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What Liability with the Internet of Things? Insights from the European Case-Law of the PIP Affair

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Abstract: The purpose of this article is to explain why it is relevant to connect the European case-law on the Medical Devices Directive (MDD), by focussing on the defective breasts prostheses saga, to the future regulation of liability for healthcare IoT objects. I believe that by examining the recent case-law dealing with shortcomings in the regulation of medical devices, it will be possible to build a future liability scheme for defective IoT objects with medical functions. The article discusses how the new Medical Devices Regulation (MDR) is different from the previous MDD and whether it is likely to influence liability schemes for healthcare IoT objects. In conclusion, I argue that, however imperfect, the MDR could support the application of national liability systems in order to provide more effective and more protective liability schemes for IoT objects with medical functions.

Keywords: IoT, liability, EU law, national private law theories

1 Introduction

This article deals with several topics that, at a first glance, have very few things in common. Its purpose is to connect the question of liability under EU law with an effective risk-management policy and strategy when deploying new objects and technologies. The focus of this article will be the Internet of Things technology (IoT), whose characteristics will be outlined shortly (2). The core question that will be addressed in the following pages is why it is relevant to connect European case-law on the Medical Devices Directive (MDD)[1] to the future regulation of liability for healthcare IoT objects. It is believed that examining the recent case-law dealing

1 Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices [1993] OJ L 169/1.

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with some serious shortcomings in the regulation of medical devices under that Directive will be helpful in order to build a future liability regime for defective IoT objects entering the medical devices environment. The through-line connecting the three judicial cases that will be analysed and compared (3) lies not just in the applicability of the MDD but also in the facts themselves: they all originate as a consequence of the tragic scandal of the defective breast prostheses manufactured by French company PIP. At the moment, in case of negligent or fraudulent certification of complex medical devices, solutions for protecting citizens still reside in the legal traditions of different Member States (MS) more than in EU law (4). The article shall then discuss how the new Medical Devices Regulation (MDR), [2] which is applicable in the member states since May 26, 2021, is different from the previous MDD and whether the MDR is going to influence the liability regime applicable to IoT objects with healthcare functions (5). In conclusion, I will argue that the above mentioned case-law highlighted several problems in the certification method previously used for medical devices. Moreover I will argue that, however imperfect, the MDR could actually support the application of national liability systems in order to provide more effective and more protective liability regimes for IoT objects with medical functions (6).

2 The IoT

In technological terms, the IoT is an application of infra-red (RFID) technology and was originally known as M2M, meaning machine-to-machine communication. It works through different layers, and the most important of these for the legal field are the physical/perception layer (in or through the device) and the application/processing (in the fog or cloud) layer (Rayes and Salam 2019). IoT devices are equipped with sensors and actuators that transform physical data such as movement, voice commands, and temperature into electric inputs, and ultimately into data, which passes through a gateway in a cloud/proprietary network where it will be analysed and sent back for the device to react to (Ali and Awad 2018).

Since its inception, the IoT has had the potential to connect not only things but also *people* and things in an unprecedented way. Thanks to sensors, actuators, and radio-magnetic waves (Perry and Roda 2016), an environment can be truly connected, and, in some ways, intelligent. It is worth noting that two of the IoT investment targets that are receiving relevant funding for research are healthcare

2 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 [2017] OJ L 117/1.

(Quinde, Augusto, and Ouhbi 2020) and the smart home (Nativi et al. 2020). Most likely, in the near future it will be quite difficult to tell apart IoT objects specifically connected to healthcare and to the home environment: IoT technology is the ultimate result of the larger phenomenon of technological convergence, which sees the merging of different technologies into a single device. This makes it a major objective to achieve interoperability among smart devices so as to enable a single IoT object to perform different functions even within the same physical environment, e.g. to monitor our physical activity while checking on a reactive electronic equipment-management system through a series of applications for the smartphone.

The IoT is not just going to change the objects we use daily. The presence of software in these objects, and new techniques in edge computing (Hu and Seo 2019), and of the tactile internet (ITU 2014), are also bound to become the main co-generating technology for new consumer goods, such as educational robots for children, and new ways to treat people, both physically and psychologically.

As far as official efforts, the European Data Strategy of February 2020 refers indirectly to the IoT in dealing with the creation of several data clouds for industrial manufacture and healthcare.[3] In fact, the IoT would not work properly without access to data stored and processed in the cloud. The IoT is also a focus of the European Commission (EC) in its Liability Report, which also addresses AI and Robots.[4] Ultimately, the Toolbox on the construction of a safe 5G technology infrastructure will enable the IoT to reach its full potential (NIS Group 2020). Although some of the most recent EU consumer law regulations and directives seem to 'nod' at the IoT-market stakeholders whenever they list down words such as data sharing, algorithms, and software,[5] which are essential IoT-object parts or processes: they do not mention this technology explicitly; or rather, the IoT does get a mention, in the Free Flow of Data Regulation,[6] but this regulation does not say what the IoT is or how it works. Nevertheless, it seems that change is in progress within the framework of the EU Commission Digital Strategy. The recently presented proposal for a Regulation on harmonised rules on fair access to and use of data (better known as Data Act) does not describe IoT objects as such. However, there is an equivalence of the word 'product' to the concept of IoT object in the

3 European Commission, A European Strategy for Data, COM(2020) 66 final, 22.

4 European Commission, Report on the Safety and Liability Implications of Artificial Intelligence, the Internet of Things and Robotics, COM (2020) 64 final, 14–16.

5 Directive (EU) 2019/770 of the European Parliament and the Council of 20 May 2019 on certain aspects concerning contracts for the supply of digital content and services [2019] OJ L 136/1 at recital 14.

6 Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a Framework for the Free Flow of Non-personal Data in the European Union [2018] OJ L 59.

definition part (Article 2). This definition describes product as '*[…] a tangible, movable item where incorporated in an immovable item, that obtains generates or collects data concerning its use or environment, and that is able to communicate data via a publicly available electronic communications service and whose primary function is not the storing or processing of data*'.[7] Instead, to read the 'Internet of Things' expression one has to read the first recital of the proposal and it just refers to objects that process huge amounts of data.[8] It is worth noticing that the Data Act is still in the proposal phase and it is impossible to know today whether its indirect IoT definition as products will go unchanged throughout the ordinary legislative procedure. As concerns healthcare, neither the MDD nor the upcoming Medical Devices Regulation (MDR) mentions IoT objects. Still, it is important that they both consider software a possible component of devices in these objects.[9] Taking into consideration the Product Liability Directive (PLD),[10] the Commission set up two working groups: one has been charged with drafting guidelines for updating the PLD in light of the evolution of the jurisprudence issued by the Court of Justice of the European Union (CJEU, hereinafter Court of Justice);[11] the other one will be evaluating the impact of new technologies on the PLD.[12] How the PLD might suitably be adapted to new technologies is a matter of interest not only to the Commission but to academics and think thanks as well (Koch et al. 2022; Twigg-Flesner 2021).

At present, establishing a novel form of liability in connection with the use of domestic or personal IoT objects is still a power reserved for the single MS. One of the biggest challenges now being addressed is to determine whether past risk-management policy instruments and liability models can be adapted to the context that has emerged around this new technology (Guerra 2018). It is clear that the IoT

7 Article 2(2) of the Proposal for a Regulation (EU) of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act), COM(2022) 68 final 2022/0047.

8 Recital 1 Proposal for a Regulation (EU) of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act), COM(2022) 68 final 2022/0047.

9 Art. 2.1 RMD and Art. 1(2)(a) DMD.

10 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 210/29.

11 European Commission, REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE on the Application of the Council Directive on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products (85/374/EEC) COM/2018/246 final.

12 Expert Group on Liability and New Technologies – New Technologies Formation, *Liability for Artificial Intelligence and other emerging digital technologies* (2019), <https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeetingDoc&docid=36608> accessed 06 August 2022 hereinafter Expert Group Liability 2019.

is likely to revolutionise the functioning of medical devices (in practice, this process has already started) as it dramatically improves the quality of human–machine interaction and the possibility to monitor the patient virtually at any moment, even at a distance. Hence, it is worthwhile to consider the current cases on liability for defective medical devices in order to anticipate problems that might happen when the IoT will be fully integrated in the medical devices environment.

In order to start thinking about the practical and legal issues surrounding IoT liability, we can take as a good study case the model for certifying medical devices based on the so-called New Approach, a system under which responsibility is shared between private and public stakeholders (Wallerman 2018). Both the MDD and MDR were drafted taking this approach as a conceptual basis. The MDR is bound to have stronger effects on the creation of the single market by also including hybrid products such as IoT objects, even without mentioning them explicitly (see infra Section 5). One of the main points of discussion still under the MDD was whether Notified Bodies (NB/s)[13]—entities entrusted with certifying conformity with health and security standards for medical devices—have some kind of liability towards people injured by medical devices which turned out to have been defective and harmful because of negligence on the NB's part.

3 The PIP Affair: European Legislative Acts and Case-Law

As a preliminary matter, it will be necessary to address a legitimate question. One might wonder what the points of contact are between the IoT and medical devices. Apart from the fact that new medical devices could also very soon coincide with healthcare IoT (e.g. monitoring vests for telemedicine), medical devices as much as the IoT involve several actors, even across different states, in the manufacturing process. This implies that when accidents happen involving an IoT object or a medical device, there will frequently be a transnational element and a structural uncertainty about which liability rules to apply and how to allocate liability. That is precisely what happened with the PIP saga, which also sets the background for the three cases selected. These cases are important for different reasons. In the first case the Court of Justice set out its position on NB liability under EU law (3.1). The second one is a French case that applied the Court's previous judgement in an

13 Private, public, or private-public entities which have a role in auditing some classes of products under the former MDD and current RMD. More in 3.1.

original way (3.2). The third one concerns the relationship between NB liability and insurance schemes (3.3).

3.1 Factual Background and Applicable EU Law

Before delving into the case law, it is necessary to briefly outline the common origin of these three cases. Until 2010, PIP was a French company specialised in the manufacture of breast implants. At the beginning of the 2000s, problems began to crop up involving patients who had received PIP breast implants: some of these ruptured or caused irritations. Overall, they caused a deep state of anxiety among the women who had received these implants. Between 16 and 17 March 2010, during an inspection of PIP's facilities, the French agency for the security of medical products and drugs (AFSSAPS) discovered that, as a cost-cutting strategy, the special gel required for this kind of implant, Nusil, was being partly or totally replaced with regular industrial silicone gel. Subsequently, PIP went bankrupt and its insurer, Allianz, in the beginning, had successfully argued that the insurance contract was null and void under French contract law because of the fraud on the part of PIP. As a result, women could not seek compensation either from PIP, because it had gone bankrupt, or from its former insurer.

However, implants such as breast prostheses were covered under the MDD, which had been drafted to address the specificities of medical devices and to ensure a higher level of safety for patients.[14] The rationale behind this legislation was to classify medical devices into several classes depending on the level of harm they might cause. For each category of devices (four in total named I, IIa, IIb and III),[15] a series of technical and standardised procedures were specified in order not only to ensure the highest possible level of safety but also to manage the inherent risk attendant on some of these devices. In order to understand how to classify a medical device according to its level of risk and which procedure is to be followed, one had to go back and forth from the recital and operative part to the annexes. In this specific case one had to combine Article 9 MDD, which concerns the different classes, with Annex IX, which is about the classification rules and with Article 11 MDD on the rules of the different procedures and then Annexes II, III, IV, V or VI according to the procedure established by Article 11 MDD. For some devices which might entail more risk, it was necessary that extra precautions be taken. That is the case with devices in class III of the MDD, which now include breast implants.

14 Recital 11 MDD.

15 Recital 19 MDD and Article 9 MDD and Annex IX MDD.

Nevertheless, it is important to remember that breast prostheses at the time of the facts of the cases were classified in a lower class of risk (II b). Because of the facts described *supra* and the extent of the PIP scandal, the EU Commission decided to reclassify these medical devices to a higher class of risk (III) through directive EC/2003/12, with retroactive effect.[16] This system does not exclusively entail the involvement of independent national authorities, this unlike the American model, where the Food and Drug Administration (FDA) is the only agency involved: the EU model is more layered (Jarman et al. 2021). For the sake of the issue at hand, the focus of this article is restricted to breast implants exclusively as treated under the MDD. In this case, the manufacturer needed to ask to a series of NBs to carry out audits and checks in order to ensure that its devices respond to the highest technical and safety standards, and in order to obtain a declaration of conformity (the EC conformity certification) (De Bruyne and Vanleenhove 2016). These NBs are not all public authorities. Most of them are private entities, or of a mixed nature. Lists of these NBs are sent out by each Member State (MS) and notified to the to the EC,[17] which also groups them by country. To be eligible, NBs need to meet the requirements set out in Annexes II and VI of the MDD. If the chosen NB does not find irregularities or negligence in the process, which starts from a self-certification of conformity by the manufacturer, it will release the declaration of conformity and the product can circulate throughout the internal market. Most of the checks that are carried out are audits, but class III devices may be subject to inspection.[18] Recommendation 13/473 also granted NBs the power to carry out surprise checks and inspections on the manufacturer's premises (Jarman et al. 2021). However, the directive does not have an explicit article concerning NB liability towards patients and consumers. The only thing that resembles a reference to liability in the MDD for NBs is point 6 in Annex XI. This annex is actually the most relevant in terms of liability as it gave rise to the *Schmitt* and the *Cour de Cassation* cases (infra subparagraph 2.2 and 2.3): it is in this part of the directive that it is stated that '[…] it is mandatory for the body to take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member Stste itself carries out the inspections directly'.[19]

Even if the MDD is the EU law that applies to the three cases that will be discussed, it is useful to very briefly outline how it compares and contrasts with the upcoming MDR. The principal similarities and differences between the MDD and

16 Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices [2003] OJ L 028.

17 Art. 16 MDD.

18 MDD, Annex II, 1. And see in detail 5.

19 6 Annex XI.

the MDR and their relationship with the upcoming IoT for health and mixed IoT with consumer and medical functions are presented and discussed in Section 5, below.

3.2 The *Schmitt* Case

In Germany, where the *Schmitt* case originated, no courts in similar situations had found the defendant, TÜV, liable (Rott and Glinski 2015). This case gave the Court of Justice an opportunity to give its opinion in the matter.[20] However, it did that in what has been described as an 'incomplete and confused way' (Wallerman 2018). In the case at hand, the plaintiff had to endure the de-implantation of the PIP prostheses and decided to undergo another surgery with compliant prostheses. She sought compensation for the moral damage sustained. This case was brought to the attention of the *Bundesgerichtshof*, which decided to stay the proceedings and refer two questions to the Court of Justice on the interpretation of the MDD on the basis of Article 267 of the Treaty on the Functioning of the European Union (TFEU). The first one was whether the NB was liable as a result of the medical devices at issue not being compliant (not affording the requisite level of protection), making them unsafe. The second question was whether the NB was under a general obligation to make unannounced visits at the company site where these devices were being manufactured.

Here it is necessary to outline the main differences between the opinion of Advocate General (AG) Sharpston and the legal reasoning of the Court. AG Sharpston delivered an opinion[21] delving into the history of the Internal Market, citing even the *Cassis de Dijon* case as the true origin of the need for the New Approach. Sharpston then characterises the relationship between the patient and the NB (TÜV) as horizontal, such that the MDD cannot be applied directly and the patient cannot ask for compensation.[22] She also points out that the MDD provision requiring the NB to take out civil liability insurance[23] suggests a form of liability of the NB and the need to define what it might be.[24] Given how critical the role of the NB is in guaranteeing the safety of patients and consumers, the same NB could be

20 Case 219/15, *Schmitt* v *TÜV*, ECLI:EU:C:2017:128 (hereinafter *Schmitt*).
21 AG Sharpston opinion in *Schmitt*, ECLI:EU:C:2016:694, para 24 (hereinafter Opinion *Schmitt*).
22 Opinion *Schmitt*, para 27.
23 Opinion *Schmitt*, para 34.
24 Opinion *Schmitt*, paras 35–36.

deemed liable 'in the event of culpable infringement of an obligation under that directive' (the MDD),[25] provided that the principle of proportionality and effectiveness are respected. How to apply these instructions is a matter for national lawmakers to decide. As far as the question of a general duty for NBs to carry out surprise audits or checks, the AG points out that the duties of NBs can be of two kinds: they can be either general or particular.[26] However, she argues that even if the scope and content of the particular obligations imposed on an NB were to be clearly defined, there would still remain the fact that the CE marking system is not an infallible one.[27] In describing scenarios of the manufacturer's fraud towards its NB, the AG points out that an NB 'is under a duty to be alert',[28] especially with class III devices such as breast implants. The NB must take all the necessary steps, which must be evaluated in each scenario on a case-by-case basis. In this case, there was no need to do extra checks, just an audit, as the quantities of gel purchased were clearly insufficient. In any case, the NB must act with all due diligence and care. The Court of Justice accepted the liability outcome suggested by the AG but took a more restrictive approach (Wallerman 2018). One of the differences with the AG's opinion is the different way in which the Court decided to answer the questions asked by the national court (Wallerman 2018). It first addressed the issues concerning the NB's diligence: NBs have to act between the two parameters of acting with due diligence and being alert whenever there is the possibility of something going wrong (Wallerman 2018). As far as the evidence of liability for NBs is concerned, the Court objected to the position of AG Sharpston: just because the MDD mentions insurance against third-party liability, this should not be taken to mean that the MDD covers the NB's liability towards patients and consumers.[29] It *is* possible to find the NB liable, to be sure, it is up to the Member States to implement such a scheme.

The second main difference between the judgment and the opinion is the temporal limitation on the effects of the judgement. The Court disagrees with the opinion about its temporal effects.[30] Overall, the opinion shows more explicitly that protecting patients is a fundamental value of the EU even if the MDD does not explicitly provide any practical insights about how and to whom the NB can be liable. The positive aspect of the judgment is that it gives MSs the ability to address the issue of liability and to compete for the most efficient system. The drawback of this approach, dictated by the principle of conferral, is that it maintains legal

25 Opinion *Schmitt*, para 40.
26 Opinion *Schmitt*, para. 42.
27 Opinion *Schmitt*, para. 52.
28 Opinion *Schmitt*, para. 54.
29 *Schmitt*, paras. 55–56.
30 *Schmitt*, paras 61–63; cf Wallerman (2018).

fragmentation in a field, such as the one concerning cutting-edge technologies (IoT included), in which almost all the legal disputes are transnational. In practice, only multinational corporations will able to adapt their contractual clauses to the requirements established by laws of the several European countries (and to their procedural rules concerning damages). Start-ups will instead have more difficulties in entering the EU market for this reason and might thus lose competitiveness. In the end, the result would be less choice and maybe less quality of devices for EU patients and consumers. It would therefore be preferable to have a single model of liability: this could also favour the consolidation of the single market. However, it seems unlikely that this is going to happen anytime soon.

3.3 Latest Developments of the PIP Saga in France

In France the *PIP* cases drew a good deal of attention, in part because of the number of women (180) who sued in 2018.[31] This made the procedure a very complex one, not least from a national and international civil procedure standpoint (Fulli-Lemaire 2015).

Originally, it was the *Tribunal de Commerce* of Toulon that heard the case, as PIP had its registered offices in the Var region. At that stage, the international distributors of PIP implants as well decided to join the proceedings on their own accord. The defendants were both TÜV, the main NB, and TÜVF, TÜV's subcontractor in France. The court found both of them liable for negligence in certifying the safety and conformity level which required of PIP as well as of TÜV and TÜVF as NBs.[32] On appeal, the *Cour d'Appel* of Aix-en-Provence held that neither TÜVF nor TÜV was liable.[33] The *Cour de Cassation* had to settle some preliminary questions about several plaintiffs' standing in France before turning to the main issue, that of the NB's liability.

This case's webpage includes a link to a *communiqué de presse* (official press release) stating that the *Schmitt* judgment is taken into account as a reference point.[34] One of the main differences from the *Schmitt* judgment is that TÜVF is the company which materially carried out the audit operations and never found any

31 Cour de Cassation, Première Chambre Civile, Arrêt n° 616 du 10 octobre 2018 (17–14.401), ECLI:FR:CCASS:2018:C100616 (hereinafter *PIP*).

32 Judgement of Tribunal de Commerce de Toulon of 14 November 2013, no. 2011F00517.

33 Judgement of the Cour d'Appel of Aix-en-Provence of 5 February 2015, no. 14/22491.

34 Cour de Cassation, Communiqué, 'Implants mammaires', 10 October 2018, at <https://www.courdecassation.fr/jurisprudence_2/premiere_chambre_civile_568/616_10_40404.html> accessed 06 August 2022.

irregularity.[35] The second main difference is that this judgment is very technical and procedural. The procedural part is quite extensive, as the *Cour* also thought it necessary to lay out the basis of its jurisdiction and competence. Jurisdiction is established on the basis of the Brussels I Regulation[36] as follows. TÜV and TÜVF argued that the correct jurisdiction for tort liability cases under this regulation is the one where the fact or event takes place that either causes the damage (*fait dommageable*) or gives rise to an obligation (*fait générateur*). In this case, the main NB was a German private company, and therefore Germany was the place where the proceedings should have been initiated. Contrary to this thesis, the *Cour* held that under the Brussels I Regulation, in cases involving *responsabilité délictuelle* or *quasi-délictuelle* (intentional or negligent tort liability) the lawful jurisdiction is where the event has happened or is determined to have happened. Therefore, the *Cour de Cassation* has both the jurisdiction and the competence to hear this case.

On this occasion, the request to ascertain the liability of TÜV and TÜVF was based on both the negligence exhibited throughout the certification procedure and the negligence in the *mise en œuvre* (implementation) of the surveillance (oversight) and audit procedures required to be carried out in France. The legal reasoning of the *Cour de Cassation* follows three steps. Firstly, it argues that the *Cour d'Appel* erred in law in holding that the complainants had not proven their standing, since not all the plaintiffs had provided evidence that PIP was at fault. According to the *Cour de Cassation*, the simple fact that the plaintiffs' names appear in the certificates issued by TÜV and TÜVF alike as people having received a PIP implant was in itself sufficient to demonstrate their legitimate interest in the suit against TÜV and TÜVF. Secondly, *Cour d'Appel* also erred in evaluating the criterion of impartiality that is key to selecting the NB and certifying the safety of the devices at issue. The appeals court was satisfied that TÜV and TÜVF were both independent relative to PIP, and yet the trial court had not placed the proper weight on the fact that TÜVF was also under contract with PIP for devices other than breast implants—a circumstance that could compromise the NB's impartiality. The *Cour de Cassation* could not analyse the case on the merits, but it noted that this point should be subject to revision. Thirdly, taking up one of the points in AG Sharpston's opinion in *Schmitt*, the *Cour de Cassation* found the lower appeals judgment to be null. The appeals court was in possession of a document that mentioned an irregularity and did not act on that information.[37] Therefore, the

35 Audits were conducted on 22/10/1997, 17/10/2002, 15/03/2004, and 13/12/2007.

36 Council Regulation (EC) No 44/2001 of 22 December 2000 on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters [2001] OJ L 12/1.

37 The irregularity mention reads as follows: '03/01/2000 Mise en place d'un circuit informatique des commandes des fournisseurs suite à audit de TÜV Rheinland: non conformité'.

appeals court in Paris needs to go back to the matter and issue a new pronouncement on it on the basis of these directives. The hearing is reported to have been held on 17 November 2020 (Le Hars 2020).[38] The final judgment was instead published on 20 May 2021, and the *Cour d'Appel de Paris* applied the reasoning of the *Cour de Cassation*. In a very long judgment which synthetises the whole previous judgments (more than 200 pages) the *Cour d'Appel de Paris* established that the plaintiffs admitted in the previous judgment needed to be compensated because of the negligence of TÜV France and TÜV Germany. All women were awarded 3000 euros of damages.[39]

It is important to put the *Cour de Cassation* judgment into context as a necessary follow up of the *Schmitt* judgment. Although this judgment does not explicitly mention the distinction between obligations and particular obligations for NBs or the obligations to be alert to, it seems to be more protective towards the plaintiffs than the Court of Justice as far as the results as concerned: the *Cour* maintains, with AG Sharpston, that simply by fulfilling the general obligation of diligence (i.e. by carrying out a correct standard audit), it could have been possible to find out that the quantity of *Nusil* gel purchased was inferior to the quantity needed for prostheses being manufactured. Therefore, in this case there was no need for surprise checks.

It appears that the French *Cour* was the first supreme court to recognise a form of liability of NB: it did so by following a path that was already standard in deciding PLD cases and the application of the *obligation de sécurité* (more on the *obligation de sécurité* in Section 4 below).

3.4 The *Allianz IARD* Case

In 2006, a German national residing in Germany, underwent breast surgery, and PIP prostheses were used. In 2012, having discovered that these prostheses were not compliant with safety standards, she underwent another surgery in Germany. She later claimed compensation for the costs incurred, seeking payment from TÜV and also Allianz IARD. Allianz was PIP's insurance company. One of the clauses in

38 See Anne Le Hars, 'Prothèses PIP: l'affaire revient devant la Cour d'appel de Paris ce mardi', *franceinfo: 3*, 17 Nov. 2020, <https://france3-regions.francetvinfo.fr/provence-alpes-cote-d-azur/var/toulon/protheses-pip-affaire-revient-devant-cour-appel-paris-ce-mardi-1895546.html> accessed 06 August 2022.

39 Cour d'Appel de Paris, Pôle 4-Chambre 10, Arrêt du 20 Mai 2021, RG 19/02242. See also Communiqué de presse, Cour d'Appel de Paris <https://www.cours-appel.justice.fr/sites/default/files/2021-05/D%C3%A9cision%20Cour%20d%E2%80%99appel%20de%20Paris%20implants%20mammaires.pdf> accessed 06 August 2022.

the insurance contract stated that it would cover the costs incurred by any damage caused by PIP, but the scope of this coverage was limited to the French territories, including the *Territoires d'Outre-Mer et the Domaines d'Outre-Mer* (TOMs and DOMs), which are part of the French state. The plaintiff claimed that this clause was discriminatory under the first paragraph of Art. 18 TFEU, which includes nationality among the grounds covered by the principle of non-discrimination.

This case is particularly interesting, as it presents a *rationale* in the history of the movement of goods and services in the EU single market, a history that is examined closely in the opinion delivered by AG Bobek. The final judgment[40] reflects the AG's opinion in its result, but takes a very different view of Art. 18 TFEU, arguing that the non-discrimination principle does not apply.

At issue here was whether Art. 18 TFEU also covers a service, such as that provided by an insurance company, in order to be applied 'horizontally', or, using the AG's words 'diagonally.'[41] In this case, apparently, there is no direct cross-border element that would ensure the application of EU law. In point of fact, the implants were manufactured in France, marketed in the Netherlands, and then implanted in Germany in a German national. However, according to AG Bobek, the previous jurisprudence of the Court of Justice establishes that the transnational element need not be evident, provided it is not too indirect.[42] However, to assert that this case falls outside the scope of EU law does not seem right. It is in fact true that it does not have the makings of a case study, but it undeniably involves the dynamics of the Internal Market and the freedom to provide goods and services as well as the rights of patients and consumers to invoke remedies for harms they have suffered.

The correct analysis of Art. 18 TFEU according to AG Bobek is the following. It is indeed an abstract and general principle that must always be used in combination with other provisions. Articles 34 and 35 TFEU on the freedom of circulation of goods can indeed be jointly used with Art. 18 TFEU. However, in the case at hand the subsequent use and consequent damage caused by the goods at issue[43] are not direct. This assessment is based on the fact that the injured patient is a German national who received the implant in Germany, while the marketing and production of the implants were done in other EU countries. Member States have the ability to decide whether a manufacturer of medical devices should be insured and whether the insurance against civil liability can cover just one country. If Art. 18

40 Case C-581/18, *TÜV Rheinland LGA Products and Allianz IARD*, C-581/18, ECLI:EU:C:2020:453 (hereinafter *Allianz IARD*).

41 Opinion of Advocate General Bobek (hereinafter Opinion *Allianz IARD*), ECLI:EU:C:2020:77, para 22.

42 Opinion *Allianz IARD*, para 69.

43 Opinion *Allianz IARD*, para 65.

TFEU were to be used in a generalised manner[44] to justify the view that an insurance provision enacted on one country (say, France) has to also be applicable in another country where this provision is not present (say, Germany), this would not be justifiable, even if one can be empathetic with the plaintiff's condition.[45] That would cause an implicit expansion of EU competences (powers), in contrast with what is stated at Art. 5 of the Treaty on European Union (TEU).[46]

The Court of Justice is more compact in its analysis: it just examines the first questions, as it regards this as a preliminary step needed to analyse the other ones.[47] The Court establishes that there are two alternative conditions for Art. 18 TFEU to apply: It '*can apply to that dispute only where (i) that dispute relates to a situation which falls within the scope of the application of the EU law and (ii) that situation does not fall within the scope of a specific rule on non-discrimination laid down by the FEU treaty*'.[48] In order to reply to the first question, it has to be determined whether there is an obligation for a manufacturer of medical devices to have civil liability insurance.[49] The Court concludes that no such provision is present in the MDD. Point 6 of Annex XI mandates it just for the NB.[50] Likewise, the PLD is silent in that regard.[51] Therefore, in order to check whether the second step of the test should be applied, the Court of Justice finds it necessary '*to determine whether the situation giving rise to the discrimination claimed in the present case falls within the scope of a fundamental freedom laid down by the FEU Treaty*'.[52] In order to make that ascertainment, it is necessary to determine whether there is a 'specific connecting factor', one that '*is particularly evident when the person who has suffered the alleged discrimination is a person who has moved within the European Union* […] *or where discrimination is the direct result of the national rules applicable to goods from other Member States*'.[53] Contrary to AG Bobek, the Court did not deem the matter at hand pertinent to EU law, despite the fact that the products were made and marketed in two other Member States. The applicant did not move from her state; therefore, the EU law on the movement of goods and services cannot be applied.[54] The Court took a restrictive approach on the case and held that the

44 Opinion *Allianz IARD*, para 119.
45 Opinion *Allianz IARD*, para 115.
46 Opinion *Allianz IARD*, para 93.
47 *Allianz IARD* (supra n 40), para 61.
48 *Allianz IARD*, para 35.
49 *Allianz IARD*, para 37.
50 *Allianz IARD*, para 40.
51 *Allianz IARD*, paras 41–42.
52 *Allianz IARD*, para 45.
53 *Allianz IARD*, para 46.
54 *Allianz IARD*, para 49.

personal connection is the only element that can establish the transnationality of a case when dealing with the economic freedoms in connection with Art. 18 TFEU.

In the end, AG Bobek seemed to understand and be concerned about the way the circulation of goods may harm the safety of EU patients and consumers, but he pointed out that the state of the constitutional balance of competences between the states and the EU did not warrant a surreptitious expansion of EU competences by the judiciary. The Court of Justice decided to apply a more linear and restrictive line of reasoning. It first considered whether the case fell under the purview of any legislation mandating insurance. After that, it established that there was no transnational link in light of which the case might fall within the purview of the provision on the freedom of circulation of goods, as the person concerned was a German national residing in Germany, where the operation and moral damage took place. In this way, a strategy also used in *Schmitt*, the Court avoided any issue relating to the principle of conferral of competences between the EU and MSs. However, the problem at hand still remains an EU-related one, given the fact that PIP took advantage of the freedom of movement of goods in order to sell its prosthesis across the EU. Therefore, AG Bobek's view on the case seems to be the more correct one. The AG's opinion also has the merit of underscoring the importance of its precedent (the *Schmitt* case), which implicitly called for recourse to national schemes for liability against negligence on the part of NBs. In fact, NBs are generally more solvent than manufacturers and are also required to take out civil liability insurance. This case seems to have influenced the recent proposal for a regulation on AI by the EU,[55] as it obligates the NBs in charge of certifying high-risk AI technology to take out insurance for civil liability whenever national law does not expressly mandate it.

4 National Liability Theories

The *Schmitt* judgment gave Member States an opportunity to regulate the issue of NB liability through their own liability rules. It is interesting to understand what the national outcome of the *Schmitt* case was in Germany (the German *Allianz IARD* case judgment is expected to come out soon). This section is devoted to an essential analysis of national liability theories or doctrines that were advanced to deal with

55 European Commission, Proposal for a Regulation of the European Parliament and of the Council Laying down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts, Brussels, 21 April 2021, COM/2021/206 final, Article 33 (8).

the problems created by the PIP scandal. The focus will be on the most remarkable liability theories worked out in France and Germany, as well as in Italy. This is done for a few reasons: these liability theories can be garnered from the preliminary references the German judges addressed to the Court of Justice and from the approach taken by the French *Cour de Cassation*, but I think this will also help us consider how Italian law could deal with similar problems. Methodologically, the English concept of duty of care connects conceptually to these Continental liability theories. As we will see, however, these are different in their rationale and in how their remedies function.

At first, in Germany, where a conspicuous part of PIP litigation took place, the courts did not see in the MDD any kind of link explicitly recognising a right to seek compensation from the NB (Van Leeuwen 2015). Nevertheless, a German legal theory that from the outset might have extended protections for women who had had PIP implants is the one that goes by the name of *Schutzpflicht* (obligation to protect). Obligations to protect (*Schutzpflichten*) were first theorised in the 1930s, initially as consequence of the closed tort liability system introduced by the BGB (the German Civil Code). Some wrongful acts were connected to contract and thus needed to be established on the basis of contractual liability rules, as they were breaches of the *Treu und Glauben* (good faith) rule in § 242 BGB. The *Schutzpflichten* theory has since evolved with the 2002 *Schuldrechtsmodernisierung* (reform of the obligations system) law, which introduced a notion of obligations similar to those generated by a legal act (*rechtsgeschäftsähnliche Schuldverhältnisse*) (Danneman and Schulze 2020). These obligations serve a protective function especially with regard to two situations: (i) when a contract does not yet exist between the parties or (ii) when a third party, on account of its 'position of trust', can influence the content of a contract. They now have their place in the BGB at §§ 241(II) and 311(II, III). The rationale behind §311 BGB was to ensure that the parties to a contract take each other's duties and interests in earnest (§241 BGB II) and can be held accountable for the lack of these behavioural and conduct elements under the rules of contractual liability. To an external observer, these rules could apply to the PIP cases, as TÜV was not privy to the contract for medical services between the patients and the physician or medical clinic that performed the surgery, but held a position of significant trust (§311, III) that could, among other things, influence a specific decision to choose PIP prostheses. However, the lawyers in *Schmitt* decided to test another legal construct, namely, the contract affording protections to third parties (*Vertrag mit Schutzwirkung zugunsten Dritter*). This theory is based on the contractual parties' hypothetical will to protect someone who is not formally part of the contract but who can nevertheless seek

compensation for damage suffered by non-performance of that same contract. That is why the German judges who referred the *Schmitt* case to the Court of Justice asked whether (i) the MDD provided protection for a class of people or (ii) protection was afforded under a contractual provision.[56] The Federal Court of Justice in Karlsruhe (*Bundesgerichtshof*) took the view that the contract between the NB and PIP could not be deemed a contract capable of protecting third parties such as the claimants, as PIP had no obligations of any sort towards the women affected by the medical treatment.[57] Last year, in another *Bundesgerichtshof* judgement involving an insurance in the aftermath of the previous PIP cases, the court once more rejected the theory of a contract affording protections to third parties as a technique that might apply to the case at hand. What is interesting in the latest *Bundesgerichtshof* judgment in this matter is that the German court modified its previous views on remedies by stating that, in any case, the women who had received defective PIP breast implants could act on the basis of tort liability.[58] However, this basis of liability is generally more difficult to establish.

France, too, elaborated a jurisprudential construction that responds to the same function as the obligation/duty to protect, under a doctrine called *obligation de sécurité* (safety obligation). Traditionally, the *obligation de sécurité* is connected to former Article 1135, now 1194, of the French Civil Code (FCC) as a further source of obligations whose rationale resides in the equity principle (Mouly-Guillemaud 2006). That is why the *obligation de sécurité* became so popular among judges, who started to identify *obligations de sécurité* which were connected to standard contracts (as for transport) in order to protect injured parties. It has also been characterised as *une obligation judiciaire sentimentale* (a sentimental judge-made obligation) (Mazeaud 1997). Although it was first developed in connection with specific contracts, the *obligation de sécurité* has become part of the *devoirs extracontractuels* (extracontractual duties) (Viney 2013), as the obligation to protect the other party is not always plainly stated in the contract, but its source is external and universal (a source that, as just noted, is rooted in equity). On this construction there can be brought to bear Demogue's distinction in *obligation de résultat* (obligation as to result) and *obligation des moyens* (best efforts obligation). The main difference between these obligations lies in the way they require that an actionable loss or injury be proved: for the *obligation de moyens*, it is sufficient for

56 *Schmitt* (n 22 supra), paras 24, 34, 35, 36.

57 Judgement of the VII Civil Senate of 22.6.2017 - VII ZR 36/14, ECLI:DE:BGH:2017:220617UVIIZR36.14.0 <http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&nr=78997> Accessed 06 August 2022.

58 Judgement of the VII Civil Senate of 27.2.2020 - VII ZR 151/18, ECLI:DE:BGH:2020:270220UVIIZR151.18.0 <http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=pm&Datum=2021&nr=104766&linked=urt&Blank=1&file=dokument.pdf> Accessed 06 August 2022.

the defendant to prove that he or she exercised the level of diligence required for the situation at hand; by contrast, if an obligation is considered *de résultat*, the plaintiff just needs to show that the result was not what it should have been. The importance of the *obligation de sécurité* derives from the rule against concurrent liability known as *défense du cumulus*, under which it is not possible to sue for breach of contract and for tort in the course of the same judicial proceeding. In addition to that, French legal doctrine, with few exceptions, never really questioned the fact that this construction could give rise to different solutions to the same problem (Mazeaud 1997; Mengoni 1954). Despite that, the *obligation de sécurité*, either *de moyens* or *de résultat*, persisted in French law. It also became the main instrument for protecting consumers when the PLD was adopted at a European level but still needed to be transposed into national French law. Even after the PLD came into force in France, the phrasing of the FCC, which incorporated the PLD, clearly stated that the product was defective when *'il n'offre pas la sécurité à laquelle on peut légitimement s'attendre'* (it does not deliver the safety that can be legitimately expected)[59] and it kept referring to the *obligation de sécurité* in a new EU context. In the *Cour de Cassation*'s press release of the judgment, the duty to be alert set out by AG Sharpston was translated as *obligation de vigilance*. This could be interpreted in conjunction with the *obligation de sécurité* or as one of the specifications it may have. The application of this concept to the NB's liability would then be a new chapter in the history of this adaptable judge-made theoretical construct.

Italian legal theory borrowed from German legal theory the idea that the relationship should be the focus when discussing the nature of liability. Whenever there is a *contatto sociale qualificato* (special social contact) between two parties (Castronovo 1988, 2009, 2018), which is identified by the element of *affidamento* (trust/reliance), the relationship must be protected. Even if there is no formal contract, the essence of this kind of liability is contractual. That is because the contractual relationship does not confine itself to the terms of the contract. In fact, the relationship begins *before* the contract is formed, when the parties begin to negotiate or are put into contact with each other in a qualified way. What we have here is a paradigm switch, under which the contractual obligation is no longer conceived (according to the Continental tradition) as a unidirectional relationship tying a creditor to an indebted party (Castronovo 1988; Lambo 2007; Pasquino 2018) but is instead conceived as a bidirectional relationship, with both parties working together in fairness, correctness, and good faith to extinguish the obligation. Italian legal scholarship went on to further elaborate on the concept of *contatto sociale qualificato*, whose origin is the *affidamento*, meaning trust in or

59 Art. 1245-3 FCC.

reliance on someone's profession or fairness (Sacco 1958). Castronovo believes that the relationship between two parties is in itself necessary and sufficient to give rise to an obligation without a duty of performance, which he terms *obbligo di protezione senza prestazione* (Castronovo 2009). This carries a series of practical consequences when seeking compensation. The plaintiff does not have to prove any fault, causal link, or *danno ingiusto* (unjust/unfair damage). This kind of liability is of a pre-contractual nature, which, for Italian legal scholars and jurisprudence, is contractual as far as the burden of the proof is concerned.[60] Unlike in Germany, these theories did not prompt any effort to update in the Italian Civil Code. Even today, some Italian legal scholars think this absence is justifiable, as the Italian theory about *obblighi di protezione* does not reflect the true historical meaning of the corresponding German *Schutzpflichten* theory and risks being used arbitrarily by judges (Zaccaria 2013). Although still not translated into law, the Italian theory has mainly been developed in scholarship and commentary and is applied quite extensively by the judiciary. Its protective scope could also be used in cases involving defective medical devices.

What these models have in common is that they extend protection to individuals whenever it is unclear what kind of link there is between the damage and who contributed to causing it, even if there are no direct links with the injured person. In a way, they offer a better solution to the purpose set out in Article 168 TFEU, requiring a high level of health protection for EU citizens, than do both the MDD and the MDR as far as the remedies they offer. It is worth asking whether these models, reflecting a deeper concern for the most vulnerable parties, will be taken up in other Member States and whether these models will in some way be harmonised or transplanted pending an IoT liability regulation or directive that may be adopted in the EU, and whether they will serve as a starting point in constructing a common European concept of the duty of care.

5 The MDR: What is New for the IoT?

Section 3.1 described the structure of the MDD to better understand the cases aring under it (3.2, 3.3 and 3.4). In this section, I will describe the scope and structure of the MDR and how it is different from the MDD. I will also consider whether the MDR is already applicable to IoT objects with medical devices functions and how it shall impact the civil liability rules applicable to healthcare IoT objects.

60 The Italian *Corte di Cassazione* explicitly accepted Castronovo's theories on the contractual nature of pre-contractual liability in July 2016. Cf. Case no. 14188, Cass. Civ., sez. I., 12 July 2016.

The recitals to the MDR set out two main reasons for its adoption: the necessity to put an end to the scandals which happened under the MDD and the intention to support technological development. Trying to avoid new health scandals is probably also be the reason why the directive was substituted by a regulation, that is a EU legislative act which is binding in every aspect, not only as far as the results to be attained.[61] By trasforming the directive into a regulation, the EU institutions and the MS can exrcise better control over manufacturers and NBs. Moreover, another important reason to adopt the new regulation is that medical technologies have progressed very quickly since the '90s and an update of the MDD was thus needed anyhow. Several elements show how the increasing pace of technological evolution influenced the MDR, and how the same MDR could turn out to be applicable to IoT objects with healthcare functions as well. As a first remark, the MDR lays down several rules applicable to connected devices, such as IoT objects, without ever mentioning them: they mostly refer to technical issues such as standards[62] and specifications,[63] and the obligation to draw up a plan for continuos risk management,[64] which in the MDR is defined as the: '[…] *continuous iterative process throughout the entire lifecycle of a device, requiring systematic updating*'.[65] Clearly, continuous risk management would be made easier by incorporating a IoT in any medical device that could thus be monitored at a distance. More significantly, in the MDR software can be judged autonomously and be put in one of the four risk classes as a standalone medical device,[66] which was not possible under the MDD.

A comparative analysis of the MDD, shows that several pillars of the previous directive are reproduced in the MDR. The structure of the MDR is the same as the MDD: there is a longer list of recitals, followed by general rules or principles that must be integrated with the details of the annexes. Surprisingly, the rules on classification of the new Annex VIII are still those of the old Annex XI as well as the classes of risks: they still have the same nomenclature (I, IIa, IIb and III). All the

61 The Regulation makes several references to the protection of patient's and users' health. See recitals 1, 2,5,15,37, and, especially, 50 which states that '[t]he functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level'.

62 Article 8 MDR.

63 Article 9 MDR.

64 Article 10 MDR to be read in conjunction with Section 3 of Annex I.

65 3, Chapter I, Annex I MDR.

66 3.3 Chapter II Annex VIII MDR.

procedures for conformity are in Annexes IX, X and XI. They are all inspired by the previous procedures in the annexes of the MDD. Further, the system based on NBs is still in place.[67] There are new, more detailed rules on how the MS must select them and there are also more rules concerning the interaction of standards (harmonised, ad hoc or more general) with the MDR itself.[68] Something new is also the list of post-market surveillance duties[69] and, finally, a harmonisation of the rules on clinical investigations.[70]

There are a few novelties concerning the liability theme at large and they are clearly originated by the problems highlighted by the PIP saga.

The first one is that the manufacturer of medical devices should have formal obligations according to Article 10 MDR. Among these, there is the obligation to: '[…] *in a manner that is proportionate to the risk class, type of device and the size of the enterprise, 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*'.[71] Even if this is an improvement compared to the lack of a similar provision in the MDD, this obligation does not specify which type of measures medical devices producers should take to have enough resources to meet liability for defective devices. The most obvious measure would be civil liability insurance. However, since any of these measures will be governed by the applicable national rules on these issues the possibility of insufficient coverage is not completely ruled out. Let us remember that *Allianz* (the insurer) was not involved in the *Schmitt* case because the contract of insurance for PIP (governed by French law) had been found void and null due PIP's fraudulent conduct, according to French law. It will depend on the Member States to make rules that fairly balance the interests of insurances companies (which are not happy to bail out fraudsters or negligent producers at a EU level, comprehensibly) and the expectations of consumers and patients about the protection of their health.

The second new rule introduced by the MDR to consider for present purposes is that NBs will be supervised by an independent authority based in each Member State.[72] Although an improved oversight of NBs is to be welcomed, there is still no formal provision in the MDR regulating liability for negligence on their part (Rott 2019). Even so, NBs will be held liable for the activities of subsidiaries and

67 The system is extensively detailed in Chapter IV of the MDR and in its Annex VII.
68 Article 8, 9 MDR.
69 Annex XIV MDR.
70 Annex XV MDR.
71 Article 10(16) MDR.
72 Article 35 MDR.

subcontractors in issuing the conformity certifications required for specific classes of medical devices.[73]

It is too soon to tell whether the MDR will perform better than its predecessor. In any case, its connection with the PLD (and its future updated version) is more explicit than it used to be because of Article 10(16) of the MDR: '*Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law*.' As a consequence, the PLD is likely to become a harmonised system of liability even for high risk IoT objects that are used as medical devices. It will then depend on the MS to make sure that manufacturers and NBs established on their national territory have enough resources to meet potential liabilities at European level, to avoid failures exemplified by the PIP saga. The easiest option would be to have recourse to mandatory civil liability insurance schemes for producers-manufacturers and for NBs. Moreover, because of the expression '*without prejudice to more protective measures under national law*' of Article 10(16) MDR, the national courts could rely on the *Schmitt* judgment to apply national liability theories that would establish the liability of NB towards patients in case of negligent certification of the defective device. Hence, protective national liability theories could be more easily applied to compensate damages in this sector because of Article 10(16) MDR.

6 Lessons Learned and Future Perspectives for the IoT

This article had one main purpose: to connect a rapidly developing technology such as the IoT, specifically when applied to healthcare, to the past case-law involving the MDD, one of the most important regulatory instruments that the EU ever created.

Section 2 of this article explained why it is important to highlight the connection between the regulation of IoT objects and medical devices through the study dedicated to the EU case-law regarding civil liability for medical devices. This is because these cases highlighted past mistakes in the design of the rules governing with the liability regime applicable to high risk-objects such as medical devices (a characteristic shared with IoT for medical purposes). Hopefully, this analysis should help to avoid the repetition of similar mistakes in the future.

Section 3 synthetized the outcomes of three different European and national judgments. All these cases originated from major failures of the MDD as the PIP

73 Article 37 MDR.

breast prosthesis scandal tragically showed. Nevertheless, this analysis would have not been complete without a critical examination of the national liability theories underpinning these judgments.

As discussed in Section 4, despite some structural differences, the German *rechtsgeschäftsähnliche Schuldverhältnisse*, the Italian *obbligo di protezione* and the French *obligation de sécurité* have a common feature: they all accept a relationship of trust as a legal basis for the protection of the weaker party, whenever the user of the device cannot establish a contractual relationship with the manufacturer. It was possible to find a trace of the German dogmatic and French judge-made legal constructions through the analysis of the preliminary questions asked in *Schmitt* and in the French *Cour de Cassation* judgment. The Italian *obbligo di protezione* offered an interesting point of comparison as the Italian civil law tradition has been influenced by both the French and the German legal tradition. The focus on the protection of the weaker party by the subject which can exercise more control on a situation because it has a duty to do so is conceptually similar to the risk management rationale which underpinned the MDD. This approach now is developed through the long list of manufacturer's duties set out in the MDR.

In order to assess what the future holds for the regulation of liability for defective healthcare IoT objects, in Section 5 I highlighted the modifications to the medical devices regulatory regime brought by the MDR. I also considered whether they can be applied to the healthcare IoT objects that are already on the market. After concluding that, apart from mentioning software, the MDR does not refer to IoT technology, I discussed what are the most probable scenarios for the regulation of the liability for IoT devices. Given that even the recently proposed Data Act does not explicitly define IoT objects, it is unlikely to expect an *ad hoc* regulatory or liability framework for them. The work of the Expert Group on Liability (Expert Group 2019) indicates that technologies will probably be divided into two main groups: high-risk and low-risk level technologies. The recent proposal for the regulation of AI makes it clear that some algorithms are considered, potentially, high-risk technologies which will require an *ad hoc* regulatory (and administrative) regime. They will be checked by specialised NBs tasked with controlling their level of risk. This is likely also to happen to autonomous driving cars, whenever they will be fully commercialised. For high-risk technological applications like these, it is likely that compulsory insurance (under a special, separate regime) will be included in compensation or refund schemes, as it is already the case nowadays for everyday cars.

The situation remains more fluid for IoT healthcare devices. The new Article 10(16) MDR connects medical devices to the liability rules of the PLD. Furthermore, it imposes the adoption of measures under the laws of the Member States to avoid

that manufacturers evade liability by simply declaring bankruptcy, like it happened in the PIP case. In the future, it is highly probable that the PLD will be a generalised system of civil liability both for IoT with health, consumer and mixed consumer and health functions such as wearables smartwatches, which could also save lives (Neely 2022). Nevertheless, with respect to IoT that are medical devices it will always be possible to apply more protective liability theories because Article 10(16) MDR is: '*without prejudice to more protective measures under national law*'. This means that the rule laid down in the *Schmitt* judgment[74] has been incorporated in the MDR to protect human health. The *Cour de Cassation*[75] indeed already adopted the same rule. Accordingly, national liability theories (such as the ones mentioned in Section 4) could still be applicable to grant a level of protection higher than the one resulting from the MDR and the PLD, as far as IoT that are medical devices are concerned. On the other hand, as shown by the *Allianz IARD*[76] judgment, the competence over how the producer/manufacturer's or the NB's insurance coverage extends in the different MS will still be a matter of national law, at least until the actual repartition of competences between the EU and the MS remains the same.

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74 *Schmitt* judgment, as commented in sub-paragraph 2.2 supra and referenced at note 22 supra.
75 *PIP* judgment, rendered by the *Cour de Cassation*, as commented in sub-paragraph 2.3 supra and referenced at note 33 *supra*.
76 *Allianz IARD* judgment, as commented in sub-paragraph 2.4 supra and referenced at note 42 supra.

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