborate regulatory framework to improve the free movement of goods, it should also take responsibility for regulating situations where these products turn out to be defective. Second, consumer protection was an important right protected

[24] Ibid., para 65.
[25] Case C-267/91, *Keck*, EU:C:1993:905, para 16.
[26] Case C-110/05, *Commission v Italy (Italian Trailers)*, EU:C:2009:66.
[27] Case C-142/05, *Mickelsson and Roos*, EU:C:2009:336.
[28] Opinion of AG Bobek in *Allianz, supra* n 5, para 77.
[29] Ibid., para 78.
[30] Ibid., paras 81-89.
[31] Case C-186/87, *Cowan*, EU:C:1989:47.
[32] Opinion of AG Bobek in *Allianz, supra* n 5, para 99.
[33] Ibid., paras 105-108.

EU law – now explicitly recognised by Article 38 of the Charter of Fundamental Rights of the EU ("the Charter"). Third, Union citizenship had led to a significant expansion of the scope of protection of free movement law and an erosion of the concept of purely internal situations.

Although AG Bobek recognised the validity of these arguments, he ultimately concluded that Article 18 TFEU should not applied to RB's case because it would turn Article 18 TFEU into a "limitless provision" that could be used to harmonise issues of national law that were beyond the proper reach of EU law.[34] He emphasised the importance of regulatory diversity.[35] If Article 18 TFEU were applied to the present case, this would be a significant expansion of the scope of application of free movement law. It would make Article 18 TFEU into a "*Dassonville* formula on steroids"[36] and would effectively make it possible for citizens to challenge almost every national rule. Furthermore, it would lead to direct conflicts between regulatory regimes without any clear rules or limits on how these conflicts should be resolved.[37] He re-iterated that the subsequent use of products after they have been placed on the market should be regulated at the national level. This was consistent with the Court's approach in *Schmitt*. As a result, AG Bobek's overall conclusion was that Article 18 TFEU did not preclude the territorial limitation of compulsory liability insurance for medical devices.

4. Judgment of the Court

The Court started by assessing whether Article 18 TFEU was applicable to the case. It emphasised that Article 18 TFEU was only applicable to situations "governed by EU law" in respect of which "the Treaties lay down no specific rules on non-discrimination".[38] The Court then identified two conditions for the applicability of Article 18 TFEU. First, the situation must fall within the scope of application of EU law. Second, there cannot be any specific rule in the Treaties which prohibits discrimination on the ground of nationality in the specific circumstances of the case.[39]

The Court started its analysis with the first condition and assessed whether the situation in *Allianz* was governed by primary or secondary EU law. First, the Court assessed whether there was an obligation in EU secondary law for manufacturers to take out liability insurance for medical devices.[40] The Court held that there was no such obligation. The Medical Devices Directive only imposes an obligation on notified bodies – the certification bodies that have to verify whether manufacturers comply with the relevant European standards – to take out liability insurance. The Product Liability Directive only establishes the strict liability of manufacturers for defective products. It does not regulate in an exhaustive way other issues related to the liability of manufacturers – such as whether or not they should have compulsory liability insurance. Finally, financial services such as insurance were expressly excluded from the scope of application of the Services Directive. As a result, the issue in this case was not regulated by secondary EU law.

The Court then turned to the free movement provisions. It emphasised that it is the exercise of one of the free movement provisions that brings a case within the scope of application of EU law. Moreover, there has to be "a specific connecting factor linking the person, service or goods concerned and the alleged discrimination".[41] As such, the task of the Court was to identify whether

[34] Ibid., para 109.
[35] Ibid., para 110.
[36] Ibid., para 111.
[37] Ibid., paras 115-117.
[38] *Allianz*, supra n 5, paras 30-31.
[39] Ibid., paras 32-33.
[40] Ibid., paras 36-44.
[41] Ibid., para 47.

the alleged discrimination in this case could be linked to either the free movement of goods or the freedom to provide or receive services. The Court first dismissed Union citizenship as a possible connection. The claimant had not moved to another Member State. The potential application of the freedom to receive services in Article 56 TFEU was rejected on a similar basis: the claimant had not received medical services in another Member State. The Court took a stricter approach to the freedom to provide insurances services than AG Bobek. It held that, because the insurance contract was concluded between Allianz and PIP, which were both French companies, there was no cross-border element. The claimant was not a party to this contract and, as such, Article 56 TFEU was not applicable.[42]

Finally, the Court focussed on the free movement of goods. It held that the cross-border movement of goods had not been affected in this case. After all, the goods had been manufactured in France, marketed in the Netherlands and sold in Germany. The Court followed AG Bobek in making a distinction between the movement of goods and the harm caused by goods that have been moved.[43] An obligation to obtain civil liability insurance does not affect the free movement of goods in the internal market. As a result, the Court held that the situation in *Allianz* was not linked by any specific factor to Article 34 TFEU.

Since the case was not covered by secondary or primary EU law, the Court concluded that the claimant's situation did not fall within the scope of application of EU law. As such, the first condition for the applicability of Article 18 TFEU was not satisfied.[44] Therefore, Article 18 TFEU was not applicable to the present case.[45] The questions about the horizontal direct effect of Article 18 TFEU and the justifications for the indirect discrimination did not have to be answered.

5. Comment

The focus of the analysis will be on four aspects of the judgment in *Allianz*. First, we will discuss the Court's approach in identifying the outer boundaries of the scope of application of the free movement provisions. Second, the judgment shows that the Court relied on a static definition of the concept of market access, which focussed on obstacles that goods encounter in *entering* the market of another Member State. With this approach, liability issues in private law, which are linked to the use of a product *after* it has been placed on the market, are not regulated by the free movement provisions. Third, it will be shown that *Allianz* has clarified that, for Article 18 TFEU to be applicable, there must be a direct link between the alleged discrimination and the exercise of free movement rights. Finally, we will discuss the question that was not answered by the Court: could Article 18 TFEU have been applied to a (seemingly) horizontal dispute between a patient and a private insurer?

5.1 Between jurisdiction and substance: the outer boundaries of free movement law

It is clear that *Allianz* is situated in the "hinterland" of free movement law. In the last decades, the Court has developed several "techniques" to find that the free movement provisions are not applicable to a particular situation.[46] Despite – or perhaps because of – the extensive catalogue, it

[42] Ibid., para 52.
[43] Ibid. para 56.
[44] Ibid., paras 58-59.
[45] Ibid., paras 59-60.
[46] See, for a detailed overview, N. Nic Shuibhne, *The Coherence of EU Free Movement Law* (OUP, 2013), 115-188. For Article 34 TFEU, see T. Horsley, "Unearthing Buried Treasure: Art. 34 TFEU and the Exclusionary Rules" (2012) 37 *EL Rev* 734.

is not clear which test should be applied to which type of case. The judgment in *Allianz* provides a good example of the difficulties in identifying the outer boundaries of the free movement provisions.

In its judgment, the Court did not make a distinction between the scope of EU law for the purposes of establishing its jurisdiction and the potential application of Article 18 TFEU. It did not deal with the argument that the preliminary reference was inadmissible because it involved a purely internal situation. It simply held that Article 18 TFEU was not applicable to the case. Although it gave a substantive ruling, it ended up not answering the specific substantive questions posed by the *Oberlandesgericht*. It is not surprising that the Court gave a substantive rather than a procedural ruling – the case raised some fundamental questions about the scope of application of Article 18 TFEU.[47] AG Bobek had proposed a more principled approach that started by making a distinction between the scope of application of EU law for the purposes of the Court's jurisdiction and the scope of application of EU law for the purposes of the application of Article 18 TFEU.[48]

Unlike the Court, AG Bobek argued that the case fell within the scope of application of EU law. He relied on the same line of reasoning he had followed to establish the jurisdiction of the Court: there was a sufficiently clear link to two pieces of secondary legislation and to the free movement of goods and services. According to AG Bobek, to make a distinction between the jurisdictional and the substantive assessment would be "intellectually dishonest".[49] Because he had already found that the case came within the scope of EU law, the first condition for the application of Article 18 TFEU was satisfied. And since the territorial restriction clause was indirectly discriminatory and there were no specific provisions of EU law applicable, the AG found that all conditions for the application of Article 18 TFEU were satisfied. He then had to find a "way out" to justify why Article 18 TFEU should not be applied to the present case. He ended up having to do some legal acrobatics to justify why Article 18 TFEU should not be applied when the conditions for its application were satisfied. The Court's approach was more straightforward – it simply held that the case did not come within the scope of application of EU law at all. The difference is clearly visible in the language used: the Court found that Article 18 TFEU "was not applicable to"[50] this case while AG Bobek found that Article 18 TFEU "did not preclude"[51] the territorial restriction clause.

In *Allianz*, the Court appeared to regard RB's situation as purely internal, while AG Bobek relied on the concept of remoteness. The Court simply discussed the potential free movement provisions and found none of them to be applicable because there was no effect on trade between Member States. However, AG Bobek did identify a link to the free movement of goods and services. He then argued that the impact on free movement was too hypothetical and remote. His Opinion is full of remoteness language: the impact on the free movement of goods was "too remote and hypothetical"[52] and the territorial restriction clause did not "directly and immediately"[53] hinder access to the market. The problem was the "remote and hypothetical relationship to any clear rule

[47] See. A. Arena, "*The Wall* Around EU Fundamental Freedoms: The Purely Internal Rule at the Forty-Year Mark" (2019) 38 *YEL* 153, 168-170.
[48] This approach may have been inspired by the Court's recent attempt to lay down guidelines on when preliminary references are admissible in (potentially) purely internal situations: Case C-268/15, *Ullens de Schooten*, EU:C:2016:874.
[49] Opinion of AG Bobek in *Allianz*, *supra* n 5, para 99.
[50] *Allianz*, *supra* n 5, para 60.
[51] Opinion of AG Bobek in *Allianz*, *supra* n 5, para 122.
[52] Opinion of AG Bobek in *Allianz*, *supra* n 5, para 78.
[53] Ibid., para 80.

of EU law".[54] This is very similar to the Court's often-used formula that the effect on cross-border movement was "too uncertain and indirect".[55]

Overall, the outcome of the two approaches does not necessarily have to be different. Both the purely internal situation test and the remoteness test usually take a case outside the scope of the free movement provisions. However, the difference in approach between the Court and its AG does not only show that they are struggling to be consistent in the application of the "outer boundaries" tests,[56] which leads to uncertainty for national courts and parties who want to rely on the free movement provisions. The difference in approach also has other implications – for example, for the potential application of the Charter to free movement cases. If a case only has a remote link to the free movement provisions, the orthodox position would be that the case falls outside the scope of EU law and the Charter would not be applicable. However, with AG Bobek's approach, remoteness cases could still "spill over" into the scope of application of EU law. This approach could have consequences for the applicability of the Charter. The relationship between the scope of application of the free movement provisions and the protection of fundamental rights will be discussed in more detail in the next section.

5.2 The concept of market access under Article 34 TFEU and the protection of health under the Charter

Allianz does not only raise questions about how to identify the scope of application of the free movement provisions. The case also highlights the Court's approach to the concept of market access under Article 34 TFEU.[57] The Court made a clear distinction between rules that have an impact on the *exit* or *entry* of goods and rules that regulate the use of goods *after* they have been placed on the market. While the former category of rules comes within the scope of free movement law, Article 34 TFEU does not regulate the subsequent use of products *after* they have been placed on the market.

The Court held that this case "relates not to the cross-border movement of goods in itself, but to the harm caused by the goods that have been so moved".[58] Civil liability insurance which does not cover harm that occurs in other Member States "does not affect the marketing in another Member State of the products the risk from which that insurance is intended to cover".[59] As a result, there was no impact on trade in goods and there was no restriction of Article 34 TFEU. In reaching this conclusion, the Court relied on a presumption that traders and consumers would not stop importing or buying products if they knew that these products were not insured for damage that occurred in the Member State where they were going to be used. This creates a direct link to the Court's judgments in *Commission v Italy (Italian Trailers)* and *Mickelsson and Roos*. It is surprising that the Court did not refer to these cases in *Allianz*, because they were precisely about national rules that affected the use of products *after* they had been placed on the market. In both cases, the Court had made a link between national rules on the use of products and consumer behaviour. If a national rule had a considerable impact on consumer behaviour (i.e. fewer consumers would buy

[54] Ibid. para 89.
[55] See Horsley, *supra* n 46, 738-744.
[56] See Nic Shuibhne, *supra* n 46, 126-128.
[57] On the concept of market access, see J. Snell, "The Notion of Market Access: A Concept or a Slogan?" (2010) 47 *CML Rev* 437. See also C. Barnard, "Fitting the Remaining Pieces in the Goods and Services Jigsaw" (2001) 26 *EL Rev* 35.
[58] *Allianz*, *supra* n 5, para 56.
[59] Ibid.

the product), this could lead to lower imports.[60] The Court assumed that a complete or significant ban on the use of a product would directly lead to fewer imports of that product. However, in *Mickelsson and Roos*, the Court did not provide a detailed justification for this presumption.[61]

A similar lack of justification – or explanation – can be observed in *Allianz*. The Court did not investigate what the impact of the territorial exclusion could be on the recipients of breast implants. It did not explain on what basis it concluded that traders and recipients of breast implants were not affected by the territorial restriction clause. The risk of this omission is that the Court's approach could be inconsistent with its general approach to identifying restrictions of Article 34. The *Dassonville* test remains incredibly broad and only requires an indirect or potential impact on trade between Member States.[62]Although the Court implicitly concluded that the territorial restriction did not have such an effect, it did not explain *why* this was the case.

AG Bobek had addressed this issue much more explicitly. He argued that "Article 34 and 35 TFEU catch national provisions that hinder the *entry* or the *exit* of a product".[63] As such, "the free movement rules are not there to regulate the *subsequent use* or consumption of the goods in the host Member State".[64] While AG Bobek accepted that the Court had extended the application of Article 34 TFEU to rules on the use of goods in *Mickelsson and Roos*, this extension only covered rules that banned or greatly limited the use of products so as to prevent "their effective access to the market".[65] AG Bobek argued that, in *Allianz*, most recipients of breast implants would not know whether the breast implants they were going to receive were insured by the manufacturer for damage suffered in France only. It was not realistic to expect consumers to have this kind of knowledge. However, AG Bobek could have focussed on the clinics and medical doctors as consumers or users of breast implants. After all, doctors and clinics will usually be the first buyers of breast implants. And unlike the end-consumers, doctors and clinics would want to have detailed knowledge about potential liability issues. The test proposed by AG Bobek – focussing on the *direct* and *immediate* impact on market access – seems too strict from the perspective of *Dassonville*, which explicitly refers to the *indirect* and *potential* impact of national rules on cross-border movement.[66] It cannot be the case that the market access test would have a higher threshold than the *Dassonville* test.[67]

The Court's approach in *Allianz* confirms that the concept of market access under Article 34 TFEU operates only "at the border". After goods have successfully entered another Member State, free movement law leaves the picture. This "static" definition of market access[68] is primarily based on a competence argument: the scope of free movement law does not – and should not – reach to liability issues in private law. Therefore, the review of national rules on the use of products does not extend to questions about liability in private law that arise *after* a product has been placed on the market. The EU has adopted the Product Liability Directive to provide a right of action against the manufacturer, but this is as far as EU law has gone to enable consumers to obtain

[60] *Mickelsson and Roos*, supra n 27, paras 26-27.
[61] See I. Lianos, "In Memoriam Keck: the reformation of the EU law on the free movement of goods" (2015) 40 *EL Rev* 225, 230-232.
[62] Case C-8/74, *Dassonville*, EU:C:1974:82, para 5.
[63] Opinion of AG Bobek in *Allianz*, *supra* n 5, para 64 (emphasis in the original).
[64] Ibid., para 65 (emphasis in the original).
[65] Ibid. para 66.
[66]*Dassonville*, *supra* n 62, para 5.
[67] See L. Gormley, "Inconsistencies and Misconceptions in the Free Movement of Goods" (2015) 40 *EL Rev* 925, 928-929.
[68] B. van Leeuwen, "Market Access, the New Approach and Private Law" (2019) 27 *ERPL* 269, 276-278.

compensation for harm suffered as a result of defective products. As can be seen in the aftermath of the PIP breast implants scandal, the Product Liability Directive is not of much use if the manufacturer has gone bankrupt. PIP's bankruptcy has led to a number of cases – like *Schmitt* and *Allianz* – in which health protection-based arguments were advanced to push the Court to expand the scope of application of EU law. However, so far, the Court has not come to the rescue of consumers.

Although this is understandable from the perspective of the principle of conferral in Article 5 TEU,[69] it highlights the existence of a gap between the free movement of goods and the protection of health. The EU has been successful in creating a regulatory framework that has greatly improved free movement of goods. At the same time, it does not take full responsibility for protecting users of goods from harm. A parallel can be drawn with the judgment in *Schmitt*, where the Court refused to extend the application of the Medical Devices Directive to the liability of notified bodies vis-à-vis end-users of PIP breast implants. It remained for national law to regulate the conditions for liability. Again, the Court held that the role of the Medical Devices Directive was limited to regulating the conditions under which products could be placed on the market. Although the Court explicitly recognised that one of the aims of the Medical Devices Directive was to protect the health of patients,[70] this did not extend the application of the Medical Directives Directive to liability issues in private law. A similar approach was taken in *James Elliott* with regard to contractual liability.[71] In *James Elliott*, the Court held that, while the European standard regulated the conditions under which the product could lawfully be placed on the market, it did not regulate the conditions under which a supplier could be held liable in contract law because the supplied goods were not of satisfactory quality.[72] This was an issue for national law, which was not regulated by EU law. As a result, the role of EU law was again limited to regulating the *entry* of the product to the market.[73]

A more dynamic interpretation of the concept of market access could encourage the Court to extend the concept of the "use" of goods and its link to consumer behaviour to national rules on liability for damage caused by moved goods.[74] The foundations for such a consumer-based approach were laid in *Mickelsson and Roos*, in which the Court made a link between rules on the use of a product, the impact of these rules on consumers and the impact on trade. The next step would be for the Court to recognise that health protection is an essential pre-condition for consumers to be able to use a product in a safe and effective way. Such an approach would interpret market access as a *process* rather than a moment.[75] From the consumer's point of view, free movement of goods does not end at the border – consumers are mostly interested in the safe and effective use of a product.

The Court's recognition in *Schmitt* that the Medical Devices Directive has as one of its aims to protect the health of end-users could be relied on to make a more explicit connection between free movement of goods and health protection. Consumer protection and health protection are not only justifications that allow Member States to restrict free movement – they are also essential conditions for the exercise of free movement of goods to be successful. This is explicitly recognised in Article 114(3) TFEU, which provides the legal basis for EU regulation of the internal

[69] See S. Weatherill, *The Internal Market as a Legal Concept* (OUP, 2017), 90-93.
[70] *Schmitt*, *supra* n 6, paras 49-53.
[71] Case C-613/14, *James Elliott*, EU:C:2016 :821.
[72] For a detailed analysis, see A. Volpato, "The harmonised standards before the ECJ: *James Elliott Construction*" (2017) 52 *CML Rev* 591.
[73] Van Leeuwen, *supra* n 68, 276-278.
[74] Ibid., 282-284.
[75] Ibid., 282.

market. EU law has an important role to play in ensuring that free movement of goods is about the free movement of *safe* and *healthy* goods.

One way to push the Court towards a more extensive interpretation of the concept of market access could be to establish a link to the protection of fundamental rights. One only has to look at cases like *Ruiz Zambrano*[76] or *Carpenter*[77] to understand the crucial role of fundamental rights in the decision of the Court to extend the scope of application of free movement law to cases with a marginal connection to movement between Member States. In both cases, the Court did not explicitly rely on the Charter. It held that the national rules constituted an obstacle to the effective exercise of free movement rights. However, as has been argued by Nic Shuibhne, the Court's desire to protect the right to family life constituted an important reason to be more flexible in finding that the cases fell within the scope of application of the free movement provisions.[78] In other words, if a case has a strong fundamental rights dimension, this could be a reason for the Court to be more "generous" in finding that cases fall within the scope of free movement law.

This generosity was not shown by the Court in *Allianz*, although there was a clear link to the protection of fundamental rights. While the Court did not refer to the Charter at all, AG Bobek did recognise the relevance of Article 38. The Court could have made a more explicit link to Article 38, which provides that the EU "shall ensure a high level of consumer protection", and Article 35 of the Charter, which provides that "a high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities". However, neither Article 35 nor Article 38 is a directly effective right that can be enforced by individuals before the national courts, and both articles are primarily aimed at the EU ("Union policies shall ensure…") rather than the Member States. As such, it would be difficult to argue that these articles can be directly relied on to extend the scope of application of the free movement provisions.

Nevertheless, since the free movement of goods remains one of the core policies of the EU – both through positive and negative integration –, the fundamental rights dimension of cases like *Allianz* could be relied on to make a stronger connection between free movement law and the protection of (consumer) health. If this protection cannot be provided by the free movement provisions, an alternative approach would be to include more precise rules on liability in the directives adopted under the New Approach. We will return to this in the conclusion.

5.3 Article 18 TFEU as a free-standing prohibition on non-discrimination

Allianz confirms the limited role of Article 18 TFEU as a free-standing right to non-discrimination in free movement law. Article 18 TFEU can be relied on only if there is a connection to another provision of primary or secondary EU law that brings the case within the scope of application of EU law. The Court requires "a specific connecting factor linking the person, service or goods concerned and the alleged discrimination" for Article 18 TFEU to be applicable.[79] In other words, Article 18 TFEU does not have the independent "power" to bring a case within the scope of application of EU law. Its role is to fill existing gaps in EU law – it does not dig new ones.

There are very few cases in which the Court found a breach of Article 18 TFEU alone. The most prominent case was *Collins*,[80] which concerned the ability of non-nationals to protect their

[76] Case C-34/09, *Ruiz Zambrano*, EU:C:2011:204.
[77] Case C-60/00, *Carpenter*, EU:C:2002:434.
[78] Nic Shuibhne, *supra* n 46, 131-143.
[79] *Allianz*, *supra* n 5, para 46.
[80] Case C-92/92, *Collins*, EU:C:1993:847.

intellectual property rights before the German courts. The German legislation at the time provided for a right of action for German nationals only. This case was brought on the basis of Article 18 TFEU – primarily because there was some uncertainty (at the time) about whether intellectual property rights were covered by Article 34 TFEU. In his Opinion, AG Jacobs had emphasised the important role played by Article 18 TFEU in closing "any gaps left by the more specific provisions of the Treaty".[81] The Court found a breach of Article 18 TFEU because the case had a close connection to the free movement of goods, the free movement of services and competition law.[82] In fact, if a similar case was brought today, it would probably have been brought on the basis of Article 34 TFEU. Similarly, in *Data Delecta*, an English company was made to pay security of costs in a contractual claim (relating to the supply of goods) brought against a Swedish company before the Swedish courts.[83] This obligation was not applicable to Swedish companies. The Court followed its judgment in *Collins* and held that Article 18 TFEU was applicable without there being a need to assess the case under any of the specific Treaty provisions.[84] The fact that there was a link to the free movement of goods was sufficient to bring the case within the scope of application of EU law for the purpose of Article 18 TFEU.[85]

The common feature of these cases was that individuals or companies were being discriminated in the enforcement of contractual or intellectual property rights which were closely linked to the exercise of their free movement rights. All cases had a strong procedural dimension – the relevant national procedural rules discriminated against individuals or companies from other Member States. The Court made a link between (1) the primary exercise of free movement rights and (2) the subsequent enforcement of rights before the national courts linked to the exercise of these free movement rights.[86] Article 18 TFEU could be applied to situations under (2) only because there was a direct link between (1) and (2).

What distinguishes these cases from *Allianz* is that there was a *direct* and *personal* link between (1) and (2). In all cases, the party relying on Article 18 TFEU had previously exercised their free movement rights. In other words, they were responsible for bringing the case within the scope of application of EU law. In *Allianz*, the connection between (1) and (2) was missing – there was a "mismatch" between (1) and (2). RB, who was relying on Article 18 TFEU in a private liability claim against Allianz (2), had not exercised any free movement rights herself. And although the breast implants had been moved from France to Germany (1), the claim under (2) was not brought by a party which was responsible for their production or import. *Allianz* shows that the party which is relying on Article 18 TFEU must have been responsible for bringing the case within the scope of application of EU law.

As a result, the main focus of *Allianz* is on the requirement of a link between the primary exercise of free movement rights and the subsequent reliance on Article 18 TFEU – the "specific connecting factor" between the exercise of free movement rights and the alleged discrimination. It could be argued that the Court has effectively introduced an additional condition for the application of Article 18 TFEU as a free-standing right. Article 18 TFEU can only be relied on by a party which has previously exercised their free movement rights, and which has established a link

[81] Opinion of AG Jacobs in *Collins*, *supra* n 80, para 12.
[82] *Collins*, *supra* n 80, paras 22-26.
[83] Case C-43/95, *Data Delecta Aktiebolag*, EU:C:1996:357.
[84] Ibid., para 15.
[85] See also C-398/92, *Mund & Fester*, EU:C:1994:52; and C-122/96, *Saldanha*, EU:C:1997:458.
[86] Although most cases were about the enforcement of private law (contractual, tort or IP) rights, *Cowan* is a famous example of an Article 18 TFEU case about the enforcement of a public right for compensation against the State for harm caused by crimes: Case C-196/87, *Cowan*, EU:C:1989:47.

between the alleged discrimination and their own exercise of free movement rights. There was no need to emphasise this condition in the older cases, because there was a direct link between the exercise of free movement rights and the discrimination. Nevertheless, the Court could have been much more precise and explicit in setting out this requirement in *Allianz*. Rather than talking about "a situation" which is linked to one of the free movement provisions, it would have been clearer if the Court had stated that the party who is relying on Article 18 TFEU should have exercised their free movement rights and that the reliance on Article 18 TFEU should be directly linked to the exercise of these free movement rights. This requirement of a direct and personal link between the discrimination and the exercise of free movement rights would be clearer than the requirement of a "situation linked by a specific connecting factor".

To conclude, it is clear that the Court has limited the role of Article 18 TFEU to situations where the party who is relying on it has previously exercised free movement rights. This limits the significance and scope of application of Article 18 TFEU. It cannot be applied if there is a specific provision of EU law which is applicable, but it cannot be applied without a link to a specific provision of EU law either. This best way to make sense of this paradox is to say that Article 18 TFEU can be relied on in situations where the primary exercise of free movement rights is not affected, but where the discrimination occurs in the "aftermath" of the initial exercise of free movement rights. In other words, Article 18 TFEU can still be relied on in "secondary" free movement situations. While this interpretation leaves some room for the application of Article 18 TFEU, it is clear that this role will remain limited. *Allianz* confirms that Article 18 TFEU cannot independently bring a case within the scope of application of EU law without a pre-existing link between the discrimination and the exercise of free movement rights.

5.4 The elephant in the room: the horizontal application of Article 18 TFEU

Because the Court concluded that the case did not come within the scope of application of EU law, it did not have to grapple with the substantive questions asked by the *Oberlandesgericht*. This is disappointing from an academic point of view, because it had asked some interesting questions about the horizontal application of Article 18 TFEU. German law has very well-developed constitutional law approaches to direct effect and indirect effect, and these were reflected in the questions submitted to the Court.[87] Although the analysis below remains entirely hypothetical – but hopefully not too remote –, it is important to analyse these questions in more detail. This is primarily because *Allianz* represents a good example of the complicated interaction between public and private parties in the regulation of the internal market.[88] This interaction has consequences for the question of which party should ultimately bear responsibility for breaches of free movement law.

The *Oberlandesgericht* had proposed two different approaches – one based on the horizontal direct effect of Article 18 TFEU; the second based on indirect effect, namely the obligation of the French State to respect free movement law. First, Article 18 TFEU could be applied horizontally to *Allianz* on the basis of *Angonese*.[89] In that case, which was assessed under Article 45 TFEU, the Court had stated explicitly that the prohibition of discrimination on the ground of nationality was applicable

[87] For a detailed analysis of these approaches, see E. Frantziou, *The Horizontal Effect of Fundamental Rights in the European Union* (OUP, 2019), 38-44.
[88] See B. van Leeuwen, "Private Regulation and Public Responsibility in the Internal Market" (2014) 33 *YEL* 277, 278-280.
[89] Case C-281/98, *Angonese*, EU:C:2000:296.

to private parties.[90] Alternatively, the *Oberlandesgericht* had referred to cases like *Walrave and Koch*[91] and *Ferlini*,[92] in which the free movement provisions were applied to private parties that exercised collective regulatory power – that were in a position to set "the rules of the game". Under this approach, it would be less clear whether Article 18 TFEU could be applied to Allianz. After all, Allianz was obliged by the French State to provide an insurance policy to PIP under the relevant French legislation. At the same time, Allianz was in a position to impose the terms of the policy on PIP – including the territorial restriction clause. Although Allianz might not have been in a general position of regulatory power in the insurance market for medical devices, it was in a position of power towards PIP in this particular situation.

The second approach proposed by the *Oberlandesgericht* was to focus on the relationship between Allianz and the BCT, the French supervisory authority that had the power under French law to force Allianz to conclude an insurance policy with PIP. Although French lawyers might argue about whether the BCT had the power to do this under French law, the BCT could in theory have objected to the territorial restriction clause. When the clause was proposed by Allianz, the BCT could have said "no" to it. As a result, it could be argued that the BCT implicitly authorised Allianz to adopt a discriminatory clause.

It seems likely that, regardless of the preferred approach, Article 18 TFEU would have been applied to this case if it had come within the scope of EU law. Nevertheless, the choice between focussing on Allianz or the French State would have consequences for the question which party would ultimately be held responsible for compensating patients like RB for the harm they suffered.[93] The link between direct effect, responsibility and liability remains underdeveloped by the Court.[94] With a horizontal direct effect approach, Allianz would have to compensate RB directly. It would have no recourse against the French State. If an indirect effect approach were preferred, Allianz might initially have to compensate RB. However, in the end, it would be able to claim the damages back from the French State through a claim for State liability.

It is submitted that this would be the preferred approach in this case. After all, the BCT's non-objection to the territorial restriction clause can ultimately be traced back to – and was based on – the relevant French legislation. There was no requirement in the French legislation to protect against harm that occurred outside France. The BCT did not have the power to impose an EU-wide cover of the insurance policy on Allianz. Against this background, it is not surprising that Allianz sought to include this clause and that the BCT did not object to it. It is clear example of a case where the discriminatory actions of a private party were authorised by the State. As an insurer, Allianz operated in a regulatory framework that was developed and controlled by the State.[95] Therefore, if the Court had found a breach of Article 18 TFEU, it should have recognised that the French State was responsible for paying compensation to victims like RB.

6. Conclusion

[90] Ibid., para 36. See C. Krenn, "A Missing Piece in the Horizontal Effect Jigsaw: Horizontal Direct Effect and the Free Movement of Goods" (2012) 49 *CML Rev* 177, 192-195

[91] Case C-36/74, *Walrave and Koch*, EU:C:1974:140.

[92] Case C-411/98, *Ferlini*, EU:C:2000:530.

[93] Van Leeuwen, *supra* n 88, 284-285. See also H. Schepel, "Constitutionalising the Market, Marketising the Constitution, and to Tell the Difference: On the Horizontal Application of the Free Movement Provisions in EU Law" (2012) 18 *ELJ* 177.

[94] See also E. Frantziou, "The Horizontal Effect of the Charter: Towards an Understanding of Horizontality as a Structural Constitutional Principle?" (2020) 22 *CYELS* 208.

[95] Van Leeuwen, *supra* n 88, 289-290.

The broader conclusion of *Allianz* is that EU law has not come to the rescue of the many women who received defective breast implants manufactured by PIP across the EU. Similarly to the judgment in *Schmitt*, in which the Court held that secondary EU law did not regulate the conditions for the liability of notified bodies under national law, *Allianz* makes it clear that the free movement provisions do not regulate the conditions under which insurers can be held liable in national law for harm caused by defective products. In both cases, the Court was unwilling to establish a broader link between the free movement of goods and liability for defective products in private law. This is understandable from the principle of conferral in Article 5 TEU. At the same time, it leaves something of a gap between facilitating free movement of goods in the EU and protecting the health of consumers who receive and use these goods. In bridging this gap, a more important role could be given to the fundamental rights of consumer and health protection in the Charter. Another way of looking at this, referred to by AG Bobek in his Opinion,[96] is that there has been a lack of responsibility on the part of the EU to take action against the negative consequences of free movement of goods in the EU.

Overall, the victims of the PIP breast implants scandal could not be blamed for arguing that free movement of goods in the EU is not really about the free movement of *safe* goods. The extent to which the EU is taking responsibility for protecting victims of defective products remains limited. The Product Liability Directive is not of much use if the manufacturer has gone bankrupt. The regulatory framework for medical devices was improved with the adoption of the Medical Devices Regulation in 2017.[97] However, the changes made by this Regulation were not very extensive. Most importantly, the new Regulation does not provide an obligation on the manufacturer to take out liability insurance. This remains an issue that is regulated by national law.

The various cases in the aftermath of the PIP scandal have shown that the current regulatory framework for medical devices does not provide sufficient protection to the right to health of consumers. Although the EU has introduced a stricter regulatory framework for medical devices in 2017, it is not difficult to identify gaps in the current consumer and health protection provided by the Medical Devices Regulation.[98] Articles 35 and 38 of the Charter explicitly provide that the Union "shall ensure a high level" of consumer protection and health protection. Similarly, Article 114(3) TFEU confirms that the EU will take a high level of health protection as its base for the adoption of harmonisation.

To improve this situation, the EU should adopt more precise rules on the liability of manufacturers, notified bodies and insurers who are operating under the New Approach. The most effective and consistent way of doing this would be to include these rules in the directives that are adopted under the New Approach. Although the Court may have pushed the ball back to national law in *Allianz*, the judgment is likely to lead to an increased pressure on the EU legislature to take additional action to protect the health of consumers.

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[96] Opinion of AG Bobek in *Allianz*, *supra* n 5, para 105.

[97] Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation 178/02 and Regulation (EC) 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] OJ L 117.

[98] Verbruggen and Van Leeuwen, *supra* n 4, 404-405.

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