

Case Note

The Court as Pontius Pilate: Reflecting on Missed Opportunities in the PIP Decision

Case C-219/15 Judgment of the Court (First Chamber), Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH [2017] ECLI:EU:C:2017:128

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On 16 February 2017 the Court of Justice issued a long-awaited preliminary ruling on three questions referred by the German *Bundesgerichtshof* on the interpretation of Directive 93/42/EEC regarding the scope of and conditions for liability (to end users) of notified bodies responsible for quality assurance assessments of Class III medical devices.¹ The case involves a woman affected by the notorious PIP breast implants scandal, and the questions referred provided a unique opportunity for the Court to address pressing issues relating to the EU's New Approach regulatory architecture, in particular as regards the scope of liability of private or hybrid bodies exercising public regulatory functions. Unfortunately the issue was not tackled at its core, and the judgment ap-

pears to throw the ball back to national courts without providing effective guidance as to how the EU designed ex ante regulatory framework should interact with the ex post management of risks and allocation of liabilities.

I. The Facts and Dispute in the Main Proceedings

In late 2008 Mrs Elisabeth Schmitt had silicone breast implants, manufactured by the French company Poly Implant Prothèse (PIP), fitted in Germany. TÜV Rheinland had been appointed by PIP as the notified body (NB) in charge of the quality control leading to the EC declaration of conformity under article 16.6 of the Medical Devices Directive 93/42 (MD Directive).² It is worth recalling from the onset that a notified body is 'a certification body which has been accredited to undertake conformity assessment procedures by the Member State in which it is based and which has been notified by the Member State to the European Commission.'³ The assessment carried out by the NB is the essential step leading to the manufacturer putting the CE mark on their devices, which serves as a declaration that the device complies with the required technical standards. The nature of these bodies depends on how they are framed in national law, the vast majority, including TÜV Rheinland, being private.⁴ Between 1998 and 2008, TÜV Rheinland visited PIP's premises eight times, always announced, during which it never inspected business records or individual devices. Between 2009 and 2010 the responsible French authority discovered that a significant amount of breast implants had been produced using low-grade industrial silicone instead of

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1 Case C-219/15 Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH [2017] ECLI:EU:C:2017:128.

2 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ 1993 L 169, in its version amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in art 251 of the EC Treaty [2003] OJ L284. Subsequent amendments do not apply to this case. The Directive will be replaced by spring 2020 by the recently adopted Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, 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/EEC.

3 Barend Van Leuween, 'PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies' (2014) 5 European Journal of Risk Regulation 338, 340. See also art 16 of the MD Directive.

4 TÜV Rheinland is a leading testing service provider, based in Germany but operating worldwide, offering, inter alia, products and components certification of quality, as well as compliance certification of manufacturing processes. In the year 2015, TÜV Rheinland set a revenue record of € 1,88 billion for the provision of safety and quality testing and certification services.

the medical graded silicone required by the relevant quality standards.

Mrs Schmitt had her implants removed in 2012. She then sued TÜV Rheinland for failure to adequately fulfil its obligation under the MD Directive, arguing that simply inspecting PIP's business records (delivery notes and invoices) would have been sufficient to discover the manufacturer's fraud. Having been unsuccessful at first instance and on appeal, Mrs Schmitt brought a final appeal before the *Bundesgerichtshof* (the referring court). Under German law, for TÜV Rheinland to incur liability it must have infringed either a rule conferring legal protection on an individual interest or a contractual obligation. The referring court turned to the Court of Justice (CJEU) for guidance as the resolution of the controversy depends on the precise purpose of a NB's involvement in quality assurance processes and its obligations therein under the MD Directive. Three questions were referred:

1. Whether the NB should act to protect all potential patients and may, in case of culpable infringement of an obligation, have 'direct and unrestricted liability towards the patients concerned';
2. Whether the NB is under a general obligation to examine devices, or to do so when there is due cause;
3. Whether the NB is under a general obligation to examine the manufacturer's business records and/or carry out unannounced inspections, or to do so when there is due cause.

II. Judgment of the Court

1. Obligations to Examine Devices and/or Business Records

Starting with a joint answer to the second and third questions, the Court begins by observing that while Annex II to the MD Directive sets out a series of specific obligations to be complied with by the NB, no reference is made to a general obligation to carry out unannounced inspections, examine devices and/or business records.⁵ On the other hand, several provisions make room for the NB to carry out such measures,⁶ which the manufacturer is under an obligation to allow, in the procedure leading to EC declaration of conformity. The Court adopts the observation made by interested parties that the wording and over-

all scheme of the Directive makes these measures optional.⁷ There is, in other words, a necessary component of discretion that a NB should be able to exercise in the discharge of its duty. The Court acknowledges the reasoning of AG Sharpston who, in her Opinion, stresses the importance of such discretion to be granted to NBs that must satisfy the highest degree of professional integrity and competence in the field. Burdening these bodies with over-prescriptive requirements would essentially defeat the purpose of relying on their expertise for the conduct of quality assurance processes.⁸ However, for such discretion not to defeat the purpose of quality assurance, the Court concludes that while there shall be no general obligation to conduct unannounced inspections and/or inspect devices or business records, the NB must, in the exercise of its due diligence, 'take all steps necessary to ensure that it fulfils its obligations' as set out in the Directive (including such inspections, which are, as noted above, optional in the wording and general scheme of the Directive).⁹

2. General Duty to Protect End Users and Liability

The first question asks whether it is the purpose of a NB's involvement in the EC declaration of conformity to protect end users of medical devices, and whether a culpable failure of that body to comply with its obligations would make it liable to such users.

The Court starts by making reference to its judgment in *Nordiska Dental*¹⁰ to clarify that the aim of the Directive is indeed to protect end users of medical devices as it is not limited to 'the protection of

⁵ C-219/15 Elisabeth Schmitt (n 1) para 39-40.

⁶ *ibid* para 41-43.

⁷ C-219/15 Elisabeth Schmitt (n 1), para 44, it is not yet possible to establish to which interested parties the Court is referring to specifically here, but see Opinion of Advocate General Sharpston in Case C-219/15 *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH* [2016] ECLI:EU:C:2016:694, para 23: 'Written observations have been submitted by Ms Schmitt, TÜV Rheinland, the French and German Governments, Ireland and the Commission. At the hearing on 26 May 2016, Ms Schmitt, TÜV Rheinland, the German Government, Ireland and the Commission presented oral argument.'

⁸ Opinion C-219/15 Elisabeth Schmitt (n 7), para 44.

⁹ C-219/15 Elisabeth Schmitt(n 1) para 47-48.

¹⁰ Case C-288/08 *Kemikalieinspektionen v Nordska Dental AB* [2009] ECLI:EU:C:2009:718.

health *stricto sensu*, but also the safety of persons'.¹¹ The burden of protection is primarily incumbent on the manufacturer but it extends to Member States and NBs. The Court notes that Member States have a specific obligation as regards surveillance of the market, which, as noted in *Lohmann & Rauscher International*,¹² in combination with pre-marketing assessment duties, 'ensures protection of health and safety of persons'.¹³ Regarding NBs, the court simply notes that 'it is apparent from the wording and overall scheme of [the MD Directive] that the purpose of [the EC declaration of conformity] procedure is to ensure protection of health and safety of persons'.¹⁴

Having solved the first part of the puzzle in the affirmative, the question is now whether an NB should be liable to an end user in case of culpable infringement of its obligations. The Court refers to *Peter Paul* to reiterate their position on the consequences of the imposition of surveillance duties, even when a Directive's aim includes the protection of identified parties.¹⁵ For the Court it does not necessarily flow from the existence of such duties that the protected parties should have a right and a consequent remedy

when relevant surveying bodies fail to fulfil their obligations, particularly when the Directive makes no explicit provision for it. The Court goes on to reason that it cannot be extrapolated from the wording and general scheme of the MD Directive that it aims at establishing the conditions for end users of medical devices to sue NBs in compensation.¹⁶ After underlining that the simple requirement that NBs take out civil liability insurance is insufficient to establish the existence of a right for end users to seek compensation from them, the Court brings its reasoning to an end. Observing that the Product Liability Directive 85/374¹⁷ does not 'preclude the application of other systems of contractual or non contractual liability based on other grounds',¹⁸ the Court concludes that it is for national law, subject to the principles of equivalence and effectiveness, to establish the conditions allowing an end user to sue a NB in liability for culpable failure to fulfil its obligations under the MD Directive.

III. Comment

In the author's opinion this is a rather unsatisfactory judgment. The Court appears to have taken a 'Pilatesque' attitude and ultimately washed its hands of the fundamental issue at the core of the case: whether and to what extent there should be liability of private parties exercising public regulatory functions within the framework of the New Approach to regulation of goods, and specifically medical devices.¹⁹ The issue remains essentially unresolved leaving national courts to deal with an EU made problem without proper EU judicial guidance.

1. Some Background on the Pip Scandal and Notified Bodies

Before going on to analyse the decision it will be useful to give a little more background on the PIP breast implants scandal. The case of Mrs Schmitt did not happen in a vacuum: some 400,000 women worldwide have received PIP implants, 30,000 of whom were in France, and 5,000 in Germany. As simply and effectively put by Clotilde Jourdain-Fortier: '*L'affaire PIP n'illustre pas autre chose que la difficulté à construire un droit protecteur de la personne dans un contexte de mondialisation.*'²⁰ In order to cut costs,

11 C-219/15 Elisabeth Schmitt (n 1) para 50.

12 Case C-662/15 *Lohmann & Rauscher International GmbH & Co. KG v BIOS Medical Services GmbH* [2016] ECLI:EU:C:2016:903.

13 C-219/15 Elisabeth Schmitt (n 1) para 52. The monitoring role of Member States is expected to be increased by the entry into force of the new Medical Devices Regulation in 2020 (n 2).

14 C-219/15 Elisabeth Schmitt (n 1) para 53.

15 Case C-222/02 *Peter Paul, Cornelia Sonnen-Lütte and Christel Mörkens v Bundesrepublik Deutschland* [2004] ECLI:EU:C:2004:606.

16 C-219/15 Elisabeth Schmitt (n 1) para 56.

17 Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regs and administrative provisions of the Member States concerning liability for defective products [1985] OJ L210.

18 C-219/15 Elisabeth Schmitt (n 1) para 58.

19 The New Approach to regulation of goods is that eminently EU construction whereby framework directives refrain from dictating technical requirements, the contents and monitoring of which are effectively outsourced to standardization, monitoring or certification bodies (public, private or hybrid). See Harm Shepel, *The Constitution of Private Governance – Product Standards in the Regulation of Integrating Markets* (Hart, Oxford 2005); and more recently Harm Shepel, 'The New Approach to the New Approach: the Juridification of Harmonized Standards in EU Law' (2013) 12 *Maastricht Journal of European and Comparative Law* 521.

20 Clotilde Jourdain-Fortier, 'L'affaire PIP ou la difficile réparation en Europe des dommages corporels de masse causés par un dispositif médical défectueux' (2015) *Revue Internationale de Droit Economique* 2015/1 (T. XXXIX) 5, 6: 'The PIP case illustrates but the difficulty of creating adequate legal protections for individuals in a global context'.

through a complex scheme of deceit, PIP started producing and distributing breast implants filled with low-grade industrial silicone gel instead of the required medical graded one. As early as 2000, the US Food and Drug Administration (FDA) discovered that PIP was using sub-standard silicone and temporarily took PIP implants off the market. In 2009, the *Agence Française de Sécurité Sanitaire des Produits de Santé* (AFSSPS)²¹ was notified of repeated sub-standard silicone use in PIP implants. AFSSPS took them off the market in 2010, and simultaneously warned all other regulatory agencies throughout the EU. Around that time PIP went bankrupt and into liquidation.

Several complications need to be considered here. First, the deceitful scheme was essentially random: some implants were made with medical graded silicone, some with a mixture of medical and industrial silicone, and others only with the industrial one. It has been (and still is) extremely difficult to ascertain how many women (and which ones) got which type of implant. Secondly, the effects of having implants with industrial silicone gel are far from certain. While there is consensus that these implants are at significantly higher risk of rupture than the medically graded ones, the risks to health of industrial gel leaking into the body are hotly contested. It is noteworthy that studies looking into the matter have come up with differing conclusions. One European study refuted the claim that such sub-standard implants carry a higher risk to health,²² while an analogous French study remained agnostic on that assertion.²³ Unsurprisingly, victims of the deceit continue to advocate for the existence of an increased risk (which, in turn, would make the PIP case a product safety one, triggering different sets of remedies, such as the liability of the manufacturer as further discussed below).²⁴

Given the inherent randomness of the scheme and the uncertainty regarding risks to health, a number of women decided to have their implants removed without waiting for the potential rupture. Elisabeth Schmitt is one of these women and as the manufacturer PIP is no longer solvent, she decided to sue the NB in charge of quality control seeking 40,000 euro 'by way of compensation for non-material damage and a declaration that the [notified body] is liable for any material damage that may arise in the future'.²⁵ The CJEU was then asked, in essence, to delineate the contours of the NB's liability.

2. Limited Guidance for National Courts

a. A Positive Doctrinal Clarification

The decision in *Schmitt* has one positive element, and that is a clarification in no uncertain terms, as discussed above, that the protection of end users of medical devices is an integral part of the aim of the MD Directive and, therefore, of the function of NBs. In providing this clarification, the decision was able to answer the first question referred to the Court of Justice.

It should be noted here that when Mrs Schmitt sued TÜV Rheinland in Germany, the action failed at first instance and on appeal on the grounds that there could be no liability of the NB for infringing an obligation under a contract with the manufacturer. The activities connected with the certification process serve only the purpose of ensuring compliance with requirements to place a medical device on the market and not that of protection of third parties. The inclusion of a third party such as Mrs Schmitt, when it was clearly not the intention of the NB to have that third party included, would extend the liability of the NB beyond reason, *in the absence of any legitimate interest in that regard*.²⁶ There could be no civil liability either as, in the German courts' reading of the MD Directive, it was not the purpose of the NB's activity to protect patients, and in any event no fault could be established in the case at hand as TÜV Rheinland had conducted regular announced visits to the manufacturer's premises.²⁷

The finding of the Court in *Schmitt* is particularly important from a doctrinal perspective for the future claims against NBs in German courts. So far, every single lawsuit brought against TÜV Rheinland as a

21 Subsequently replaced by *Agence Nationale de Sécurité du Médicament et des Produits de Santé*.

22 European Commission, Scientific Committee on Emerging and Newly Identified Health Risks, 'Preliminary Opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants (2013 update)', September 2013.

23 Agence Nationale de Sécurité du Médicament et des Produits de Santé, 'Prothèses mammaires et cas de lymphomes anaplasiques à grandes cellules' (Communiqué, 17 March 2015).

24 Jourdain-Fortier (n 20) 7-9.

25 C-219/15 Elisabeth Schmitt (n 1) para 28.

26 *ibid* (n 1) para 30.

27 *ibid* para 31.

consequence of the PIP scandal has failed because,²⁸ just as in the case of Mrs Schmitt, no court has accepted that it is the purpose of the MD Directive to burden NBs with a protected interest of patients. The clarification offered by *Schmitt* is certainly to be welcomed as a legitimate interest is now undisputable. However, by leaving the point of specific obligations open to national interpretation the Court only offers a halfway solution that runs the risk of making such a positive clarification toothless.

b. Specific Unsatisfactory Outcomes

The second reason German courts (including in the case at hand) have been reluctant to impose liability on NBs is the fact that courts have relied on the black letter wording of Annex II of the MD Directive, which, as suggested above in the summary of the judgment, does not include compulsory inspections of individual devices and/or business records, or unannounced inspections. These are all optional measures the NB can choose to perform. If this is to be the reading of specific obligations guiding courts in the future for the establishment of ‘culpable infringements’ triggering ‘direct and unrestricted liability’ towards patients, there is a concrete possibility that very little might change in future case law. The CJEU has introduced an obligation to ‘take all necessary steps’ when, in the face of emerging evidence, it is apparent that the medical device does not comply with the MD Directive’s requirements. It is to be assumed that the evidence can emerge in a variety of ways, e.g. from the NB’s inspections to whistleblowing. Yet, by avoiding the issue of what can be expected to fall within the general due diligence obligation of an NB entrusted with patient protection, the court appears to wash its hands of a cru-

cial factor in the equation. It is to be expected that the case of Mrs Schmitt will fail, when the proceedings resume, as no specific culpable infringement of an obligation laid down in Annex II appears to have happened, notwithstanding the fact that the NB has failed to perform a function as banal as inspecting business records. Why this function would not be considered as an integral part of an NB’s general due diligence, beyond the pure black letter of Annex II, remains a little mysterious.²⁹ A key issue in this regard is that monitoring the market for the protection of safety, according to German courts, is the prerogative of public authorities, not certifying bodies such as NBs.³⁰

The halfway attitude adopted by the court is frustrating for a number of reasons. The protection of patients, while resoundingly affirmed in principle, is left to national courts to figure out in practice. It is concerning that the Court refers to its decision in *Peter Paul*, adapting to the *Schmitt* context the controversial notion that the existence of a surveillance duty on specific bodies to protect identified parties does not necessarily imply the existence of a remedy for injured parties against the failures of such bodies.

It should be clear now that German courts will be able to maintain their current course of action, and it is interesting to observe that radically contrasting decisions have been upheld elsewhere. French courts in particular have held TÜV Rheinland liable in the past on the basis that NBs exercise delegated public functions,³¹ and embraced a broader notion of due diligence, whereby the incidents of 2000 should have been sufficient to trigger a duty to conduct thorough (and unannounced) inspections which would have easily revealed PIP’s deceit. Unless German courts were to change their conception of due diligence in light of the clarification of the Directive’s scope, *Schmitt* leaves the door wide open to continuing uneven levels of protection of end users in cases involving NBs.

3. Ignoring the Elephant in the Room?

The elephant in the room is the EU regulatory framework known as the ‘New Approach’ to regulation of goods, and specifically, for the purposes of this case, medical devices.³² While a full account of the consequences of *Schmitt* in the field is beyond the scope

28 For an in-depth discussion see Van Leuween (n 3) 343-345; Peter Rott and Carolina Glinski, ‘Le Scandale PIP devant les Jurisdictions Allemandes’ (2015) T. XXXIX Revue Internationale de Droit Economique 2015/1 87, 92-96.

29 This point is discussed in general terms by Rott and Glinski (n 28) 95 who go further and lament the fundamental inadequacy of relying exclusively on announced visits.

30 This was one of the central points of the important Judgment of Landgericht Frankenthal (Pfalz) of 14 March 2013 – 6 O 304/12, discussed at length by Van Leuween (n 3) 343-345.

31 The key decision is the Judgment of Tribunal de Commerce in Toulon of 14 November 2013, discussed in Jourdain-Fortier (n 20) 32-33.

32 See n 19.

of this case note, a few preliminary reflections can be made. Let us start by observing that, under the MD Directive, the major actors responsible for the protection of health and safety of patients are the manufacturer, the Member State (MS), and the NBs.

The manufacturer is clearly identified in the MD Directive as the actor principally responsible for the safety of its products.³³ This regulatory provision is backed up by a very stringent product liability regime emerging from the recent reading of the Product Liability Directive 374/85/EC (PL Directive) in *Boston Scientific*.³⁴ Much has been written on this decision,³⁵ but in a nutshell, the major point of contention is that, for the Court, products having a potential defect can be considered defective without the need to prove that a specific product has a specific defect.³⁶ This broad and general conclusion is essentially motivated by the fact that implantable medical devices are inherently potentially very dangerous, and patients should therefore be entitled to elevated levels of protection and effective remedies against the entity who places the product on the market for a profit. Reading between the lines of Advocate General Bot's Opinion in *Boston Scientific* the impression is that such a stringent regime is particularly necessary in a regulatory context (the New Approach context) that is far from flawless in its quality and safety control mechanisms.³⁷ From this perspective *Schmitt* is a disappointing decision for two sets of reasons.

First, it mentions product liability rules only to differentiate that scenario from the one of a liability emerging from violations of the MD Directive. While the judgment makes a passing reference to the Product Liability Directive simply to confirm that it allows for coexistence with different liability regimes based on other grounds, AG Sharpston makes it very clear that Product Liability rules are of no assistance in the context of the liability of NBs. This is because, she argues, the Product Liability Directive is solely concerned with the strict liability of manufacturers and therefore, since the fault of the NB is of the essence in the case at hand, no useful guidance can be drawn from it.³⁸ This seems to (at least temporarily) shut the door to the option nursed by scholars that NBs could be considered 'companions' of manufacturers in order to fall within the scope of application of the Product Liability Directive.³⁹

Secondly and more importantly, there is a clear and hardly explicable mismatch between the decisive

stance of *Boston Scientific* and the halfway attitude of *Schmitt*. This mismatch translates into significantly unbalanced liability regimes under the two legal frameworks, which is particularly surprising in light of the fact that both regimes share the fundamental aim of protecting end users. Yet NBs' liability receives a much lighter treatment, leaving a significant margin of manoeuvre for national law and national courts, while clear reference is made to the concept that from a breach of obligation a remedy does not necessarily ensue. This is not good news for patients who, in everyday reality, are often left without a remedy against the manufacturer who becomes insolvent (as is the case with PIP).

The third actor involved is the MS (and its emanations), to which the MD Directive clearly allocates an important share of the responsibility for product safety and market monitoring.⁴⁰ It must be noted at this point that on 5 April 2017 a new regulation on medical devices has been adopted (the new rules will apply as of spring 2020).⁴¹ The new regime will still be based on a New Approach framework involving NBs, and place particular emphasis on the responsibilities of State and public entities towards the achievement of end users' safety. Yet the problem here is that the CJEU case law on state liability, and particularly the principle that no rights and remedies should necessarily flow from the imposition of surveillance duties established in *Peter Paul*, might very

33 See in particular arts 1 and 2 of Annex II (headed 'EC declaration of conformity') to the MD Directive.

34 Joined Cases C-503/13 *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt - Die Gesundheitskasse* and C-504/13 *Betriebskrankenkasse RWE* [2015] ECLI:EU:C:2015:148.

35 See for example Lukas Bergkamp, 'Is there a Defect in the European Court's Defect Test? Musings about Acceptable Risks' (2015) 6 *European Journal of Risk Regulation* 309; Barend Van Leuween and Paul Verbruggen, 'Resuscitating Product Liability Law?' [2015] *European Review of Private Law* 899; Erdem Büyüksagis, 'La responsabilité du fait des produits 'défectueux sans défaut' [2016] *Droit de la consommation* 17.

36 C-503/13 *Boston Scientific* (n 35) para 43.

37 Opinion of AG Bot, Joined Cases C-503/13 *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt - Die Gesundheitskasse* and C-504/13 *Betriebskrankenkasse RWE* [2014] ECLI:EU:C:2014:2306, Opinion of AG Bot para 73.

38 *ibid* paras 31-32.

39 Van Leuween (n 3) 344.

40 See for example art 2(1) and (2) of the MD Directive.

41 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, 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/EEC.

well create a difficult obstacle to successful claims by injured patients even in the presence of failures to adequately supervise the market.

IV. Conclusion

The decision in *Schmitt*, read in conjunction with *Boston Scientific* and the controversial *Peter Paul*, creates a short-circuit in the overall scheme of allocation of tasks and liabilities in the field of implantable med-

ical devices. While the issue of state liability is a problem of its own (a much wider one, that cannot be adequately tackled here),⁴² as regards medical devices specifically it is hard to explain why the same court would adopt such contrasting attitudes towards the manufacturer and the NB, who have shared responsibilities in ensuring the safety and quality of marketed products. The first impression is that of a defense of the New Approach architecture. While a few years ago an interesting study conducted by Rob Van Gestel and Hans-W. Micklitz suggested that the CJEU was getting increasingly involved in the judicial review of the activities of EU private standardization bodies ('breaking down the club house'),⁴³ it appears when it comes to *preliminary rulings* involving the essence and architecture of the New Approach regulation (in this case of medical devices) the Court may remain standing in the 'club house's' corner, or at least, as Pontius Pilate would, wash its hands of the outcome of the contest. It will be for national courts and national laws to struggle their way out of an EU-made problem.⁴⁴

42 For an excellent overview of the state of state liability across EU jurisdictions see Rónán Condon and Barend Van Leuween, 'Bottom Up or Rock Bottom Harmonization? Francovich State Liability in National Courts' [2016] Yearbook of European Law 1.

43 Rob Van Gestel and Hans-W. Micklitz, 'European Integration through Standardization: How Judicial Review is Breaking Down the Club House of Private Standardization Bodies' (2013) 50 Common Market Law Review 145.

44 This case note was finalised at the end of May 2017. Since then, on the 22 June 2017, the German *Bundesgerichtshof* ruled in favour of TÜV Rheinland in the domestic controversy, following the interpretation of the MD Directive offered by the CJEU in *Schmitt* – BGH, 22 June 2017, VII ZR 26/14.