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Liability in the Medical Sector: The 'Breast-Taking' Consequences of the Poly Implant Prothèse Case

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Abstract: The article deals with the liability of third-party certifiers in the medical sector and especially focuses on the role of TüV Rheinland in the recent Poly Implant Prothèse (PIP) breast implant case. The aim of the contribution is twofold. Firstly, it provides an overview of the different challenges that courts face when having to decide on the liability of certifiers of medical devices towards third parties. These, for instance, relate to the strict conditions under which certifiers can incur third-party liability under national law. Whether product certifiers can be held liable depends on the jurisdiction where the claims have been filed. Therefore, the PIP breast implant case is also interesting from a private international law perspective. Third-party certifiers can be sued before the courts of their domicile. Whether they can be brought before courts in other Member States depends inter alia on the interpretation of the place of the damaging event and the place of the damage. The difficulty to pinpoint these locations not only emerges in the field of jurisdiction but also manifests itself within the search for the applicable law as identical connecting factors are employed in that area of private international law. Secondly, the article examines the decisions that have been issued by national courts in the PIP breast implant case. Rulings in France and Germany denied compensation for patients who purchased the defective breast implants. The PIP case is currently pending before the European Court of Justice (ECJ). It thus remains to be seen what stance the ECJ will take and especially what the consequences might be for certifiers in the medical sector. Based on the analysis of these decisions, the contribution puts forth a number of reasons why the threat of liability seems the most effective way to guarantee that third-party certifiers issue accurate and reliable certificates. This in turn ensures that only safe medical devices are placed on the European market and safeguards the health of consumers. Future scandals with medical devices might in this way be prevented.

Zusammenfassung: Der Beitrag behandelt die Haftung von unabhängigen Zertifizierungsstellen im medizinischen Bereich und konzentriert sich speziell auf die Rolle des TÜV Rheinland in dem aktuellen PIP Brustimplantat-Fall. Das Ziel des Beitrages is zweierlei. Zum einen soll er einen Überblick über die unterschiedlichen

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Herausforderungen, mit denen Gerichte konfrontiert sind, wenn sie über die Haftung von Zertifizierungsstellen medizinischer Produkte gegenüber Dritten entscheiden, bieten. Diese Herausforderungen stehen beispielsweise im Zusammenhang mit den strengen Vorraussetzungen im nationalen Recht, unter denen für eine Zertifizierungsstellen eine Haftung gegenüber Dritten angenommen wird. Ob eine solche Haftung entsteht, hängt von der durch den Ort der Klageeinreichung bestimmten Jurisdiktion ab. Vor diesem Hintergrund erscheint der PIP Brustimplantat-Fall auch aus der Perspektive des Internationalen Privatrechts interessant. Unabhängige Zertifizierungsstellen können am Ort ihres Sitzes gerichtlich verklagt werden. Ob sie auch vor Gerichten anderer europäischer Mitgliedsstaaten verklagt werden können, hängt inter alia von der Interpretation des Ortes des schädigenden Ereignisses und des Schadensortes zusammen. Die Schwierigkeit der Feststellung dieser Orte entsteht nicht nur im Bereich der Bestimmung der zuständigen Jurisdiktion, sondern manifestiert sich auch bezüglich der Frage des anwendbaren Rechts, da in diesem Bereich des Internationalen Privatrechts identische Anknüpfungspunkte zur Anwendung kommen. Zum anderen untersucht der Beitrag die Urteile, die durch nationale Gerichte im PIP Brustimplantat-Fall ergangen sind. Gerichtliche Entscheidungen in Frankreich und Deutschland lehnten eine Entschädigung für Patienten, die die mangelhaften Brustimplantate gekauft hatten, ab. Der PIP-Fall ist gegenwärtig beim Europäischen Gerichtshof anhängig. Es bleibt daher abzuwarten, welche Haltung der EuGH einnehmen wird und insbesondere welche Folgen möglicherweise für Zertifizierungsstellen im medizinischen Bereich entstehen. Auf der Grundlage der Analyse dieser Entscheidungen zeigt der Beitrag eine Anzahl von Gründen auf, warum die Gefahr der Haftung der effektivste Weg scheint um zu garantieren, dass unabhängige Zertifizierungsstellen fehlerfreie und vertrauenswürdige Zertifikate ausstellen. Dies wiederum stellt sicher, dass nur sichere medizinische Produkte auf dem europäischen Markt platziert werden, und schützt die Gesundheit der Verbraucher. Zukünftige Skandale mit medizinischen Produkten könnten so möglicherweise verhindert werden.

Résumé: L'article traite de la responsabilité des tiers certificateurs dans le secteur médical et étudie spécialement le rôle de TüV Rheinland dans l'affaire récente des implants mammaires PIP. L'objectif de la contribution est double. D'abord elle fournit un aperçu des différents problèmes auxquels les tribunaux font face lorsqu'ils doivent connaître de la responsabilité de certificateurs de produits médicaux envers des tiers. Il s'agit, par exemple, des conditions strictes dans lesquelles les certificateurs peuvent encourir une responsabilité civile vis-à-vis des tiers dans la loi nationale. La mise en cause de la responsabilité d'un certificateur de produits dépend de la juridiction devant laquelle les recours ont été intentés. C'est pourquoi l'affaire des implants mammaires PIP présente également un intérêt du point de vue du droit international privé. Les tiers certificateurs peuvent être poursuivis devant les tribunaux de leur domicile. La question de savoir s'ils peuvent être poursuivis devant les tribunaux d'autres Etats membres dépend entre autres de l'interprétation du lieu du fait dommageable et du lieu du dommage. La difficulté de localiser ces endroits n'apparaît pas seulement en ce qui concerne la juridiction mais se manifeste aussi dans la recherche de la loi applicable, dans la mesure où des facteurs de rattachement identiques sont utilisés dans ce domaine du droit international privé. Deuxièmement, l'article étudie les jugements de tribunaux nationaux dans l'affaire des implants mammaires PIP. Des décisions en France et en Allemagne ont refusé une indemnisation pour des patientes qui avaient reçu les implants mammaires défectueux. L'affaire PIP est actuellement pendante devant la Cour européenne de justice. Il reste donc à voir quelle position prendra la CJE et en particulier quelles pourraient être les conséquences pour les certificateurs dans le secteur médical.

En se basant sur l'analyse de ces décisions, l'article avance un certain nombre de raisons pour lesquelles la menace d'encourir une responsabilité semble être le moyen le plus efficace pour assurer la délivrance, par les tiers certificateurs, de certificats corrects et fiables. Ce qui permet de garantir que seuls des produits médicaux sûrs sont mis sur le marché européen et de protèger ainsi la santé des consommateurs. De futurs scandales concernant des produits médicaux pourraient ainsi être évités.

1. Introduction

1. This article deals with the third-party liability of certifiers in the medical sector. Despite recent developments in case law, there is (still) not much scholarship on the role and liability of third-party certifiers in the medical sector,[1] especially in comparison to other certifiers such as classification societies[2] or credit rating agencies (CRAs).[3] After a brief discussion of the different players involved in the field of product safety (s. 2), we give an

1 There are, however, some exceptions: B. Van Leeuwen, 'La responsabilité des organismes notifiés du fait d'implants mammaires défectueux: TÜV Rheinland devant les tribunaux français et allemands', 24. *R.I.D.E* (*Revue Internationale de Droit Économique*) 2015, p 69; B. van Leeuwen, 'PIP Breast Implants, the ElU's New Approach for Goods and Market Surveillance by Notified Bodies', 5. *EJRR (European Journal of Risk Regulation)* 2014, p 338; S.M. Singh, 'Symposium on the EU's New Medical Device Regulatory Framework What Is the Best Way to Supervise the Quality of Medical Devices? Searching for a Balance Between Ex-Ante and Ex-Post Regulation', *EJRR (European Journal of Risk Regulation)* 2013, p 465; B.M. Fry, 'A Reasoned Proposition to a Perilous Problem: Creating a Government Agency to Remedy the Emphatic Failure of Notified Bodies in the Medical Device Industry', 22. *Willamette J. Int'l L. & Dispute Res (Willamette Journal of International Law & Dispute Resolution)* 2014, p 161.

2 *See* in this regard: N. Lagoni, *The Liability of Classification Societies* (Berlin: Springer 2007), p 380; M.A. Miller, 'Liability of Classification Societies from the Perspective of United States Law', 18. *Tul. Mar. L.J. (Tulane Maritime Law Journal)* 1997, p 75; J.De Bruyne, 'Liability of Classification Societies: Cases, Challenges and Future Perspectives', 45. *J. Mar. L. & Com. (Journal of Maritime Law & Commerce)* 2014, pp 181–232 with further references.

3 *See* in this regard: N.S. Ellis, L.M. Fairchild & F. D'Souza, 'Is Imposing Liability on Credit Rating Agencies a Good Idea?: Credit Rating Agency Reform in the Aftermath of the Global Financial Crisis', 17. *Stan. J.L. Bus. & Fin. (Stanford Journal of Law, Business & Finance)* 2012, p 175; A. Darbellay, *Regulating Credit Rating Agencies* (Cheltenham: Edward Elgar 2013), 296 p; F. Partnoy, 'The Siskel and Ebert of Financial Markets?: Two Thumbs Down for the Credit Rating Agencies', 77. *Wash. U. L. Q. (Washington University Law Quarterly)* 1999, p 619; J.C. Coffee, 'Ratings Reform: The Good, the Bad, and the Ugly', 1. *H.B.L.R. (Harvard Business Law Review)* 2011, p 231; I.H.Y. Chiu, 'Regulating Credit Rating Agencies in the EU: In Search of a Coherent Regulatory Regime', 25. *E.B.L.R.* (*European Business Law Review*) 2014, p 269; J.De Bruyne, 'Liability of Credit Rating Agencies Regulatory Changes & Tendencies in Case Law Following the Financial Crisis', 3. *I.C.C.L.R. (International Company and Commercial Law Review)* 2016, p 87; J. De Bruyne & C. Vanleenhove, 'Rating the EU Regulatory Framework on the Liability of Credit Rating Agencies: Triple A or Junk?', 4. *Edinburgh Student L. Rev. (Edinburgh Student Law Review)* 2015, p 117.

overview of the challenges that courts face when having to decide on the liability of third-party certifiers in the medical sector. The focus thereby lies on the role and liability of certifier TüV Rheinland in the recent Poly Implant Prothèse (PIP) breast implant scandal. This case illustrates that the liability of third-party certifiers mainly depends on the jurisdiction where the claims have been filed. Therefore, the PIP breast implant case also poses challenges in the field of private international law, especially as to the interpretation of the place of the damaging event and the place where the damage occurred (s. 3). Based on an analysis of the decisions that have been issued so far by national courts in the PIP case, the contribution puts forth a number of reasons why the threat of holding third-party certifiers liable seems the most effective way to guarantee that they issue accurate and reliable certificates. This in turn increases the safety of medical devices and safeguards the health of their users (s. 4).

2. Standardization, Accreditation and Certification: *What's in a Name*

2. There are several actors involved in the process of guaranteeing that products are safe. Each of them has different obligations and responsibilities in the field of product safety. In this regard, a distinction can be made between entities offering services of standardization (s. 2.1), accreditation (s. 2.2) and certification (s. 2.3). Considering that certification in the medical sector is the main focus of this article, particular attention is given to so-called notified bodies. These bodies are involved as third-party certifiers in the conformity assessment procedure of medical devices (s. 2.4).

2.1. Standardization and Standard-Setting Bodies

3. The first major players offering their services in the field of product safety are standard-setting bodies. They develop technical and safety standards that products or their manufactures have to comply with. The International Organization for Standardization (ISO) is the most prominent example in this regard. The ISO is an independent non-governmental organization and the world's largest developer of standards. The ISO already adopted more than 20,500 standards in different sectors. ISO-standards provide guidelines for products, services and systems to ensure their quality, safety and efficiency.[4] Besides the ISO 9,000 family, addressing aspects of quality management,[5] and ISO 17065, containing requirements for entities that certify

4 International Organization for Standardization, *About ISO*, www.iso.org/iso/home/about.htm (accessed 26 Sep. 2016).

5 International Organization for Standardization, *ISO 9000 – Quality Management*, www.iso.org/iso/home/standards/management-standards/iso_9000.htm (accessed 26 Sep. 2016).

products, services and processes,[6] specific ISOs have been adopted in the field of medical devices. For example, ISO 13485 contains requirements regarding the quality management system of manufacturers of medical devices.[7] Under this ISO, manufactures have to demonstrate that they are able to design and produce devices that meet the applicable (safety and technical) requirements.[8] In addition to the ISO operating at the international level, three European Standardization Organizations establish and develop standards at the supranational level, namely the European Committee for Standardization (CEN),[9] the European Committee for Electrotechnical Standardization (CENELEC)[10] and the European Telecommunications Standards Institute (ETSI).[11][12] Finally, there are also national standard-setting bodies. In this regard, there is a difference between national standard bodies (NSBs) and standard developing organizations (SDOs).[13] Whereas the NSBs coordinate the national standard-setting process, SDOs develop the actual content of the standards.[14]

2.2. Accreditation and Accreditation Bodies

4. The second important group of actors contributing to the safety of products are accreditation bodies. Accreditation is the 'third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks'.[15] Accreditation is thus one step higher

6 International Organization for Standardization, *ISO/IEC 17065:2012*,www.iso.org/iso/catalogue_detail?csnumber=46568 (accessed 26 Sep. 2016).

7 EMERGO Group, *What Is ISO 13485 Certification?*, www.emergogroup.com/resources/articles/what-is-iso-13485-certification (accessed 26 Sep. 2016); BSI, *Quality Management System (QMS) ISO 13485 Certification*, www.bsigroup.com/en-GB/medical-devices/our-services/iso-13485/ (accessed 26 Sep. 2016).

8 International Organization for Standardization, *ISO 13485:2003*,www.iso.org/iso/catalogue_detail?csnumber=36786 (accessed 26 Sep. 2016).

9 *See* for more information: www.cen.eu/about/RoleEurope/Pages/default.aspx (accessed 26 Sep. 2016).

10 *See* for more information: www.cenelec.eu/ (accessed 26 Sep. 2016).

11 *See* for more information: www.etsi.org/ (accessed 26 Sep. 2016).

12 Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 Oct. 2012 on European standardization, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council, OJL 316, 14 Nov. 2012.

13 The ISO gathers national standard bodies within an international framework, namely one for each country. *See* International Organization for Standardization, *ISO Members*, www.iso.org/iso/about/iso_members.htm (accessed 26 Sep. 2016).

14 Durham College, *Standards: Standards Bodies*, guides.library.durhamcollege.ca/c.php?g=316842&p=2116950.

15 Clause 3.1. in International Organization for Standardization, *ISO/IEC 17011:2004 Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment*

than the actual certification of products.[16] One could, therefore, say that accreditation bodies are guarding the guards in the sense that they guarantee that certifiers are competent to perform their certification functions. Accreditation is not always compulsory and non-accreditation does not necessarily mean that a third-party certifier is incompetent. However, the accreditation of certifiers provides an independent confirmation of their competence which is likely to be relied upon by purchasers of products.[17]

Accreditation bodies use different criteria to determine whether third-party certifiers are capable to perform certification functions.[18] Those criteria, for instance, include ISO 17021 (certification of management systems),[19] ISO 17065 (requirements for bodies certifying products, processes and services)[20] and ISO 17024 (requirements for bodies certifying persons).[21] Accreditation bodies themselves demonstrate that they are competent by showing compliance with the standards lied down in ISO 17011 (e.g. on impartiality and management).[22]

As is the case for standard-setters, accreditation bodies operate at different levels. For instance, the International Accreditation Forum (IAF) gathers bodies that accredit third-party certifiers of management systems, products, services and personnel. The primary function of the IAF is to develop a single and global program which assures parties that the certificates they use are issued by accredited certifiers.[23] The International Laboratory Accreditation Cooperation (ILAC) is an international organization for bodies involved in the accreditation of medical test-

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Bodies, 1 Sept. 2004, www.iso.org/iso/catalogue_detail?csnumber=29332 (accessed 26 Sep. 2016).

16 R. Muse, 'What's in a Name: Accreditation vs. Certification?', *Quality Magazine*, 2 June 2008, www.qualitymag.com/articles/85483-what-s-in-a-name-accreditation-vs-certification (accessed 26 Sep. 2016).

17 International Organization for Standardization, *Certification*, www.iso.org/iso/home/standards/certification.htm (accessed 26 Sep. 2016).

18 International Accreditation Forum, *About Us*, www.iaf.nu//articles/About/2 (accessed 26 Sep. 2016).

19 International Organization for Standardization, *ISO/IEC 17021-1:2015. Conformity Assessment – Requirements for Bodies Providing Audit and Certification of Management Systems – Part 1: Requirements*, www.iso.org/iso/catalogue_detail?csnumber=61651 (accessed 26 Sep. 2016).

20 International Organization for Standardization, *ISO/IEC 17065:2012. Conformity Assessment – Requirements for Bodies Certifying Products, Processes and Services*, www.iso.org/iso/catalogue_detail.htm?csnumber=46568 (accessed 26 Sep. 2016).

21 International Organization for Standardization, *ISO/IEC 17024:2012. Conformity Assessment – General Requirements for Bodies Operating Certification of Persons*, www.iso.org/iso/catalogue_detail?csnumber=52993 (accessed 26 Sep. 2016).

22 International Organization for Standardization, *ISO/IEC 17011:2004. Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*. *See* in this regard also: EEFC Energy, *Product Verification & Certification Division*, eefcenergy.com/product-verification-certification-division/.

23 International Accreditation Forum, *IAF Membership*, www.iaf.nu/articles/IAF_Membership_/33 (accessed 26 Sep. 2016).

ing laboratories and inspection bodies.[24] At the supranational level, European Union (EU) Regulation 765/2008 contains requirements that have to be followed by national public authorities when accrediting third-party certifiers. In this regard, the European co-operation for Accreditation (EA) is responsible for managing the peer assessment between national accreditation bodies and monitors their responsibilities and functioning.[25]

2.3. Certification Process and Third-Party Certifiers in General

5. Certifiers also contribute considerably to the safety of products. They attest that a certified product possesses certain qualifications or meets particular safety or technical standards.[26] The certification process can take different forms and often involves several parties. First-party certification implies that the certification process is carried out by the manufacturers of the products themselves. It is thus a form of self-certification in the sense that the party that markets the products (e.g. the manufacturer of medical devices) determines whether they comply with the applicable standards.[27] Second-party certification, on the other hand, occurs when a person or organization interested in a particular product (e.g. purchasers of medical devices) examines whether the product meets the applicable safety and technical standards.[28] Finally, third-party certification is performed by organizations which are independent *vis-à-vis* the entity that is manufacturing the products. Such certification occurs at the end of the design or production process when an independent body establishes whether the product complies with the applicable technical and safety standards or requirements.[29] Most certified products bear the certifier's mark to help consumers or other parties make decisions.[30] The certificate

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24 International Laboratory Accreditation Cooperation, *About ILAC*, ilac.org/about-ilac/.

25 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, OJ L218, 13 Aug. 2008.

26 B.A. Garner, *Black's Law Dictionary* (St. Paul: West 2009), pp 220–221; D. Greenberg, *Jowitt's Dictionary of English Law* (London: Sweet & Maxwell 2010), pp 304–305. *Also see* the definition of 'to certify' in Oxford English Dictionary, 3th ed. 2010.

27 American National Standards Institute, *U.S. Conformity Assessment System: 1st Party Conformity Assessment*, www.standardsportal.org/usa_en/conformity_assessment/suppliers_declaration.aspx (accessed 26 Sep. 2016).

28 American National Standards Institute, *U.S. Conformity Assessment System: 2nd Party Conformity Assessment*, www.standardsportal.org/usa_en/conformity_assessment/2party_conformity_assessment.aspx; European Federation of National Associations of Measurement (Testing and Analytical Laboratories), 'First-, Second- and Third-Party Testing – How and When', *Eurolab Position Paper No. 1/2000*, May 2000, p 3.

29 American National Standard Institute, *U.S. Conformity Assessment System: 3rd Party Conformity Assessment,* www.standardsportal.org/usa_en/conformity_assessment/3party_conformity_assessment.aspx#Accreditation.

30 NSF International, *What Is Third-Party Certification?*, www.nsf.org/about-nsf/what-is-third-party-certification.

serves as a signal of quality when it is issued by an independent third-party certifier.[31] As such, third-party certification provides a non-biased analysis of the product and enhances consumer confidence in it.[32]

6. The following parts of this article focus on the liability of third-party certifiers. Such certifiers provide services at the request of their client. The certificate they issue is the performance under their certification contract. However, the certificate can and will also be used by persons with whom third-party certifiers do not have any contractual relationship or by the public at large. In other words, third-party certifiers moderate informational asymmetries that distort or prevent efficient transactions by providing the public with information it would otherwise not have. This function is so important that one could say that without certifiers 'efficient trade would often be distorted, curtailed or blocked'.[33] Third-party certifiers provide services in different sectors including the maritime industry (e.g. classification societies[34]) or financial markets (e.g. CRAs[35]). More importantly, third-party certifiers such as TüV Rheinland,[36] SGS,[37] Dekra[38] or Underwriters Laboratories (UL)[39] also play a key role as notified bodies in the conformity assessment procedure of medical devices under EU law. Considering the importance of notified bodies in this conformity assessment procedure, it is given further attention in the next paragraphs.

2.4. Notified Bodies as Third-Party Certifiers in the Conformity Assessment Procedure of Medical Devices: Regulatory Framework

7. A manufacturer can only place medical devices on the EU market that comply with essential requirements.[40] To that end, the manufacturer has to perform a conformity

31 G. Jahn, M. Schramm & A. Spiller, 'The Reliability of Organic Certification: An Approach to Investigate the Audit Quality', Paper presented at Researching Sustainable Systems – International Scientific Conference on Organic Agriculture, Adelaide, 21–23 Sept. 2005, p 1, orgprints.org/4378/4/4378-Jahn_etal_4p_revised-ed.pdf.

32 European Federation of National Associations of Measurement (Testing and Analytical Laboratories), *Eurolab Position Paper No. 1/2000*, May 2000, p 3.

33 J. Barnett, 'Intermediaries Revisited: Is Efficient Certification Consistent with Profit Maximization?', 37. *J. Corp. Law (Journal of Corporation Law)* 2012, p 476.

34 *See* the extensive references *supra* in n. 2.

35 *See* the extensive references *supra* in n. 3.

36 *See* for more information: www.tuv.com/en/corporate/home.jsp.

37 *See* for more information: www.sgsintl.com/.

38 *See* for more information: www.dekra-certification.com/en/home.

39 *See* for more information: www.ul.com/.

40 Art. 3, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L169, 12 July 1993.

assessment procedure. The conformity assessment is completed in accordance with technical procedures included in sectorial legislation dealing with a specific product (e.g. medical devices or toys).[41] Put differently, EU legislation prescribes the conformity assessment procedure that has to be followed by the manufacturer. In some cases, the assessment needs to be carried out by the manufacturer himself. However, the applicable legislation can also require that an independent third-party certifier is involved in the conformity assessment procedure of the product.[42] In this regard, the EU Medical Device Directive (MDD)[43] as well as the Proposal for a Regulation on Medical Devices ('Proposal')[44] refer to notified bodies that have to be engaged in the conformity assessment procedure of medical devices.[45]

A notified body is an independent entity notified by a Member State's competent authority. The body determines whether medical devices meet all the applicable essential requirements to get the necessary CE marking (Conformité Européenne). This certificate shows that the devices comply with the applicable safety and technical requirements.[46] Member States can choose notified bodies from the entities under their jurisdiction which fulfil the requirements set out in the MDD or the Proposal and the principles laid down in Decision 2008/768.[47] In essence, notified bodies have to operate in a competent, non-discriminatory, transparent, neutral and independent manner.[48] Manufacturers, in their turn, are free to choose any notified body that has been designated by Member States to carry out the conformity assessment procedure of medical devices.[49]

8. Article 11 and Annexes II–VII of the MDD regulate the role of notified bodies in the conformity assessment procedure of medical devices. The conformity assessment procedure consists of an audit of the manufacturer's quality system and,

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41 European Commission, *Conformity Assessment*, ec.europa.eu/growth/single-market/goods/building-blocks/conformity-assessment/index_en.htm.

42 European Commission, 'The "Blue Guide" on the Implementation of EU Product Rules 2016', 5 Apr. 2016, pp 62–84.

43 Art. 16, Directive 93/42/EEC.

44 Ch. IV, Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, COM/2012/0542 final – 2012/0266 (COD), 26 June 2012.

45 European Commission, *Notified Bodies*, ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies/index_en.htm; European Commission, *Need for Notified Body?*, ec.europa.eu/growth/single-market/ce-marking/manufacturers/notified-body/index_en.htm.

46 BSI Notified Body, *Want to Know More About the Notified Body?*, 2014, p 4, medicaldevices.bsigroup.com/LocalFiles/en-GB/Services/BSI-md-notifed-body-guide-brochure-UK-EN.pdf.

47 Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ L218/82, 13 Aug. 2008. *See* in this regard also: European Commission, *Notified Bodies.*

48 Art. R17 Decision 768/2008/EC; European Commission, *Notified Bodies.*

49 European Commission, *Notified Bodies.*

depending on the classification of the medical device,[50] a review of the technical documentation provided by the manufacturer. Once the notified body has determined that a manufacturer or the latter's devices comply with the applicable criteria, the certifier issues a CE certificate.[51] Chapter IV of the Proposal also addresses the role and involvement of notified bodies in the conformity assessment procedure. The Proposal follows the general lines of the MDD. Consequently, the classification of devices determines the conformity assessment procedure that the manufacturer has to follow. The conformity assessment procedures for medical devices are further laid down in Annexes VIII–X of the Proposal. For devices of classes IIa, IIb and III, the notified body is involved in the conformity assessment procedure depending on the risks and class of the device. Medical devices of class III, for instance, require a notified body's prior approval with regard to the design or the type of the device as well as concerning the manufacturer's quality management system. In the case of devices of class IIa and IIb, the notified body has to check the quality management system and the technical documentation of the device for representative samples.[52]

9. Following the PIP breast implant scandal, the European Commission issued Recommendation 2013/473/EU on audits and assessments performed by notified bodies in the field of medical devices.[53] The Recommendation contains requirements for conducting unannounced audits and stipulates the obligations for both the manufacturer and the notified body when performing such audits. Notified bodies already had the possibility to do unannounced audits under the MDD and the Proposal. However, Recommendation 2013/473 now obliges notified bodies to perform unannounced audits of manufacturers of medical devices.[54] More specifically, notified bodies have to carry out unannounced audits at least once every three year. The timing of the audits should be unpredictable. Notified bodies need to increase the frequency of unannounced audits if the devices bear a high risk, if the devices of the type in question are frequently non-compliant or if specific information gives rise to suspicions that the devices or their manufacturer do not comply with the applicable requirements. Notified bodies have to check a recently

50 There are four classes of medical devices ranging from low to high risk: medical devices of class I, IIa, IIb and III. *See* for more information: European Commission, DG Health & Consumer; 'Medical Devices Guidance Document. Classification of Medical Devices', *MEDDEV* 2. 4/1 Rev. 9, June 2010.

51 BSI Notified Body, *Want to Know More About the Notified Body?*, 2014, p 7.

52 Part 3.5. Proposal for a Regulation on medical devices.

53 Commission Recommendation 2013/473/EU of 24 Sept. 2013 on the audits and assessments performed by notified bodies in the field of medical devices, OJ L253/27, 25 Sept. 2013.

54 *See* in this regard: BEC International, *EU Commission Recommendation 2013/473/EU on Unannounced Audits*, www.3ec.sk/fileadmin/user_upload/Product_Certification/UNANNOUNCED_AUDITS_2014.pdf.

produced sample, preferably one taken from the ongoing manufacturing process, for its conformity with technical documentation and (applicable) legal requirements.[55]

3. The PIP Case: Legal Consequences for Consumers at Different Levels

10. Although the EU has addressed the involvement of notified bodies in the conformity assessment procedure of medical devices, the PIP case revealed that problems can, nonetheless, occur if they issue incorrect certificates. After a brief discussion of the underlying facts (s. 3.1), it is shown that the PIP breast implant scandal affects consumers in several ways. Court rulings in Germany (s. 3.2) and France (s. 3.3) illustrate that women who bought the implants will not always be successful to hold notified bodies liable and recover their losses. Considering that issues arose with regard to the interpretation of the MDD, a prejudicial procedure is currently pending before the European Court of Justice (ECJ) (s. 3.4). The PIP breast implant case is particularly interesting from a private international law perspective as it poses challenges regarding jurisdiction and applicable law, for instance due to the notion of damage and the difficulty to determine the place where the damage occurred (s. 3.5).

3.1. Facts of the PIP Breast Implant Case

11. PIP was a French company that produced breast implants. As from 2001, French law obliged manufacturers of breast implants to use one specific type of medical silicone gel for their products. However, PIP did not comply with this requirement. It developed an elaborate scheme of deceit and continued to use sub-standard industrial silicone gel implants to cut costs. The impact of the PIP's fraud on the manufacturing process was quite disparate. Whereas some implants contained the required medical silicone gel, others held a mixture of medical and industrial silicone gel or only industrial silicone gel. The control on the quality of the breast implants was, therefore, made extremely difficult. The French public supervisory agency (*Agence Française de Sécurité Sanitaire des Produits de Santé*-AFSSAPS) only became aware of the problems with the PIP implants in 2009. The implants were eventually taken off the market in early 2010.[56]

Hundreds of thousands of PIP implants filled with sub-standard silicone gel were distributed around the world. Women who purchased these implants claimed

55 *See* in this regard: Annex III, Recommendation 2013/473/EU.

56 *See* for extensive description and discussion of the facts: B. Van Leeuwen, 5. *EJRR* 2014, pp 339-340; B.M. Fry, 22. *Willamette J. Int'l L. & Dispute Res.* 2014, pp 169-170.

compensation for the harm caused by their (potential) rupture. However, law suits against manufacturer PIP were fruitless as the company went bankrupt in 2011. Therefore, plaintiffs had to find other targets to obtain compensation for the physical harm or the financial losses they incurred after buying the implants. Against this background, a number of victims brought proceedings against product certifier TüV Rheinland. TüV was the notified body that performed the conformity assessment procedures of the breast implants. It certified the distribution of the implants despite the devices being unsuitable for medical and cosmetic use. Claims have been filed against the certifier in Germany as well as France. The proceedings in both countries illustrate that holding a notified body liable is by no means straightforward.[57]

3.2. Liability Claims Against TüV Rheinland in Germany

12. Several women affected by defective implants filed suits against TüV Rheinland in Germany. The claims have, however, not been successful so far and plaintiffs were unable to recover their losses.[58] In a case before the District Court in Nuremberg-Fürth, the victim's claim was rejected. The court held that EU law did not require the notified body to investigate specific implants or carry out unannounced inspections on the manufacturing site.[59] In another case, the plaintiff received PIP breast implants in a German clinic and had them removed because of physical injuries. She subsequently brought an action against TüV Rheinland before the District Court Frankenthal claiming EUR 40,000 in damages for pain and suffering and a judgment declaring the third-party certifier liable for future material damage. Her claim was dismissed on three different grounds.[60]

Firstly, the plaintiff did not establish that she had suffered any medical harm. Secondly, she was not able to show that the specific implants she had bought contained industrial silicone gel. Finally, the court concluded that TüV

57 B. Van Leeuwen, 5. *EJRR* 2014, pp 341–344; B.M. Fry, 22. *Willamette J. Int'l L. & Dispute Res.* 2014, pp 169–170.

58 *See* for an extensive discussion: B. Van Leeuwen, 5. *EJRR* 2014, pp 343–346.

59 Landgericht Nürnberg-Fürth, 25 Sept. 2013, 11 O 3900/13. *See* for a discussion: H. Müller-Gerbes, 'PIP Breast Implants: TÜV Rheinland Wins Another Case', TüV Rheinland Press Release, 10 Apr. 2013, www.tuv.com/en/corporate/about_us_1/press/news_2/newscontent_cw_176262.html. It should, however, be noted that such inspections are now mandatory under Recommendation 2013/473. *See* for more information the discussion *supra* in s. 2.4.

60 Landgericht Frankenthal, 14 Mar. 2013, 6 O 304/12, JurionRS 2013, 37376, *Medizin Produkte Recht* (*M.P.R.*) 2013, pp 134–138. *See* for a discussion of the decision: M. Reiling & F. Niermeier, 'PIP Silicone Breast Implants – German Federal Court of Justice (BGH) Puts Three Questions to the ECJ on the Interpretation of the Medical Device Directive', *Noerr Publications*, 10 Apr. 2015, www.noerr.com/en/press-publications/News/pip-silicone-breast-implants.aspx.

had not breached its obligations under the MDD.[61] The court emphasized that there was a distinction between duties of notified bodies on the one hand and the obligations of national public market surveillance agencies on the other hand. Notified bodies cannot be qualified as market surveillance agencies and do not have the same powers. Instead, notified bodies only play a role in the conformity assessment procedure of medical devices.[62] In this regard, Annex II of the MDD contains the obligations of a notified body. For instance, the third-party certifier has to check the conformity of the quality management system with the provisions of the MDD. Although the notified body undertook an audit of the quality management system, it did not have to examine whether the quality management as presented by PIP was also brought into practice.[63] In essence, the audit of PIP's quality system was merely a 'document-based exercise'.[64] The notified body was also required to examine the design dossier containing information on the content and design of the breast implants. Once again, TüV was not obliged to inspect the actual implants.[65] In addition, the District Court held that the certifier had no obligation to perform unannounced visits. The MDD stipulates that the notified body *may* carry out such visits.[66] An obligation would only arise if there were specific circumstances demanding for an unannounced visit. However, the plaintiff failed to show the existence of such circumstances.[67]

13. The decision has been affirmed on appeal by the *Oberlandesgericht* (OLG) in Zweibrücken albeit on different grounds. The OLG first examined whether TüV Rheinland owed a duty of care in contract and in tort law to women who purchased the PIP-breast implants. The court then continued its analysis to determine whether the third-party certifier violated its duty of care.[68]

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61 Landgericht Frankenthal, 14 Mar. 2013, 6 O 304/12, JurionRS 2013, 37376, *M.P.R.* 2013, pp 134-138; B. Van Leeuwen, 5. *EJRR* 2014, pp 343-344.

62 *Ibid.*, pp 135-136; B. Van Leeuwen, 5. *EJRR* 2014, p 344.

63 Landgericht Frankenthal, 14 Mar. 2013, 6 O 304/12, JurionRS 2013, 37376, *M.P.R.* 2013, pp 134-137.

64 B. Van Leeuwen, 5. *EJRR* 2014, p 344.

65 Landgericht Frankenthal, 14 Mar. 2013, 6 O 304/12, JurionRS 2013, 37376, *M.P.R.* 2013, pp 134-137; B. Van Leeuwen, 5. *EJRR* 2014, pp 344.

66 As previously mentioned, Recommendation 2013/473 now obliges notified bodies to perform unannounced audits of manufacturers of medical devices. *See* in this regard the discussion *supra* in s 2.4.

67 Landgericht Frankenthal, 14 Mar. 2013, 6 O 304/12, JurionRS 2013, 37376, *M.P.R.* 2013, pp 134-137; B. Van Leeuwen, 5. *EJRR* 2014, p 344.

68 Oberlandesgericht Zweibrücken, 30 Jan. 2014, 4 U 66/13. *See* for a discussion and translation of the case: W. Rehmann & D. Heimhalt, 'Medical Devices: Liability of Notified Bodies?', *TaylorWessing*, May 2015, www.taylorwessing.com/synapse/may15.html; B. van Leeuwen, 5. *EJRR* 2014, pp 344-345.

From a contractual point of view, the court qualified the certification contract between PIP and TüV Rheinland as a contract for services, which did not have protective effects towards women who purchased the breast implants.[69] Certificates issued by notified bodies constitute a building block (*Baustein*) for manufacturers to show that they complied with the requirements in the MDD.[70] As such, the purpose and aim (*Sinn und Zweck*) of the certification is not to protect third parties. The CE label given to a medical device does not provide buyers with a right to claim compensation from the notified body involved in the conformity assessment procedure. Instead, it is only a prerequisite for the manufacturer to distribute the implants on the EU market. The certificate is an indication for the national authorities that the standards of care have been observed by the responsible parties without, however, relieving them of their responsibility.[71]

The court also relied on several other arguments to deny protective effects of the certification agreement towards women who bought the breast implants. It held that the group of persons covered by the protective effects of the certification contract may not be too large. More specifically, the circle of persons who benefit from the protective effects of the agreement should be limited to those parties in whose interest the certifier fulfils the contractual obligations as explicitly or tacitly agreed by the contracting parties.[72] The group of persons to whom notified bodies might owe a duty of care should be capable of being objectively determined. In other words, patients who purchased the implants need to be part of a group that is objectively determinable (*objektiv abgrenzbare Personengruppe*).[73] The third-party certifier must have been able to foresee that its actions could harm and affect both its co-

69 Oberlandesgericht Zweibrücken, 30 Jan. 2014, 4 U 66/13, Part II, 1. b); B. van Leeuwen, 5. *EJRR* 2014, p 344; W. Rehmann & D. Heimhalt, *TaylorWessing*, May 2015. The contract with protective effects *vis-à-vis* third parties is of particular importance in this regard as it '[opens] the contractual umbrella' (B.S. Markesinis, H. Unberath & A. Johnston, *The German Law of Contract: A Comparative Treatise* (Oxford: Hart 2002), p 207) for third parties to 'sue a promisor [certifier] for breach of one of the contract's secondary obligations, notably [...] some breach causing purely financial harm to the plaintiff [a third party]' (M. Bussani & V. Palmer, *Pure Economic Loss in Europe* (Cambridge: Cambridge University Press 2003), p 150).

70 B. Van Leeuwen, 5. *EJRR* 2014, pp 344-345.

71 Oberlandesgericht Zweibrücken, 30 Jan. 2014, 4 U 66/13, Part II, 1. b); W. Rehmann & D. Heimhalt, *TaylorWessing*, May 2015.

72 Oberlandesgericht Zweibrücken, 30 Jan.30, 2014, 4 U 66/13, Part II, 1. b); A. Zenner, 'Der Vertrag mit Schutzwirkung zu Gunsten Dritter – Ein Institut im Lichte seiner Rechtsgrundlage', 62. *NJW* (*Neue Juristische Wochenschrift*) 2009, pp 1030-1034; W. Rehmann & D. Heimhalt, *TaylorWessing*, May 2015.

73 BGH, 23 Jan. 1985, *NJW-RR* (*Neue Juristische Wochenschrift-Rechtsprechungs-Report (Zeitschrift)*) 1986, p 486; J. Joussen, *Schuldrecht I – Allgemeiner Teil* (Stuttgart: W. Kohlhammer Verlag 2008), p 413.

contractor as well as third parties such as the women who bought the implants. The risk of liability must be comprehensible, calculable and enable the certifier to seek appropriate insurance coverage.[74] However, third-party certifiers do not need to know the precise number, the name or the identity of the protected third parties.[75] Of importance is whether the expert opinion was ordered to submit it to a group of third parties who subsequently use it to take decisions.[76] In the PIP case, the contact between the patients and the manufacturer was not sufficient to conclude that the parties bound by the certification agreement intended to include all women who purchased the implants within its protective scope. The risk of liability for notified bodies arising from the certification agreement would become incalculable (*unabsehbar*) if it was accepted that TüV Rheinland had to compensate the losses suffered by all women who bought the implants.[77] Furthermore, the manufacturer did not have a particular interest in protecting the interest of the patients.[78] It did not have any special legal relationship with them and was only required by general rules of tort law and product liability not to violate their legally protected interests/goods (*Rechtsgüter*) when producing the medical device.[79]

The OLG Zweibrücken also concluded that TüV Rheinland did not owe a duty of care in tort to women who bought the implants. In this regard, the plaintiffs could have argued that the notified body breached its duty to adequately review the manufacturer's quality management system during the conformity assessment procedure. However, the court held that there is no general obligation to prevent bodily harm to others. The court then refused to accept the liability of the third-party certifier for an omission to act. In the latter hypothesis, the notified body

74 N. Lagoni, *The Liability of Classification Societies*, pp 202–203 with further reference in fn. 752; M. Liebmann, *Der Vertrag mit Schutzwirkung zugunsten Dritter* (Frankfurt am Main: Peter Lang, Europäische Hochschulschriften/European University Studies/Publications Universitaires Européennes 2006), pp 118–119; *Also see*: BGH, 20 Apr. 2004, *NJW* 2004, p 3035; BGH, 18 June 1968, *NJW* 1968, p 1931.

75 *See* for example BGH, 26 Nov. 1986, *NJW* 1987, p 1760; BGH, 10 Nov. 1994, *NJW* 1995, p 392 as referred to in N. Lagoni, *The Liability of Classification Societies*, pp 199 & 202–203, fn. 753.

76 N. Lagoni, *The Liability of Classification Societies*, p 199 with references to case law in fn. 741; J. Joussen, *Schuldrecht I – Allgemeiner Teil*, p 413; G. Wildmoser, K.J. Schiffer & B. Langoth, 'Haftung von Ratingagenturen gegenuber Anlegern?', 10. *R.I.W.* (*Recht der Internationalen Wirtschaft*) 2009, pp 665–666.

77 Oberlandesgericht Zweibrücken, 30 Jan. 2014, 4 U 66/13, Part II, 2. b) bb); W. Rehmann & D. Heimhalt, *TaylorWessing*, May 2015.

78 M. Liebmann, *Der Vertrag mit Schutzwirkung zugunsten Dritter*, p 117; B.S. Markesinis, H. Unberath & A. Johnston, *The German Law of Contract: A Comparative Treatise*, p 207; N. Lagoni, *The Liability of Classification Societies*, pp 198–202; A. Zenner, 62. *NJW* 2009, pp 1030–1034, fn. 23.

79 Oberlandesgericht Zweibrücken, 30 Jan. 2014, 4 U 66/13, Part II, 1. b) bb); W. Rehmann & D. Heimhalt, *TaylorWessing*, May 2015.

needs to be subjected to a special obligation to act (*besondere rechtliche Verpflichtung zum Handeln*). Following such an obligation, the notified body would face liability when it does not take the necessary action to protect the legal interests of other parties. Such a duty to act in the interests of patients may arise from the certification agreement if there is a contractual duty of care towards women who bought the implants and their welfare is a personal concern of the manufacturer. This can be established by examining the intent and purpose of the contract. However, such a conception was denied by the court as it considered that the purpose of the certification agreement was only to allow the manufacturer to market its devices.[80]

The duty to act in order to protect others can also be founded in the law. The MDD and the Proposal are of particular importance in this regard. The objective of the MDD is to protect patients who come into contact with medical devices. The MDD stipulates that medical devices should provide patients and users with a high level of protection and should attain the performance attributed to them by the manufacturer.[81] The Proposal aims to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high degree of safety and health.[82] The OLG Zweibrücken, however, concluded that the MDD did not impose any statutory obligation on the notified body to intervene in order to protect all patients that might come into contact with medical devices. The certification of a device is only a prerequisite for placing it on the European market. Similar to the first instance decision, the OLG in Zweibrücken held that notified bodies only have to perform a review based on the documents given by the manufacturer. They are not required to inspect the actual products themselves. The conformity assessment procedure undertaken by TüV did not create a guarantee that the implants complied with essential requirements in the MDD. The decision on appeal thereby reaffirmed the separation of duties between notified bodies on the one hand and public supervisory agencies on the other hand. Product certification cannot be placed at the same level as post-market surveillance activities. The national competent authorities are responsible to monitor and control the products that have been marketed. Considering that the third-party certifier was not required to test the conformity of the silicon used in the implants, patients could not see the certification of the quality management system as an indication of the quality of the implants.[83]

80 Oberlandesgericht Zweibrücken, 30 Jan. 2014, 4 U 66/13, Part II, 2. c); W. Rehmann & D. Heimhalt, *TaylorWessing*, May 2015.

81 Recital (5) Directive 93/42/EEC concerning medical devices.

82 Recital (1) Proposal for a Regulation on medical devices.

83 Oberlandesgericht Zweibrücken, 30 Jan. 2014, 4 U 66/13, Part II, 2. d); B. Van Leeuwen, 5. *EJRR* 2014, pp 344–3445; W. Rehmann & D. Heimhalt, *TaylorWessing*, May 2015.

3.3. Liability Claims Against TüV Rheinland in France

14. Third-party liability claims have also been filed against TüV Rheinland in France. A large group of distributors and women brought a case before the *Tribunal de Commerce* in Toulon. Contrary to the decisions in Germany, the French court held that TüV Rheinland negligently performed its obligations of control/inspection, care and vigilance.[84] The court considered that notified bodies effectively assume a public role and as a consequence guarantee that the product has reached a certain standard of safety whenever they certify it. The functions performed by TüV constituted a real delegation of public services by national authorities.[85]

In its capacity of notified body, TüV Rheinland had substantial power in its inspection role to ensure that the implants only contained the authorized gel. It was held that the certifier was not prudent or vigilant enough as it never performed unannounced inspections at the factory or on sites of the manufacturer to examine the implants despite having the right to so under the MDD. One small-scale unannounced visit would have made it possible to detect that the products did not fall under the remit of the certified manufacturing process. If TüV would have carried out unannounced inspections after finding out that the American Health Authority suspended the marketing, distribution, import and use of PIP breast implants in the US, the fraud could have been detected. In addition, TüV did also not carry out a sufficiently rigorous review of PIP's financial accounts. Such a review would have revealed the abnormalities with regard to the amount of gel bought and the volume of PIP's production.[86] The commercial court ordered TüV Rheinland to pay a provisional compensation of EUR 3,000 per person to approximately 1,700 patients. The immediate and provisional character of the compensation was upheld and confirmed by the *Cour d'Appel* of Aix-En-Provence on 21 January 2014.[87]

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84 Tribunal de Commerce Toulon, 14 Nov. 2013, n° RG 2011F00517, n° 2013F00567, p 144. *See* for a discussion: N. Carbonnelle, M.P. Martens, T. Goraya & J.B. Thienot, 'Medical Devices Liability Update', *Bird & Bird Publication*, 17 Nov. 2015, www.twobirds.com/en/news/articles/2015/global/life-sciences-november/medical-devices-liability-update.

85 *See* in this regard also: B. Van Leeuwen, 5. *EJRR* 2014, pp 245-246.

86 Tribunal de Commerce Toulon, 14 Nov. 2013, n° RG 2011F00517, 2013F00567, pp 142-143; B. Van Leeuwen, 5. *EJRR* 2014, pp 245-246; S. Mason & L. Fox, 'French PIP/TÜV Decision: What It Means for Medical Devices Regulation', *CMS Cameron McKenna Publications*, 21 Feb. 2014, www.lexology.com/library/detail.aspx?g=bc1e3486-b133-4c69-9020-2a122935cc77.

87 Cour d'appel Aix-en-Provence, 21 Jan. 2014, nr. 13/00690. *See* in this regard also: E. Montens & E. Plasschaert, 'PIP Breast Implants Patients Obtain a First 5,000,000 Euro Victory Against the Notified Body TUV Rheinland', *Crowell & Moring Publications*, 22 May 2014, www.lexology.com/library/detail.aspx?g=28a21496-a3d9-4b05-8a13-fa3027f826c8.

15. TüV Rheinland appealed against the first instance decision. The notified body claimed that it fully complied with the applicable requirements. TüV pertained that it was only responsible for controlling the design and the quality system and not the implants themselves. The certifier also argued that it had been systematically deceived by PIP which had presented false documents. TüV did not have sufficient powers under the MDD to take further actions to unmask the fraud. The *Cour d'Appel* d'Aix-en-Provence followed this reasoning and reversed the first instance decision which it held to be unfounded. The court of appeal concluded that TüV Rheinland complied with its obligations under supranational law ('*les obligations leur incombant en qualité d'organismes certificateurs*'). Consequently, it did not commit any fault engaging its tortious responsibility ('*commis de faute engageant leur responsabilité civile délictuelle*'). The role of the certifier has been defined by the MDD. The court held that TüV only had an obligation to examine the technical file and not the product itself. There were no elements in the file that should have warned the notified body that approved silicone products were replaced by other non-approved products. In addition, the MDD provides only for the possibility to make unannounced visits and there was no obligation to do so. The decision on appeal dismissed the claims brought by foreign distributors of PIP implants as well as over 3,000 persons who joined the case.[88]

3.4. Procedure Before the European Court of Justice

16. Because of the public importance of this case and the fact that a number of German courts were dealing with the same issues,[89] the OLG Zweibrücken gave permission to appeal to the German *Bundesgerichtshof* (BGH). On the 9th of April 2015, the BGH referred three questions on the interpretation of the MDD to the ECJ.[90] The first question is whether it follows from the objective and intention of the MDD that notified bodies act with the purpose to protect all potential patients or users of breast implants. This would imply that notified bodies may be directly and fully liable towards patients when they negligently perform their obligations. The second question is whether Annex II of the MDD imposes a general or at least

88 Cour d' Appel Aix-en-Provence, 2 July 2015. The case has been reported in several (online) journals and other sources: T. Klein, 'French Court Repeals Conviction Against TÜV Rheinland in PIP Case', *European Medical Device Technology, Regulatory and Compliance*, 2 July 2015 www.emdt.co.uk/daily-buzz/french-court-repeals-conviction-against-t%C3%BCv-rheinland-pip-case; QMed, 'Inspecting Company Wins Appeal in French Breast Implants Scandal', 2 July 2015, www.qmed.com/news/inspecting-company-wins-appeal-french-breast-implants-scandal; M. Croizet, 'Prothèses PIP: la justice dédouane le certificateur. Cette décision est incompréhensible', L'OBS Le Plus, 9 July 2015, leplus.nouvelobs.com/contribution/1395708-protheses-pip-la-justice-dedouane-le-certificateur-cette-decision-est-incomprehensible.html.

89 *See* the discussion *supra* in s. 3.2.

90 BGH, 9 Apr. 2015 – VII ZR 36/14.

a for-cause obligation for the notified body to test the product. The third question concerns the extent to which Annex II of the MDD imposes a general or at least a for-cause obligation to view business records of the manufacturer and/or to carry out unannounced audits of the notified body.[91]

3.5. Private International Law Aspects & the Liability of Third-Party Certifiers

17. The previous parts showed that the PIP scandal is a complex case with connections to several countries around the world. The now insolvent company PIP was located in France. Certifier TüV Rheinland, responsible for the conformity assessment of the breast implants, has its seat in Cologne, Germany. Furthermore, women from different nationalities and with various domiciles are affected by the defective and substandard implants. In such multijurisdictional cases, the rules of private international law come into play to determine the court or courts that have jurisdiction to adjudicate the dispute (s. 3.5.1). The conflict of laws rules of the chosen forum subsequently designate the law applicable to the contractual or extra-contractual claims (s. 3.5.2). The following paragraphs briefly attempt to touch upon the most challenging private international law issues regarding the third-party liability of certifiers.

3.5.1 Jurisdiction

18. In the EU, the Brussels I Recast Regulation (also known as the Brussels I*bis* Regulation) regulates the competence of the EU courts in civil and commercial cases.[92] It has replaced the Brussels I Regulation as of 10 January 2015.[93] The basic rule of the Regulation is included in Article 4 (previously Article 2 Brussels I Regulation): jurisdiction is to be exercised by the EU Member State in which the defendant is domiciled, regardless of his nationality (this is referred to as the *forum rei*). Pursuant to Article 63.1 Brussels I*bis* Regulation (previously Article 60.1 Brussels I Regulation), the domicile of companies is located in the place where the corporation has its statutory seat, central administration or principal place of business. In the context of the liability of third-party certifiers, the application of this general ground of jurisdiction in Article 4 Brussels I*bis* Regulation does not pose any great difficulties. In the PIP case, TüV Rheinland falls under the ambit of

91 ECJ, C-219/15, *Elisabeth Schmitt v. TÜV Rheinland LGA Products GmbH*, Request for a preliminary ruling from the *Bundesgerichtshof* lodged on 13 May 2015.

92 Regulation 1215/2012 of 12 Dec. 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, OJ L351/1, 20 Dec. 2012.

93 Regulation 44/2001 of 22 Dec. 2000 on jurisdiction and the recognition and enforcement of judgements in civil and commercial matters, OJ L12, 16 Jan. 2001.

the Brussels I*bis* Regulation as it has its domicile within the EU. The overview of German case law illustrated that the certifier was indeed sued in Germany on the basis of Article 4 as it has its headquarters in Cologne.

In addition to this general ground of jurisdiction, the Brussels I*bis* Regulation also contains, as did its predecessor the Brussels I Regulation, grounds of special jurisdiction. These grounds make supplementary venues available to prospective litigants. On the basis of Article 7.2 Brussels I*bis* Regulation (previously Article 5.3 Brussels I Regulation), for instance, tort actions can be brought before the courts of the place in a Member State where the harmful event occurred or may occur. For this ground to apply, it is required that the defendant of the tort claim is domiciled in the EU. In *Bier*, the ECJ established the rule of the double forum, which states that Article 5.3 Brussels I Regulation (now Article 7.2 Brussels I*bis* Regulation) grants jurisdiction to the courts of the place where the damage occurred (*locus damni* or *Erfolgsort*), as well as to those of the place of the event giving rise to that damage (*locus acti* or *Handlungsort*).[94] In other words, under Article 7.2 Brussels I*bis* Regulation the plaintiff has the choice to bring his case in the courts of the place where the damaging event took place or in the place where the damage was sustained. Contrary to the general ground of jurisdiction, the determination of the place of the damaging event and the place of the damage in terms of Article 7.2 Brussels I*bis* Regulation is often far more complex when it concerns third-party certifiers.

19. It should in that regard be noted that the type of wrongdoing TüV Rheinland has committed is completely different from the one committed by PIP. The latter has produced breast implants filled with an illicit mixture instead of the legally required silicone gel. PIP's actions have caused real damage (in the form of leakages and ruptures) to several women. TüV Rheinland, on the other hand, has allegedly failed to comply with its certification duties as a notified body. Various women have relied – in many cases probably through their doctors – on TüV Rheinland's erroneous certification of the implants when making their decisions. This difference in the inherent nature of the tort has ramifications for the application of Article 7.2 Brussels I*bis* Regulation.

20. As to the place of the damaging event, two possible interpretations can be formulated. First, it could be argued that La Seyne-sur-Mer, the commune in France where PIP was located, can be seen as the place of the event giving rise to the damage. After all, TüV Rheinland performed its (very limited) inspections/controls at PIP's factory and it failed to discover PIP's fraud there. On the other hand, TüV Rheinland granted the certification from its offices in Cologne,

94 ECJ 30 November 1976, C-21/76, *Handelskwekerij GJ Bier BV v. Mines de potasse d'Alsace SA* [1976] ECR 1735.

Germany. It is there that it applied the rules in force to the material findings and subsequently approved the CE marking.[95]

The existence of these two viewpoints is not academic but, on the contrary, rather crucial as it leads to the opening of different fora. In case the first interpretation is followed, victims cannot only litigate in Germany but they can also bring their claims against the German certifier in France. If the second stance is preferred, this option is (at least for the 'place of the damaging event' prong of the double forum test) not available. The plaintiffs can only sue in Germany as TüV Rheinland is located in Cologne and takes its certification decisions there. The *Tribunal de Commerce* of Toulon, the commercial court for the region in which La Seyne-sur-mer is located, accepted its own jurisdiction by supporting the first way of reasoning. It held that the place where the fabrication of the implants was inspected constituted the place of the damaging event and that this place could totally be separated from the place of subsequent certification and CE authorization.[96]

21. As to the place of the damage, it should be remarked that TüV Rheinland's alleged wrongdoing did not cause the harm suffered by the women. Any (past or future) physical damage suffered due to the defective breast implants is a direct consequence of the fraud committed by the French company PIP. The damage sustained by the unfortunate women as a consequence of their own (or their doctors') reliance on TüV Rheinland's assessment and subsequent granting of the CE marking cannot be equated to the damage resulting from the fraudulent use of unauthorized silicone gel. It would, therefore, be incorrect to assert that the damage caused by Tüv Rheinland manifests itself at the place where the adverse physical or other effects of the faulty implants were or will be felt.[97] Instead, one has to locate the place of the damage resulting from the inadequate inspection and certification. It should be underlined that only places within the EU will be validated in that regard as Article 7.2 Brussels I*bis* Regulation only gives jurisdiction to the courts of EU Member States.[98]

Detecting the place where a harmed woman has relied on TüV Rheinland's work seems to require an analysis of the mind of the patient. Such a subjective method of establishing jurisdiction is to be avoided. In our opinion, the connecting

95 For a similar analysis in the context of the third-party liability of classification societies, another type of certifier: J. De Bruyne & C. Vanleenhove, 'An EU Perspective on the Liability of Classification Societies: Selected Current Issues and Private International Issues', 20. *J.I.M.L.* (*Journal of International Maritime Law*) 2014, pp 116-117.

96 Tribunal de Commerce Toulon, 14 Nov. 2013, n° RG 2011F00517, n° 2013F00567, p 139.

97 *See* for a contrasting view on this matter: S. Fulli-Lemaire, 'Affaire PIP: Quelques réflexions sur les aspects de droit international privé', 1. *R.I.D.E* 2015, p 117.

98 It is of course possible (and even highly likely) that the national rules of private international law of the non-EU country provide for a basis of jurisdiction for the courts of that country.

factor of the place of the breast implant operation can be put forward as a reasonable alternative. It is there that the woman's reliance culminates and this location also has the benefit of being an easily determinable place. Furthermore, the location will usually coincide with the woman's domicile. The place of the operation, therefore, also contributes to the Brussels I*bis* Regulation's objective of providing predictable jurisdictional rules.[99] Consequently, claims might (still) be filed against certifier TüV Rheinland in those EU Member States where women had the breast implant surgery (e.g. England or Sweden).

The exercise naturally becomes more complex when the affected woman participated in medical tourism, i.e. travelling from one country to another with the sole or main objective to obtain medical treatment in that country. It could be said that the reliance in such cases is constant and ubiquitous in the sense that the female patient relies on the certification throughout the whole process. She perhaps takes the decision to trust PIP implants – inspired by TüV Rheinland's conformity evaluation and subsequent approval – in her domicile and continues to rely upon the German certifier's green light during her stay abroad to undergo surgery. Depending on the circumstances (e.g. the length of the medical stay), the place of the operation as the place of the damage might be too accidental or marginal and thus warrant a correction.

3.5.2 Applicable Law

22. In the private international law area of applicable law, the same issues surrounding the notion of the place of the damaging event and the place of the damage surface. In the EU, the private international law rules determining the law applicable to torts have been harmonized by the Rome II Regulation.[100] The Regulation has universal application, which means that the law specified by the Regulation shall apply, whether or not it is the law of an EU Member State (Art. 3).

The special ground for product liability in Article 5 does not apply to the liability of certifiers. Instead, the cornerstone of the Rome II Regulation, found in Article 4.1, comes to the foreground.[101] This article states that the law applicable to a non-contractual obligation arising out of a tort shall be the law of the country in which the damage occurs (*lex loci damni*) irrespective of the country in which the event giving rise to the damage occurred. Only if both the tortfeasor and the victim have their habitual residence in the same

99 *See* in this regard Recital (15) of Regulation 1215/2012.

100 Regulation No. 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations, OJ L199, 31 July 2007. The Regulation applies to all EU Member States except Denmark.

101 A. Dickinson, *The Rome II Regulation – The Law Applicable to Non-Contractual Obligations* (Oxford-New York: Oxford University Press 2008), p 307, no. 4.22.

country at the time the damages occurs, the law of that country will apply (Art. 4.2). Article 4.3 allows to ignore the rules of Articles 4.1 and 4.2 if it is clear from all the circumstances of the case that the tort is manifestly more closely connected with another country. The law of that country will then govern the legal relationship. This escape mechanism can perhaps serve as the basis to deviate from the application of the law of the place of the operation in cases of accidental connection due to medical tourism.

In the PIP case, the Rome II Regulation did not come into play as the Regulation replaced the national choice-of-law rules in non-contractual obligations which fall within its scope only as of 11 January 2009.[102] However, national rules equally contain references to the place of the damaging event or the place of the damage. Article 99, § 1, 2° of the Belgian Code of Private International Law, for instance, refers to the law of the state where the damaging act and the damage (will) occur.[103]

4. The Way Forward: Liability of Notified Bodies Increases Safety of Medical Devices

23. The previous parts shed light on the decisions that have been taken by national courts in the PIP breast implant case. The court rulings in France and Germany did not impose liability on TüV Rheinland. However, there are several reasons why the threat of holding notified bodies liable might increase the accuracy and quality of certificates. This in turn contributes to the objective of EU legislation to ensure the safety of medical devices and safeguard the health of their users. After a brief discussion of the certification market in general (s. 4.1), the analysis examines four reasons why the threat of liability might be an effective way to ensure that notified bodies issue accurate certificates: the least-cost avoider argument (s. 4.2), the optimum level of care argument (s. 4.3), the spreading of risk argument (s. 4.4) and irrational concerns with regard to opening the floodgates (s. 4.5).[104]

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102 Art. 32 Regulation 864/2007.

103 Act of 16 July 2004 houdende het Wetboek van internationaal privaatrecht, *Belgian Official Gazette*, 27 July 2004, 57344.

104 The analysis is based on works by several (law and economics) academics: R. Posner, *Economic Analysis of Law* (New York: Aspen Publishers 2011), 1009 p; G. Calabresi, *The Costs of Accidents: A Legal and Economic Analysis* (Yale: Yale University Press 1970), 350 p; G. Husisian, 'What Standard of Care Should Govern the World's Shortest Editorials? An Analysis of Bond Rating Agency Liability', 75. *Cornell L. Rev. (Cornell Law Review)* 1990, p 410. *See* for an extensive analysis in the field of credit rating agencies and further references: J. De Bruyne, 'How the Threat of Holding Credit Rating Agencies Liable Might Increase the Accuracy of Their Ratings', 52. *Willamette L. Rev.* (*Willamette Law Review*), 2016, pp 201-226.

4.1. General Considerations About the Certification Market

24. Notified bodies and by extension other third-party certifiers must have an incentive to issue accurate and reliable certificates. The threat of liability or actually holding third-party certifiers liable can provide for such an incentive.[105] If notified bodies are subject to a risk of liability, the likelihood of inaccurate and flawed certificates decreases.[106] In other words, the threat of liability is an effective means of deterring wrongdoing by gatekeepers such as notified bodies.[107] That is because the objective of tort liability is the deterrence of unreasonable risks.[108]

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105 R. Jones, 'The Need for a Negligence Standard of Care for Credit Rating Agencies', 1. *Wm. & Mary Bus. L. Rev.* (*William & Mary Business Law Review*) 2010, p 226.

106 F. Partnoy, *Rethinking Regulation of Credit Rating Agencies: An Institutional Investor Perspective*, San Diego Legal Studies Paper No. 09-014, pp 14–16, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1430608 (accessed 26 Sep. 2016); A. Darbellay & F. Partnoy, 'Credit Rating Agencies and Regulatory Reform', in C.A. Hill, & B.H. McDonnell (eds), *Research Handbook on the Economics of Corporate Law* (Cheltenham: Edward Elgar Publishing 2012), pp 273 & 288–289.

107 *See* in this regard: N.S. Ellis, L.M. Fairchild & F. D'Souza, 17. *Stan. J.L. Bus. & Fin.* 2012, p 182; K. Dennis, 'The Ratings Game: Explaining Rating Agency Failures in the Build Up to the Financial Crisis', 63. *U. Miami L. Rev. (University of Miami Law Review)* 2009, pp 1140–1141; S. Harper, 'Credit Rating Agencies Deserve Credit for the 2007–2008 Financial Crisis: An Analysis of CRA Liability Following the Enactment of the Dodd-Frank Act', 68. *Wash. & Lee L. Rev. (*Washington *and* Lee Law Review) 2011, pp 1957–1972. *See* in general: S.A. Law & S. Polan, *Pain and Profit: The Politics of Malpractice* (New York: Harper & Row 1978), 305 p; R. Posner, *Economic Analysis of Law*, p 1009; J.C. Coffee, *Gatekeepers: The Role of the Professions in Corporate Governance* (Oxford: Oxford University Press 2006), 400 p; F. Partnoy, 'The Paradox of Credit Ratings', in R.M. Levich, G. Majnoni & C. Reinhart(eds), *Ratings, Rating Agencies and the Global Financial System* (New York: Kluwer 2002), p 65. When third-party certifiers do not merely provide information in the form of an attestation but thereby restrict and control the access of the certified product to the market, they serve as gatekeepers. Considering that EU law requires the involvement of notified bodies in the conformity assessment of certain medical devices before a manufacturer can place them on the market, they can indeed be considered as parties keeping the gate to the EU market. *See* for an extensive discussion on the concept of gatekeeper: R. Kraakman, 'Gatekeepers: The Anatomy of a Third-Party Enforcement Strategy', 2. *J.L.E.P. (Journal of Law, Economics & Policy)* 1986, p 53; S. Mavrommati, 'The Dynamics of Gatekeepers, Corporate Culture and Whistle Blowers', 1. *Corp. Governance L. Rev. (Corporate Governance Law Review)* 2005, p 385; J.C. Coffee, *Gatekeepers: The Role of the Professions in Corporate Governance* p 400; A. Laby, 'Differentiating Gatekeepers', 1 *Brook. J. Corp., Fin. & Com. L. (Brooklyn Journal of Corporate, Financial & Commercial Law)* 2006, p 119; S. Kim, 'Gatekeepers Inside Out', 21. *Geo. J. Legal Ethics (Georgetown Journal of Legal Ethics)* 2008, p 411; A. Hamdani, 'Gatekeeper Liability', 77. *S. Cal. L. Rev. (Southern California Law Review)* 2004, p 53; F. Partnoy, 'Barbarians at the Gatekeepers?: A Proposal for a Modified Strict Liability Regime', 79. *Wash. U.L.Q.* (*Washington University Law Quarterly*) 2001, p 491; L.A. Cunningham, 'Beyond Liability: Rewarding Effective Gatekeepers', 92. *Minn. L. Rev. (Minnesota Law Review)* 2007, p 323.

108 D. Rosenberg, 'The Judicial Posner on Negligence Versus Strict Liability: Indiana Harbor Belt Railroad Co. v. Am. Cyanamid Co', 120. *Harv. L. Rev. (Harvard Law Review)* 2007, p 1212 citing *Ind. Harbor Belt R.R. Co. v. Am. Cyanamid Co.*, 662 F. Supp. 635, 1181–1182 (N.D. Ill. 1987); A. D. Miller & R. Perry, 'The Reasonable Person', 82. *N.Y.U. L. Rev.* (*New York University Law*

However, the threat of liability and holding notified bodies liable only seems useful if two conditions are met.[109]

25. Firstly, there should be no other mechanisms or incentives that already make notified bodies issue accurate certificates. In essence, the threat of liability has to be a *conditio sine qua non* for reliable certificates due to the lack of alternatives that ensure this aim.[110] This arguably is the case considering that the PIP scandal illustrated that reputational constraints alone did not prevent TüV Rheinland from issuing incorrect certificates.[111] Moreover, one can think of other ways to safeguard that third-party certifiers issue accurate certificates. In this regard, reference can be made to a number of (innovative) proposals in the field of other third-party certifiers such as CRAs and classification societies. These include tax or financial incentives, more control and supervision by (international) governmental bodies, minimizing conflicts of interest and even entirely reorganizing the certification process.[112] Arguably, those measures to increase the accuracy of certificates

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Review) 2012, p 328 (writing that '[a]ccording to economic wisdom, this deterrence of unreasonable risk is the primary objective of tort liability').

109 *See* for further references: J. De Bruyne, 52. *Willamette L. Rev.* 2016, pp 206-210.

110 G. Husisian, 75. *Cornell L. Rev.* 1990, p 440 (referring to R. Posner, *Economic Analysis of Law* (Boston: Little Brown and Company 1986), pp 513-514); F.H. Easterbrook & D.R. Fischel, 'Mandatory Disclosure and the Protection of Investors', 70. *Va. L. Rev. (Virginia Law Review)* 1984, p678.

111 *See* in this regard the analysis *supra* in part 3. *Also see*: K. Dennis, 63. *U. Miami L. Rev.* 2009, pp 1131-1140.

112 *See* for credit rating agencies: M. Gudzowski, 'Mortgage Credit Ratings and the Financial Crisis: The Need for a State-Run Mortgage Security Credit Rating Agency', 1. *Colum. Bus. L. Rev. (Columbia Business Law Review)* 2010, p 101; M. Bussani, 'Credit Rating Agencies' Accountability: Short Notes on a Global Issue', 10. *Global Jurist* 2010, p 1; T.E. Lynch, 'Deeply and Persistently Conflicted: Credit Rating Agencies in the Current Regulatory Environment', 59. *Case W. Res. L. Rev. (Case Western Reserve Law Review)* 2009, p 227; O. Schmid, 'Rebuilding the Fallen House of Cards: A New Approach to Regulating Credit Rating Agencies', 3. *Colum. Bus. L. Rev. (Columbia Business Law Review)* 2012, p 994; N.D. Horner, 'If You Rate It, He Will Come: Why Uncle Sam's Recent Intervention with the Credit Rating Agencies Was Inevitable and Suggestions for Future Reform', 41. *Fla. St. U. L. Rev. (Florida State University Law Review)* 2014, p 489; J. Manns, 'Rating Risk After the Subprime Mortgage Crisis: A User Fee Approach for Rating Agency Accountability', 87. *N.C. L. Rev. (North Carolina Law Review)* 2009, p 1011; R.J. Rhee, 'On Duopoly and Compensation Games in the Credit Rating Industry', 108. *Nw. U. L. Rev. (Northwestern University Law Review)* 2013, p 85; Y. Listokin & B. Taibleson, 'If You Misrate, then You Lose: Improving Credit Rating Accuracy Through Incentive Compensation', 27. *Yale J. on Reg. (Yale Journal on Regulation)* 2010, p 91; P. Hosp, 'Problems and Reforms in Mortgage-Backed Securities: Handicapping the Credit Rating Agencies', 79. *Miss. L.J. (Mississippi Law Journal)* 2010, p 531. *See* for classification societies: L. Lindfelt, 'A Future for Classification Societies', *CMI Yearbook* 1994, pp 253-254; N. Lagoni, *The Liability of Classification Societies*, pp 26-35; M. Hayashi, 'Toward the Elimination of Substandard Shipping: The Report of the International Commission on Shipping', 16. *Int'l J* Marine & Coastal *L. (International Journal of Marine & Coastal Law)* 2003, p 508.

could also be used for notified bodies as they are confronted with similar problems (e.g. the conflict of interest that arises because the manufacturer of the medical devices pays the notified body to certify the devices, the so-called issuer-pays business model[113]). However, most of these suggestions to increase the quality of certificates have not (yet) been adopted by supra- and national legislators in the field of rating agencies and classification societies.[114] It thus remains unlikely that they would suddenly be enacted for notified bodies involved in the conformity assessment of medical devices. In sum, there is currently no alternative available to safeguard that notified bodies issue accurate certificates, which makes the reliance on (the threat of) liability even more likely.

26. Secondly, liability only holds merit if the judicial system is capable of determining when a notified body acted negligently or when the certificate is incorrect.[115] Notified bodies will obviously not be held liable towards third parties if courts are unable to detect such conduct. Judges might, for instance, not have the proper technical expertise and knowledge and might 'have great difficulty distinguishing significant factors from insignificant ones'.[116] Even though consumers can file suits against notified bodies for their alleged misconduct, proceedings will in most cases be fruitless.[117] Adopting a negligence-based standard might thus increase claims against notified bodies but at the same time not enhance the welfare of consumers or encourage notified bodies to attain a higher level of care if courts are unable to actually hold them liable. In addition, imposing liability upon notified bodies might require substantial oversight by the government especially in developing the necessary performance standards. This in turn can lead to additional costs which will eventually be passed on by the notified body to the purchaser of the medical devices.[118] However, things need to be nuanced. The first instance decision by the French court in Toulon illustrates that courts do have the technical capacity to determine whether a notified body acted negligently. Courts are not afraid to hold notified bodies liable if they did not act with sufficient care and lacked reasonable grounds to issue the certificate.[119] The concern of the government's creation of performance standards also needs to be seen in a more optimistic light. The European Commission already adopted regulations and requirements regulating

113 *See* in this regard: L. Bai, 'On Regulating Conflict of Interests in the Credit Rating Industry', 13. *N. Y.U. J. Legis. & Pub. Pol'y (N.Y.U. Journal of Legislation & Public Policy)* 2010, p 254.

114 *See* for an overview in the context of credit rating agencies: J. De Bruyne, 52. *Willamette L. Rev.* 2016, pp 176-201.

115 G. Husisian, 75. *Cornell L. Rev.* 1990, p 440; J. De Bruyne, 52. *Willamette L. Rev.* 2016, p 208.

116 G. Husisian, 75. *Cornell L. Rev.* 1990, pp 440 & 443-444.

117 J.D. Krebs, 'The Rating Agencies: Where We Have Been and Where Do We Go From Here', 3. *J. Bus. Entrepreneurship & L (Journal of Business, Entrepreneurship & the Law)* 2009, p 158.

118 M. Gudzowski, 1. *Colum. Bus. L. Rev.* 2010, p 132; J. De Bruyne, 52. *Willamette L. Rev.* 2016, p 208.

119 *See* the discussion *supra* in s. 3.

the involvement of notified bodies in the conformity assessment procedure of medical devices. As such, legislators and regulators would not have to start from an empty sheet when implementing (additional) legislation.[120] Against this background, the following paragraphs discuss a number of arguments why the threat of liability ensures that notified bodies issue accurate certificates.

4.2. The Least-Cost Avoider Argument and Liability for Notified Bodies

27. Under the least-cost avoider argument, the tort system should impose liability on the least-cost avoider of mistakes. The latter is the actor which will incur the least amount of costs if it was the one tasked to prevent the harm (e.g. injuries because of leaking implants). In the certification business, the notified body might be one of the least-cost avoiders of mistakes (e.g. defective breast implants). Not only because of its expertise and access to the manufacturer's confidential information but also because it would cost consumers much more to examine the quality of each individual breast implant.[121] Courts founding their decision on the least-cost avoider argument would, therefore, be inclined to impose liability on notified bodies as they are able to prevent potential mistakes at a lower cost than consumers.[122]

At the same time, liability for notified bodies might result in increased costs for the latter in terms of monitoring and recordkeeping. These costs will be passed on to manufacturers resulting in higher certification fees and will, therefore, ultimately lead to higher prices for medical devices.[123] The problem is that those monitoring and recordkeeping requirements do not necessarily improve certificates or render medical devices safer. They only serve as evidence that a notified body carefully performed its activities and did not act negligently when issuing the certificates. The costs associated with maintaining the documents and records are thus wasted from a societal point of view as they have not been invested in making more accurate certificates or safer devices.[124] As such, the imposition of liability would be nothing more than a waste of resources because it actually does not increase the social welfare and health of consumers.[125] Notified bodies might also

120 *See* the discussion *supra* in s. 2.

121 G. Husisian, 75. *Cornell L. Rev.* 1990, p 431.

122 G. Husisian, 75. *Cornell L. Rev.* 1990, pp 430–431; J. De Bruyne, 52. *Willamette L. Rev.* 2016, p 210.

123 C.M. Mulligan, 'From AAA to F: How the Credit Rating Agencies Failed America and What Can Be Done to Protect Investors', 50. *B.C.L. Rev. (Boston College Law Review)* 2009, pp 1296–1297.

124 G. Husisian, 75. *Cornell L. Rev.* 1990, p 434.

125 G. Wagner, 'Gatekeeper Liability: A Response to the Financial Crisis', Paper presented at the Law and Economics Workshop of Tel Aviv University, Aug. 2013, pp 16–19, ssrn.com/abstract=2317213.

need more time and efforts to certify products if they face the risk of being held liable for defective products. Consequently, they will spend more time preparing the certificates during the conformity assessment procedure, which could delay manufacturers in marketing devices that require a certificate.[126]

However, even if the concerns in the previous paragraph might be true, encouraging notified bodies to spend more time and care when issuing certificates is a 'laudable goal'.[127] Moreover, holding notified bodies liable could make a difference in terms of 'allocative efficiency'.[128] Allocative efficiency implies that there is an optimal distribution of goods and services responding to the preferences of consumer.[129] More specifically, if certificates are accurate and reliable, consumers will not have to investigate the products and incur the costs associated with such examination. On the other hand, if certificates are unreliable, consumers will be exposed to costs because they will have to make sure that the devices they purchase are safe. Each consumer would have to collect and analyse information about the device, seek advice from other experts in the medical sector or perform their own analysis before buying the manufacturer's medical devices. The costs associated with such activities might be substantial compared to a situation in which only one expert institution, namely the notified body, issues a reliable certificate that can be used by all consumers.[130]

4.3. The Optimum Level of Care Argument and Liability of Notified Bodies

28. The optimum level of care is another argument relied on to advocate liability for notified bodies. In an ideal world, manufacturers might contract with another notified body or pay less certification fees when discovering that the initial certificate for a device is inaccurate. Consequently, the hired notified body would have to reduce the price of its certification services to reflect the below-optimum investment in accuracy. Put differently, the notified body will have to increase its investment in accuracy in order to avoid lowering the price

126 B.H. Brownlow, 'Rating Agency Reform: Presenting the Registered Market for Asset-Backed Securities', 15. *N.C. Banking Inst. J. (North Carolina Banking Institute Journal)* 2011, p 133; J. De Bruyne, 52. *Willamette L. Rev.* 2016, pp 210-211.

127 N.S. Ellis, L.M. Fairchild & F. D'Souza, 17. *Stan. J.L. Bus. & Fin.* 2012, p 216.

128 G. Wagner, Paper presented at the Law and Economics Workshop of Tel Aviv University, Aug. 2013, p 19.

129 S. Rothlin & D. McCann, *International Business Ethics: Focus on China* (Berlin: Springer 2015), p 465.

130 G. Wagner, Paper presented at the Law and Economics Workshop of Tel Aviv University, Aug. 2013, p 20; J. De Bruyne, 52. *Willamette L. Rev.* 2016, pp 211-213.

or losing market share to other notified bodies that offer more accurate and reliable certification services.[131]

However, notified bodies will invest in the accuracy of certificates only until the marginal cost of doing so equals the increase in marginal revenue achieved by displaying greater accuracy. Consequently, notified bodies are allowed to make some errors caused by underinvestment in accuracy, as these will remain undiscovered. The investment in the accuracy of certificates can also lead to a marginal change in revenue which is less than the benefits of not investing in an optimal level of accuracy. As such, underinvesting in the accuracy of certificates sometimes becomes a rational profit-maximizing strategy for notified bodies. The threat of liability in case notified bodies do not sufficiently invest in accuracy might, therefore, increase the standard of care that notified bodies will display. A notified body would have to consider whether it is exposing itself to potential liability for any degree of negligence by its failure to invest in the accuracy of certificates. Imposing the costs of underinvesting in the accuracy of certificates on notified bodies might thus create an incentive to not act negligently.[132]

4.4. Risk Spreading Argument and Liability of Notified Bodies

29. A further argument why notified bodies should face liability is related to the spreading of risk. Notified bodies will internalize potential costs in the certification fee if courts threaten to hold them liable for negligent conduct. Consequently, notified bodies will charge higher prices for their services and transfer these costs to the manufacturer paying for the certification services. Notified bodies can shift these costs to the extent that the manufacturers are willing to bear the increased costs of the certification. Consequently, notified bodies that on average act more negligent than their competitors will have higher costs to pass on to the manufacturer. This might alarm manufacturers and consumers that such bodies are not issuing accurate and reliable certificates. Underinvesting notified bodies will, therefore, be forced to invest in the accuracy of their certificates if they want to avoid losing business to other notified bodies that provide more accurate services.[133]

Furthermore, notified bodies derive a major part of their income from certification fees. In order to cover the potential costs of liability, they will have an incentive to charge higher prices to those manufacturers who misrepresent their products or provide poor information with regard to the latter (as was the situation

131 G. Husisian, 75. *Cornell L. Rev.* 1990, pp 430–432.

132 G. Husisian, 75. *Cornell L. Rev.* 1990, pp 431–432; J. De Bruyne, 52. *Willamette L. Rev.* 2016, pp 213–214.

133 G. Husisian, 75. *Cornell L. Rev.* 1990, pp 432–434; J. De Bruyne, 52. *Willamette L. Rev.* 2016, pp 214–216.

in the PIP case). They will pass on the costs of potential liability to those manufacturers that gave inaccurate information in the past or appear to not disclose all information with regard to a medical device. As a result, manufacturers are encouraged to provide the most accurate information possible with regard to a device on which the certificate will subsequently be based. If manufactures fail to provide accurate information concerning the device, the cost of marketing will raise because of the higher certification fees. In essence, a higher level of accurateness of certificates as well as safer products are also achieved by the threat of holding notified bodies liable as it triggers the least-cost providers of information, namely the manufacturers themselves, to give information of sufficient quality.[134]

4.5. Floodgate Concerns and Liability of Notified Bodies

30. Finally, there is the concern that, even if liability for gatekeepers has the effect of deterring bad behaviour, it might encourage frivolous litigation and open the floodgates against gatekeepers. This would have dramatic consequences for the certification business as a whole.[135] However, the *threat* of liability cannot be equated to the *actual* liability of notified bodies. After all, plaintiffs often have to prove several elements for their liability claims against third-party certifiers to be successful.[136]

From a Belgian perspective, for instance, and in the absence of specific legislation on the liability of notified bodies, consumers have to base their claims on Articles 1382–1383 of the Belgian Civil Code (BCC) to recover in tort from the notified body. Pursuant to Articles 1382–1383 BCC, a plaintiff will have to prove that the notified body committed a wrongful act (*faute*), that he incurred damage (*dommage*) and that there is a causal link between both elements (*lien de causalité*).[137] As such, courts will not automatically hold notified bodies liable merely because they have already incurred liability in the past.[138] Reference can in this regard be made to Belgian case law dealing with the liability of other third-party certifiers such as classification societies. A third

134 G. Husisian, 75. *Cornell L. Rev.* 1990, pp 433–434; J. De Bruyne, 52. *Willamette L. Rev.* 2016, pp 214–216.

135 *See* in this regard: C. Hill, 'Regulating Rating Agencies', 82. *Wash. U. L. Q (Washington University Law Quarterly)* 2004, p 89; C.M. Mulligan, 50. *B.C.L. Rev.* 2009, p 1297; N.D. Horner, 41. *Fla. St. U. L. Rev.* 2014, p 504; A. Pinto, 'Control and Responsibility of Credit Rating Agencies in the United States', 54. *Am. J. Comp. L. (American Journal of Comparative Law)* 2006, p 355.

136 N.S. Ellis, L.M. Fairchild & F. D'Souza, 17. *Stan. J.L. Bus. & Fin.* 2012, p 217. *See* for an extensive analysis in the context of credit rating agencies: J. De Bruyne, 52. *Willamette L. Rev.* 2016, pp 218–222.

137 H. Bocken, I. Boone & M. Kruithof, *Het buitencontractueel aansprakelijkheidsrecht en andere schadevergoedingsmechanismen* (Brugge: die Keure 2014), pp 46–203. *See* in the context of providers of information to the public the decision by the Court of Appeal Antwerp, 12 Sept. 2012, *NJW (Nieuw Juridisch Weekblad)* 2014, p 130 with annotation by J. De Bruyne.

138 *See* for an extensive discussion of these requirements in the context of the PIP case: J. De Bruyne, 'PIP-implantaten: certificeringsdienst steekt hand best in eigen boezem', *De Juristenkrant* 2014, p 3.

party (e.g. cargo-owner or ship insurer) has to prove in each case that he incurred damage (e.g. financial losses or physical harm) and that there was a causal link with the issuance of the incorrect certificate even when courts already held the certifier liable towards third parties at several occasions in the past.[139]

Another case which shows that the mere possibility of holding certifiers liable will not open the floodgates is the *Vie d' Or* decision in which the Dutch Supreme Court set the boundaries of the third-party liability of the auditor. The *Hoge Raad* held that accountants have a duty of care towards third parties when performing tasks that have a wider public importance such as the certification and control of annual accounts.[140] To determine whether auditors can be held liable towards a specific third party, the judge needs to examine how a reasonable and competent accountant who carefully performs his duties and takes into account the third party's interests, would have acted.[141] Whether the accountant violated his duty of care has to be established by taking all circumstances of the case into account.[142] The *Hoge Raad* subsequently enumerated a checklist to decide if the accountant violated his duty of care. Factors that have to be taken into account are (1) the extent to which the requirements concerning financial audit reporting incorporated in EU and national legislation have been respected, (2) the nature of the violated norm, (3) the seriousness of the violation, (4) the measures taken or information given by the accountant to limit the financial loss, (5) the degree to which the accountant could reasonably foresee that the impairment of third-party pecuniary interests would result in economic loss, and (6) the extent to which the accountant took those control measures and issued warning statements that could reasonably be expected from him in the given situation in order to avoid the economic loss.[143] Besides the violation of the auditor's duty of care, the other requirements to base a claim on Article 6:162 of the Dutch Civil Code (DCC) must also be established. For instance, there must be a causal link between the auditor's violation of his duty of care and the incurred financial losses by the third party. The *Hoge Raad* eventually concluded in the *Vie d'Or* case that the Court of Appeal erred in finding that there was a causal link. The auditor was, therefore, not held liable.[144]

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139 In the context of classification societies, the following cases illustrate that a third party has to establish a fault, damage and a causal link between the loss he suffered and the incorrect class certificate: *Spero*, Court of Appeal Antwerp, 14 Feb. 1995, *R.H.A. (Rechtspraak Haven van Antwerpen)* 1995, pp 325-327; *Paula*, Court of Appeal Antwerp, 10 May 1994, *R.H.A.* 1995, pp 313-317.

140 Hoge Raad, 13 Oct. 2006, *J.O.R. (Jurisprudentie Onderneming & Recht)* 2006, p 296, para. 5.4.1.

141 Hoge Raad, 13 Oct. 2006, *J.O.R.* 2006, p 296, para. 5.3.

142 *Ibid.*, p 296, para. 5.4.2.

143 *Ibid.*, p 296, para. 5.4.2.

144 *Ibid.*, p 296, para. 6.4.2. *See* for a discussion; I. Giesen, *Bewijslastverdeling bij beroepsaansprakelijkheid* (Deventer: Tjeenk Willink 1999), pp 77-78; B. ten Doesschate & R. Eekhof, 'Aansprakelijkheid van de accountant jegens derden', 2. *Financiële Studievereniging Amsterdam* 2008, pp 50-51; H.J. Blaisse, 'De reikwijdte van de derdenaansprakelijkheid van de accountant

5. Concluding Remarks

31. The article dealt with the liability of notified bodies acting as third-party certifiers in the medical sector. More specifically, the contribution discussed the role of TüV Rheinland in the PIP breast implant case. The decisions that have been issued so far in France and Germany denied compensation for patients who purchased the defective PIP breast implants. Several strict requirements had to be established before consumers could claim recovery. The PIP case is currently pending before the European Court of Justice. As such, it remains to be seen what stance the ECJ will take and especially what the consequences might be for notified bodies. This uncertainty is to the detriment of women who are affected by the defective PIP breast implants. A brief intermezzo showed that challenges also remain from a private international law perspective. Third-party certifiers can be sued before the courts of their domicile. Whether they can be brought before courts in other Member States depends *inter alia* on the interpretation of the place of the damaging event and the place of the damage. The difficulty to pinpoint these locations not only emerges in the field of jurisdiction but also manifest itself within the search for the applicable law as identical connecting factors are employed in that area of private international law.

In sum, at the moment the situation looks rather negative for women affected by defective PIP breast implants. The decision by the ECJ might bring clarity in this regard. Within the confines of that decision, it has to be examined how the liability of notified bodies should be given form within the existing supranational regulatory framework on medical devices. However, one thing seems clear: the threat of holding notified bodies liable might increase the accuracy of their certificates issued during the conformity assessment procedure of medical devices. This subsequently ensures that only safe medical devices are placed on the EU market and safeguards the health of consumers. Future scandals with medical devices and negligent third-party certifiers might in this way be prevented.

"Het grijze gebied tussen altijd en nooit"', 3. *Ondernemingsrecht* 2013, p 3; J. De Bruyne, 52. *Willamette L. Rev.* 2016, pp 218-223.