THE EUROPEAN COURT OF JUSTICE'S JUDGMENT IN THE PIP BREAST IMPLANT CASE: AN OCCASION TO DISCUSS THE LIABILITY OF NOTIFIED BODIES

Dr. Jan De Bruyne & Prof. Dr. Cedric Vanleenhove

ABSTRACT

This Article discusses the liability of Notified bodies regarding the recent scandal that has arisen with defective silicone breast implants produced by the French company Poly Implant Prothèse (PIP).

KEYWORDS: NOTIFIED BODIES - LIABILITY - PIP BREAST IMPLANTS

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1. Preliminary Considerations

This article shall focus on the legal implications of the recent scandal that has arisen with defective silicone breast implants produced by the French company Poly Implant Prothèse (PIP). As a starting point, it is pertinent to note that as from the year 2001, French law obliged manufacturers of breast implants to use one specific type of medical silicone gel for their products. However, PIP failed to comply with this requirement. As part of a deceitful scheme, this company continued to use sub-standard industrial silicone gel implants so as to lower its costs. The impact of 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. After several reports from across the globe on the illicit silicone products produced by PIP, the implants were eventually taken off the market by the French public supervisory agency in early 2010.[132]

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[132] See for an extensive description and discussion of the facts: B. van Leeuwen, 'PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies' (2014) 5 European Journal of Risk Regulation, 339-340; 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' (2014) 22 Willamette Journal of International Law & Dispute Resolution, 169-170; J. De Bruyne & C. Vanleenhove, 'Liability in the medical sector: the 'Breast-taking' Consequences of the poly implant prothèse case' (2016) 24 European Review of Private Law, 834-840.

Indeed, hundreds of thousands of PIP implants filled with sub-standard silicone gel had been distributed around the world. Women who purchased these implants claimed compensation for the harm caused by their (potential) rupture. Lawsuits against the manufacturer PIP were, however, fruitless as the company went bankrupt in 2011. The plaintiffs, therefore, had to seek other targets to obtain compensation for the physical harm or the financial losses they incurred after buying the implants. One of their targets was the product certifier, namely, TüV Rheinland, who had been appointed as the 'notified body' to perform the conformity assessment procedures of the said breast implants. Notified bodies determine whether medical devices meet all the applicable requirements to be marketed in the European Union. TüV had indeed certified the distribution of the implants despite the devices being unsuitable for medical and cosmetic use. A number of victims brought proceedings against certifier TüV Rheinland. Claims were filed against the certifier in different European Union (EU) Member States and the European Court of Justice (ECJ) recently issued a preliminary ruling.

The aim of this article is to examine the legal implications of the recent decision by the ECJ in the PIP case. After a brief discussion of the role of notified bodies under EU law (part 2), the contribution summarises the main findings of the national procedures against TüV Rheinland in Germany and France (part 3).[133] More importantly, the central part of this contribution looks at the judgment by the European Court of Justice in the PIP case (part 4) and examines its implications with regard to the liability of notified bodies (part 5). In the last part, we shall be formulating some concluding thoughts (part 6).

2. The Conformity Assessment Procedure

Certifiers are generally those that are responsible to attest that products or services possess certain qualifications or meet particular safety or technical standards.[134] The certification process can take different forms. For instance, third-party certification is performed by organisations which are independent *vis-à-vis* the entity that is manufacturing the products or providing the service. Third-party certifiers establish whether the product complies with the applicable technical and safety standards or

[133] See for an earlier and in-depth discussion: J. De Bruyne & C. Vanleenhove, *'Liability in the medical sector: the 'Breast-taking' Consequences of the poly implant prothèse case'* (2016) 24 European Review of Private Law, 823-854.

[134] J. Barnett, *'Intermediaries Revisited: Is Efficient Certification consistent with profit maximization?*' (2012) 37 Journal of Corporation Law, 476.

requirements.[135] Most certified products or services bear the certifier's mark to help consumers or other parties make decisions in relation to that particular product.[136] Third-party certifiers provide their services at the request of their client. The certificate they issue is the performance under the certification contract. However, the certificate can and will also be used by people with whom 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'.[137]

Third-party certifiers provide services in different sectors including the maritime industry (e.g. classification societies) and financial markets (e.g. credit rating agencies). More importantly, certifiers such as TüV Rheinland, SGS or Dekra also play a key role as so-called 'notified bodies' in the conformity assessment procedure of medical devices under EU law. Manufacturers can only place medical devices on the European market when they comply with the 'essential requirements' or 'general safety and performance requirement'.[138] To that end, the manufacturer has to perform a conformity assessment procedure. This assessment is conducted according to the procedures included in sectoral legislation dealing with a particular product.[139] EU legislation often 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 itself. The applicable legislation can also require that an independent

[135] American National Standard Institute, U.S. Conformity Assessment System: 3rd Party Conformity Assessment

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

[137] J. Barnett, 'Intermediaries Revisited: Is Efficient Certification consistent with profit maximization?' (2012) 37 Journal of Corporation Law, 476.

[138] See in this regard: Article 3 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169. Annex I of the Medical Device Directive contains the essential requirements. These requirements deal with the design and manufacture of medical devices to ensure the protection of the health and safety of patients, users and third parties. See also: Article 5 Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation 178/2002 and Regulation 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117. The article stipulates that a medical device has to meet the general safety and performance requirements set out in Annex I.

[139] See for more information: European Commission, 'Commission Notice. The 'Blue Guide' on the implementation of EU product rules 2016', 2016/C 272/01, 65-75.

third-party certifier is involved in the conformity assessment procedure of the product.[140] In this regard, Regulation 2017/745 on Medical Devices ('Medical Device Regulation' – 'MDR') taking effect mid-2020 and Directive 93/42/EEC ('Medical Device Directive' – 'MDD') refer to notified bodies that participate in the conformity assessment procedure of medical devices.

A notified body is an independent entity notified by a Member State's competent authority to assess the conformity of medical devices before being placed on the market.[141] The body determines whether devices meet all the applicable legislative requirements to get the CE marking. This marking is the manufacturer's declaration that a device meets the applicable safety and technical requirements.[142] Member States can choose notified bodies from the entities under their jurisdiction that comply with requirements set out in the MDR or the MDD and the principles laid down in Decision 2008/768.[143]
Notified bodies must operate in a competent, non-discriminatory, transparent, neutral, independent and impartial manner.[144] Manufacturers are free to choose any notified body that has been designated by Member States to carry out the conformity assessment procedure. [145]

Article 11 and Annexes II-VII of the MDD deal with the involvement of notified bodies in the conformity assessment procedure of medical devices.[146] The procedure involves an audit of the manufacturer's quality system and, depending on the classification of

[140] European Commission, 'Commission Notice. The 'Blue Guide' on the implementation of EU product rules 2016', 2016/C 272/01, 66-67.

[141] European Commission, 'Commission Notice. The 'Blue Guide' on the implementation of EU product rules 2016', 2016/C 272/01, 78.

[142] BSI Notified Body, 'Want to know more about the Notified Body?', medicaldevices.bsigroup.com/LocalFiles/en-GB/Services/BSI-md-notifed-body-guide-brochure-UK-EN.pdf; European Commission, 'Commission Notice. The 'Blue Guide' on the implementation of EU product rules 2016', 2016/C 272/01, 58-59.

[143] 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 L 218/82; European Commission, 'Conformity assessment and Notified bodies'.

[144] Article R17 in Decision 2008/768.

[145] European Commission, 'Commission Notice. The 'Blue Guide' on the implementation of EU product rules 2016', 2016/C 272/01, 78.

[146] 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' (2013) European Journal of Risk Regulation, 465.

the medical device,[147] a review of 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, it issues a CE certificate.[148]

The MDR contains similar provisions as the MDD. The classification of devices will determine the conformity assessment procedure a manufacturer has to follow. The conformity assessment procedures for medical devices are further laid down in the Articles 52-60 and Annexes IX-XI of Regulation 2017/745. For medical devices of classes IIa, IIb and III, a notified body needs to be involved in the conformity assessment procedure depending on the risks and class of the device. 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.[149] The Recommendation contains requirements for conducting unannounced audits and stipulates the obligations for the notified body. Notified bodies already had the possibility to do unannounced audits under the MDD. Recommendation 2013/473 now obliges 'notified bodies' to perform such audits at least once every year. [150]

3. The PIP Breast Implant Case and National Procedures in EU Member States

It has already been mentioned that a number of victims brought proceedings against TüV Rheinland alleging that it certified the distribution of the implants despite the devices being unsuitable for medical and cosmetic use. Claims were filed against the certifier in various EU Member States.[151] Although an in-depth discussion of these

[147] The classification of medical devices in the EU is a risk-based system grounded on the vulnerability of the human body taking account of the potential risks associated with the devices (see in this regard Annex IX of the MDD and Annex VIII of the MDR). This approach allows the use of a set of criteria that can be combined in various ways to determine the classification of a device (e.g. duration of contact with the body, degree of invasiveness and local or systemic effect). There are four classes of medical devices, ranging from low risk to high risk: medical devices of class I, IIa, IIb, III. See for more information: European Commission, 'Medical Devices Guidance document. Classification of medical devices', MEDDEV 2. 4/1 Rev. 9, June 2010.

[148] BSI Notified Body, 'Want to know more about the Notified Body?'.

[149] Commission Recommendation 2013/473/EU of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices, OJ L 253/27.

[150] Annex III, Recommendation 2013/473/EU on the audits and assessments performed by notified bodies in the field of medical devices.

[151] B. van Leeuwen, 'PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies' (2014) 5 European Journal of Risk Regulation, 341-344; B.M. Fry, 'A Reasoned Proposition to a Perilous Problem: Creating a Government Agency to Remedy

cases does not fall within the scope of this article,[152] the proceedings in France and Germany illustrate that holding a notified body liable is by no means straightforward.

In France, the Court of Appeal of Aix-en-Provence reversed the first instance decision, which it held to be unfounded.[153] The court concluded that TüV Rheinland complied with its obligations under supranational law. TüV only had an obligation to examine the technical file and not the device itself. There were no elements in the file that should have warned the body that approved silicone products were replaced by other non-approved products. Consequently, it was not at fault and, therefore, not liable.[154] In addition, the MDD provided solely for the possibility to make unannounced visits. 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.[155]

Claims against the certifier in Germany were not successful either. A reason often invoked by the rejecting German courts is that EU law does not require the notified body to investigate specific implants or carry out unannounced inspections on the manufacturing site.[156] The District Court in Frankenthal, for instance, concluded that

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the Empathic Failure of Notified Bodies in the Medical Device Industry' (2014) 22 Willamette Journal of International Law & Dispute Resolution, 169-170; J. De Bruyne & C. Vanleenhove, 'Liability in the medical sector: the 'Breast-taking' Consequences of the poly implant prothèse case' (2016) 24 European Review of Private Law, 833-834.

[152] See in this regard: J. De Bruyne & C. Vanleenhove, 'Liability in the medical sector: the 'Breast-taking' Consequences of the poly implant prothèse case' (2016) 24 European Review of Private Law, 834-840.

[153] Commercial Court Toulon, 14 November 2013, n° RG 2011F00517, 2013F00567.

[154] Court of Appeal Aix-en-Provence, July 2, 2015, no. 13/22482, 109, 113 & 119 and part II, A), 1/ in "Motifs de la décision" ('Contrairement à ce que prétendent les appelantes personnes physiques, les intimés et intervenantes, il résulte de la directive que lors de l'examen de la demande, l'organisme notifié n'avait pour obligation que d'examiner le dossier technique qui lui était soumis. Aucun élément ne pouvait laisser suspecter que le gel Nusil avait été remplacé par un gel non approuvé […] La société AM a donc respecté les dispositions de la directive dans le cadre de la certification'). This decision can be found on the online legal database Dalloz and is also available at www.doctrine.fr/d/CA/Aix-en-Provence/2015/R544A062AC137538AB085.

[155] Court of Appeal Aix-en-Provence, July 2, 2015, no. 13/22482, part II, B), 1) in "Motifs de la décision" ('Il ne peut donc être reproché à l'organisme certifié de ne pas avoir procédé périodiquement aux inspections prévues à l'article 5.3. de l'annexe II de la directive 93/42/CEE'). This decision can be found on the online legal database Dalloz and is also available at www.doctrine.fr/d/CA/Aix-en-Provence/2015/R544A062AC137538AB085.

[156] See for example: District Court Nürnberg-Fürth, 25 September 2013, 11 O 3900/13.

TüV had not breached its obligations under the MDD.[157] The court ruled *inter alia* that, although the notified body was required to examine the design dossier containing information on the content and design of the breast implants, TüV was not obliged to inspect the actual implants.[158]

The *Oberlandesgericht* (OLG) in Zweibrücken affirmed a first instance decision.[159] Certificates provided by notified bodies constitute a 'Baustein' for manufacturers to show they complied with the requirements in the MDD. Thus, the 'Sinn und Zweck' of the certification was not to protect third parties. Instead, it was only a requisite for the manufacturer to sell the implants on the European market. The purpose of the CE label given to a device is not to provide buyers with a right to claim compensation from a body involved in the conformity assessment procedure.[160] The conformity assessment procedure undertaken by TüV did not create a guarantee that the implants complied with essential requirements in the MDD. The manufacturer of medical devices remains responsible for the quality and safety of his products. Consequently, the manufacturer assumes the risks when the device turns out to be defective and causes injuries to patients.[161]

[157] Landgericht Frankenthal, 14 March 2013, 6 O 304/12, JurionRS 2013, 37376, (2013) Medizin Produkte Recht, 134-138; B. van Leeuwen, 'PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies' (2014) 5 European Journal of Risk Regulation, 343-344.

[158] Landgericht Frankenthal, 14 March 2013, 6 O 304/12, (2013) JurionRS, 37376, (2013) Medizin Produkte Recht, 134-137; B. van Leeuwen, 'PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies' (2014) 5 European Journal of Risk Regulation, 344.

[159] District Court Frankenthal, 14 March 2013, 6 O 304/12, (2013) JurionRS, 37376.

[160] Court of Appeal Zweibrücken, 30 January 2014, 4 U 66/13, (2014) JurionRS, 10232. See for a translation and discussion of the case: W. Rehmann & D. Heimhalt, 'Medical devices: liability of notified bodies?', TaylorWessing, May 2015, united-kingdom.taylorwessing.com/synapse/may15.html.

[161] Court of Appeal Zweibrücken, 30 January 2014, 4 U 66/13, (2014) JurionRS, 10232, Part II, 2. d); B. van Leeuwen, 'PIP Breast Implants, the EU's New Approach for Goods and Market Surveillance by Notified Bodies' (2014) 5 European Journal of Risk Regulation, 344-345; W. Rehmann & D. Heimhalt, 'Medical devices: liability of notified bodies?', TaylorWessing, May 2015.

4. Ruling of the European Court of Justice

Because of the public importance of this case and the fact that a number of German courts were dealing with the same issues, 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 European Court of Justice (ECJ).[162] The first question was 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 was whether Annex II of the MDD imposes a general or at least a for-cause obligation for the notified body to test the product. The third question concerned the extent to which Annex II of the MDD imposes a general or at least a for-cause obligation on the notified body to view business records of the manufacturer and/or to carry out unannounced audits. [163]

With regard to the second and third question, the ECJ held that a notified body is not under a general obligation to carry out unannounced inspections, to examine medical devices and/or to examine the manufacturer's business records.[164] However, in the face of evidence indicating that a medical device may not comply with the requirements laid down in the MDD, the notified body must take all necessary steps, to ensure that it complies with its obligations under the Directive.[165] Notified bodies must be given an appropriate degree of discretion in view of the stringent requirements they must satisfy under the applicable legislation regarding their independence and scientific expertise.[166] A notified body is not under a general obligation to carry out unannounced inspections, to examine devices and/or to examine the manufacturer's business

[162] BGH, 9 April 2015 - VII ZR 36/14.

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

[164] C-219/15, *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*, 16 February 2017, paragraph 38.

[165] C-219/15, *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*, 16 February 2017, paragraph 47-48. These obligations are included in Article 16(6) of the MDD and Sections 3.2-3.3, 4.1-4.3 and 5.1 of Annex II.

[166] C-219/15, *Elisabeth Schmitt v. TÜV Rheinland LGA Products GmbH*, 16 February 2017, paragraph 45.

records.[167] However, they have to act with all due diligence when determining whether the certification may be maintained.[168]

More importantly, the ECJ held that the aim of the MDD is not only the protection of health *stricto sensu* but also the safety of persons. The Directive does not only affect patients and users of devices, but also 'third parties' and 'other persons'. The actual aim of the MDD is to protect end users of medical devices.[169] To that end, the MDD does not only impose obligations on the manufacturer of the device but also on Member States and notified bodies.[170] With regard to the involvement of the notified body in the procedure relating to the EC declaration of conformity,[171] it is apparent from the wording and overall scheme of the MDD that the purpose of that procedure is to ensure protection for the health and safety of persons.[172]

At the same time, however, it does not necessarily follow from the fact that the MDD imposes surveillance obligations on certain bodies or the fact that one of its objectives is to protect injured parties that the Directive also seeks to confer rights on such parties, in the event that those bodies fail to fulfil their obligations. The MDD does not contain any express rule granting such rights.[173] The Directive is also silent regarding the manner in which liability of notified bodies may be incurred. Therefore, it cannot be maintained that the purpose of the MDD is to govern the conditions under which end

[167] C-219/15, *Elisabeth Schmitt v. TÜV Rheinland LGA Products GmbH*, 16 February 2017, paragraph 48.

[168] C-219/15, *Elisabeth Schmitt v. TÜV Rheinland LGA Products GmbH*, 16 February 2017, paragraphs 38-48.

[169] C-219/15, *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*, 16 February 2017, paragraph 50 referring to C-288/08, Nordiska Dental, 19 November 2009, paragraph 29.

[170] C-219/15, *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*, 16 February 2017, paragraph 51.

[171] The EC declaration of conformity is the written statement and the declaration drawn up by the manufacturer to demonstrate the fulfilment of the EU requirements relating to a product bearing the CE marking he has manufactured. See in this regard: www.ce-marking.com/required-content-for-CE-marking-EC-declaration-of-conformity.html.

[172] C-219/15, *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*, 16 February 2017, paragraph 53.

[173] C-219/15, *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*, 16 February 2017, paragraph 55; C-222/02, Paul and Others, 12 October 2004, paragraphs 38-40.

users of devices may be able to obtain compensation for a culpable failure by notified bodies to fulfil their obligations.[174]

In any event, the mere fact that notified bodies are required to take out civil liability insurance without any further information[175] is not sufficient to conclude that the MDD requires Member States to confer on end-users of medical devices, who have suffered injury as a result of culpable failure of notified bodies to fulfil their obligations, a right to turn onto those bodies for compensation.[176] Against this background, the ECJ concluded that the conditions under which a notified body's culpable failure to fulfil its obligations under the procedure relating to the EC Declaration of Conformity may give rise to its liability *vis-à-vis* the end users of medical devices are governed by national law, subject to the principles of equivalence and effectiveness.[177] The principle of equivalence requires the same remedies and procedural rules to be available to claims based on European Union law as are extended to analogous claims of a purely domestic nature. The principle of effectiveness, or effective judicial protection, obliges domestic Member State courts to ensure that national remedies and procedural rules do not render claims based on EU law impossible in practice or excessively difficult to enforce.[178]

5. Implications of the PIP Decision on the Liability of 'Notified Bodies'

The ECJ's ruling in the PIP case thus emphasises the importance of national law with regard to the question whether, and to which extent notified bodies can be held liable. Two elements are briefly discussed in the following paragraphs. On the one hand, we will examine to which extent a notified body might be held liable under Belgian law, taking into account the limitations set out by the ECJ. Belgium is an interesting case study in this regard as third parties have already filed suits against other certifiers such as auditors and classification societies to claim compensation for the damage they

[174] C-219/15, *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*, 16 February 2017, paragraph 56.

[175] See in this regard Section 6 of Annex XI Directive 93/42 on medical devices.

[176] C-219/15, *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*, 16 February 2017, paragraph 57.

[177] C-219/15, *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*, 16 February 2017, paragraph 59

[178] Opinion of Advocate General Jääskinen in Case C 536/11, Bundeswettbewerbsbehörde v Donau Chemie AG and Others, 7 February 2013, paragraph 3.

suffered due to the reliance on an incorrect certificate. Moreover, an analysis of Belgian case law might be an added value from a legal comparative approach as well. Based on an analysis of these Belgian cases, the conclusion seems to be that notified bodies might indeed be held liable towards third parties such as women that purchased the defective implants (part 5.1.). On the other hand, some issues of private international law with regard to the liability of notified bodies can also arise. 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 multi-jurisdictional cases, the rules of private international law come into play to determine which court or courts have jurisdiction to adjudicate the dispute (part 5.2.).[179]

5.1. The Liability of Notified Bodies Under National Law- Belgium as a Case Study

Certifiers, such as notified bodies, can face liability towards third parties under Articles 1382-1383 of the Belgian Civil Code (BCC). These provisions oblige the person who is guilty of a wrongful act that caused damage to someone else to compensate for this harm. Thus, claimants will have to demonstrate the certifier's wrongful act, the harm they suffered and the causal link between both elements.[180] To the authors' knowledge, there have not been any cases against notified bodies in Belgium. Third parties, however, have already filed suits against other certifiers such as auditors and classification societies, in Belgium so as to claim compensation for the damage caused by their reliance on an incorrect certificate. Based on an analysis of these cases, the conclusion seems to be that notified bodies might indeed be held liable towards third parties such as women that purchased the defective implants.

To start with, a third party will have to establish that a certifier committed a wrongful act. The wrongful act can either be a breach of a specific legal rule of conduct or a negligent act, which means a lack of compliance with an unwritten general duty of care.[181] According to the Belgian Court of Cassation (*Cour de Cassation*), the violation

[179] See for an extensive discussion: J. De Bruyne & C. Vanleenhove, 'Liability in the medical sector: the 'Breast-taking' Consequences of the poly implant prothèse case' (2016) 24 European Review of Private Law, 841-845.

[180] M. Kruithof, 'Tort Law' in M. Kruithof & W. De Bondt (eds.), Introduction to Belgian Law (Kluwer Law International, 2017) 248.

[181] H. Bocken, I. Boone with cooperation of M. Kruithof, Inleiding tot het schadevergoedingsrecht (Die Keure, 2014) 89; T. Vansweevelt & B. Weyts, Handboek

of a statutory or regulatory legal rule of conduct committed without a ground of justification is *per se* wrongful. Any form of negligence is thus, not required to be proved in court.[182] The rationale behind this is that a rule prescribing or prohibiting a specific conduct constitutes an autonomous criterion to assess the wrongfulness of a particular act. Indeed, even a reasonable breach of such a rule is wrong.[183] This also means that no foreseeable harm is required to be proved by the plaintiff in the case proceedings.[184] Victims can also claim recovery from the certifier if they prove that the latter's careless behaviour caused the damage. Negligence is generally defined as not taking the amount of care that a normally prudent person would have taken to protect the interests of others.[185]

Classification societies have already incurred third-party liability at several occasions for violating the general duty of care.[186] In these decisions, courts concluded that classification societies do not benefit from the personal immunity of a contracting party's performance agent (*agent d' exécution*).[187] This doctrine developed by the Belgian *Cour de Cassation* implies that an agent performing the contractual duties of a principal can only be liable in tort *vis-à-vis* the contracting party of the principal in

buitencontractueel aansprakelijkheidsrecht (Intersentia, 2009) 125; Court of Cassation, 25 March 2010, AR C.09.0403.N, (2010) Arr. Cass., 920.

[182] Court of Cassation, 10 April 2014, (2015) Revue Générale des Assurances et des Responsabilités, 15206 and (2015) Rechtskundig Weekblad, 338; Court of Cassation, 8 November 2002, (2002) Arr. Cass., 2417; Court of Cassation, 13 May 1982, (1981) Arr. Cass., 1134. See also: M. Kruithof, 'Tort Law' in M. Kruithof & W. De Bondt (eds.), Introduction to Belgian Law (Kluwer Law International, 2017) 250 with further references.

[183] M. Kruithof, 'Tort Law' in M. Kruithof & W. De Bondt (eds.), Introduction to Belgian Law (Kluwer Law International, 2017) 250.

[184] H. Bocken, I. Boone with cooperation of M. Kruithof, Inleiding tot het schadevergoedingsrecht (Die Keure, 2014) 92-93; T. Vansweevelt & B. Weyts, Handboek buitencontractueel aansprakelijkheidsrecht (Intersentia, 2009) 137-138; M. Kruithof, 'Tort Law' in M. Kruithof & W. De Bondt (eds.), Introduction to Belgian Law (Kluwer Law International, 2017) 250.

[185] M. Kruithof, 'Tort Law' in M. Kruithof & W. De Bondt (eds.), Introduction to Belgian Law (Kluwer Law International, 2017) 249.

[186] See for example: Court of Appeal Antwerp, 14 February 1995, (1995) Rechtspraak Haven van Antwerpen, 321-331; Court of Appeal Antwerp, 10 May 1994, (1995) Rechtspraak Haven van Antwerpen, 301-331.

[187] See in general: I. Claeys, Samenhangende overeenkomsten en aansprakelijkheid: de quasi-immuniteit van de uitvoeringsagent herbekeken (Intersentia, 2003) 143-239.

cases where the principal himself could be held liable in tort by his contracting party.[188] Considering the strict requirements for the concurrence of liability in contract and liability in tort between contracting parties in Belgium,[189] a performance agent will most likely not incur such liability. Taking into account that the performance agent cannot be held liable based on the contract between his principal and the latter's co-contractor as the agent is not a party to that contract, Belgian case law and doctrine consider performance agents to be 'immune' from liability towards the contracting parties of their principals.[190]

Courts repeatedly held that by classifying a vessel, classification societies do not perform the ship-owner's contractual obligations. A classification society is not an agent acting on behalf of the shipowner but is considered to be a 'normal' third party. Consequently, they cannot rely on the personal immunity principles developed by the Court of Cassation.[191] There is thus, no legal or procedural barrier preventing co-contractors of the shipowner and the public at large from proceeding in tort against classification societies under Belgian law.[192]

Arguably, the same conclusion applies to notified bodies. Once notified bodies are 'designated' by the authority responsible for notified bodies, they can provide services to the manufacturer during the conformity assessment of medical devices.[193]

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[188] Court of Cassation, 8 April 1983, (1984) Rechtskundig Weekblad, 163; Court of Cassation, 7 December 1973, (1974) Rechtskundig Weekblad, 1597; Court of Cassation, 3 December 1976, (1978) Rechtskundig Weekblad, 1303. The agent is the person to whom a contracting party confides the actual performance of his own contractual duties (H. Cousy & D. Droshout, 'Liability for Damage Caused by Others under Belgian Law' in J. Spier & F.D. Busnelli, Unification of Tort Law: Liability for Damage Caused by Others (Kluwer Law International, 2003) 50.

[189] See in this regard: H. Bocken, 'Samenloop contractuele en buitencontractuele aansprakelijkheid. Verfijners, verdwijners en het arrest van het Hof van Cassatie van 29 september 2006' (2007) 169 Nieuw Juridisch Weekblad, 722-731; I. Boone, 'Samenloop contractuele en buitencontractuele aansprakelijkheid verfijnd' (2006) Nieuw Juridisch Weekblad, 947; E. Dirix, 'Rechterlijk overgangsrecht' (2009) Rechtskundig Weekblad, 1756.

[190] H. Bocken, I. Boone with cooperation of M. Kruithof, Inleiding tot het schadevergoedingsrecht (Die Keure, 2014) 42-44.

[191] See for example: Court of Appeal Antwerp, 14 February 1995, (1995) Rechtspraak Haven van Antwerpen, 321-329.

[192] E. van Hooydonk, Eerste Blauwdruk over de Herziening van het Belgisch Scheepvaartrecht (Maklu, 2011) 195-196.

[193] J. O'Grady, I. Dobbs-Smith, N. Walsh & M. Spencer, Medicines, Medical Devices and the Law (Cambridge University Press, 2011) 7.

Manufacturers are free to enlist the services of any notified body that has been designated to carry out the conformity assessment procedure.[194] The relationship between the notified body and the manufacturer is based on a contract, even though certain notified body's actions might have regulatory authority.[195] This regulatory authority stems from the specific relationship between notified bodies and the national authority responsible for notified bodies. The national authority remains responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity with assessment bodies.[196] It needs to continuously monitor notified bodies to ensure ongoing compliance with the applicable requirements.[197] The national competent authority can withdraw the notification if it finds that a notified body no longer meets the applicable criteria.[198] Due to this relationship, some argue that a notified body performs delegated regulatory functions.[199] Nevertheless, notified bodies cannot rely on the personal immunity of a performance agent as they do not perform any part of the obligations of the national authority responsible for notified bodies, nor any obligation of the manufacturer of the devices. Whereas the notified body certifies the devices during the conformity assessment procedure, it has been shown that the national authority has other obligations. There is no actual 'delegation' of power but only a 'designation' of a notified body.[200] Notified bodies do not become part of the public administration.[201]

[194] 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' (2013) 4 European Journal of Risk Regulation, 465.

[195] J. O'Grady, I. Dobbs-Smith, N. Walsh & M. Spencer, Medicines, Medical Devices and the Law (Cambridge University Press, 2011) 7.

[196] Article 28 Proposal for a Regulation on medical devices, and amending Directive 2001/83/EC, Regulation 178/2002 and Regulation 1223/2009.

[197] Article 35 Proposal for a Regulation on medical devices, and amending Directive 2001/83/EC, Regulation 178/2002 and Regulation 1223/2009.

[198] Article 16 Directive 93/42/EEC concerning medical devices; Article 36 Proposal for a Regulation on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009.

[199] J. O'Grady, I. Dobbs-Smith, N. Walsh & M. Spencer, Medicines, Medical Devices and the Law (Cambridge University Press, 2011) 7.

[200] Article 34 Proposal for a Regulation on medical devices, and amending Directive 2001/83/EC, Regulation 178/2002 and Regulation 1223/2009.

[201] 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' (2013) 4 European Journal of Risk Regulation, 465; S. Frank, 'An

Notified bodies only need to suspend or withdraw certificates when they find that a manufacturer or medical device no longer complies with the essential requirements.[202] Notified bodies also do not perform any part of the manufacturer's obligations. Notified bodies have to remain independent towards the manufacturer during the conformity assessment procedure of medical devices.

It is difficult to match this notified body's independence with the requirement that a performance agent assists or replaces a principal in the performance of the latter's contractual obligations.[203]

Certifiers, such as notified bodies that negligently issue a certificate can thus, violate the general duty of care, potentially leading to their third-party liability. However, there seems to be no consensus on the question relating to 'when' exactly is a certifier deemed to have negligently issued a certificate. In this regard, reference can be made to cases dealing with the liability of classification societies. In the *Paula* case, for instance, the Antwerp Court of Appeal held that a classification society acts negligently when issuing a certificate to a vessel with (major) shortcomings in its construction.[204] This comes close to a so-called *obligation de résultat* (obligation to achieve a given result) and implies that a classification society will act negligently when it certifies a vessel with (major) defects. As such, a classification society that carefully surveys the vessels and subsequently issues the certificate still faces the risk of liability when it later turns out that the ship had (major) shortcomings.[205]

Things were different in the *Spero* case, before the same Antwerp Court of Appeal. The Court of Appeal held that surveyors of the classification society applied insufficient attention and time to the examination of the vessel's (heavily corroded) water pipe. The inability to identify this defect in the construction of the vessel was a professional fault, which also constituted a breach of the classification society's general

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Assessment of the Regulations on Medical Devices in the European Union' (2001) 56 Food & Drug Law Journal, 112.

[202] L. Hancher & M.A. Földes, 'Revision of the Regulatory Framework for Medical Devices in the European Union: The Legal Challenges. Symposium on the EU's New Medical Device Regulatory Framework' (2013) 4 European Journal Risk Regulation, 429.

[203] Article R17 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 L 218.

[204] Court of Appeal Antwerp, 10 May 1994, (1995) *Rechtspraak Haven van Antwerpen*, 313-317.

[205] J. De Bruyne, 'De aansprakelijkheid van classificatiemaatschappijen in België en enkele (recente) ontwikkelingen en pijnpunten vanuit een rechtsvergelijkend perspectief' (2014) 4 Tijdschrift Vervoer en Recht, 85.

duty of care.[206] Such a wording corresponds with an *obligation de moyen* (obligation to perform to the best of one's ability): a classification society will only be held liable if it negligently surveys and certifies the vessel and not merely because it later turns out that the vessel was defective.[207] Based on this analysis, a judge might thus decide that a notified body can be held liable on two grounds. On the one hand, the notified body might incur liability because it issued a certificate for a medical device that later caused damage regardless of the way in which it performed the conformity assessment procedure (cf. *Paula* case). On the other hand, the notified body might be held liable only when it did not carefully perform the conformity assessment procedure, regardless of the question whether the medical device causes damage after the certification process (cf. *Spero* case).

Another element interesting to examine is the extent to which the certifier's violation of an obligation contained in the certification agreement (the contractual setting) can also lead to liability towards third parties (the extra-contractual setting).

Third parties often suffer damage following a certifier's violation of the certification agreement with the entity that requests for the certification services, such as the manufacturer of the medical devices. For instance, women that purchased PIP breast implants did not have any contract with notified body TüV Rheinland. Nonetheless, those women were victims of TüV's violation of its contractual obligations with the manufacturer Poly Implant Prothèse. In other words, the question arises whether a notified body's violation of the agreement with the manufacturer also constitutes a wrongful act towards third parties for which it can potentially face liability in tort. Pursuant to the doctrine of the *coexistence passive* under Belgian law,[208] the certifier's improper performance of the contract will only lead to its liability towards third parties

[206] Court of Appeal Antwerp, 14 February 1995, (1995) *Rechtspraak Haven van Antwerpen*, 321-329.

[207] J. De Bruyne, 'De aansprakelijkheid van classificatiemaatschappijen in België en enkele (recente) ontwikkelingen en pijnpunten vanuit een rechtsvergelijkend perspectief' (2014) 4 Tijdschrift Vervoer en Recht, 85.

[208] See for more information on the doctrine of *coexistence passive*: H. Vandenberghe, 'Contractuele en delictuele aansprakelijkheid-Co-existentie' (2011) 2 Tijdschrift Privaatrecht, 639-656; A. De Boeck, 'De schade bij samenloop en co-existentie. Een verkenning van de grens tussen contractuele en buitencontractuele schade' in A. De Boecke, I. Samoy, S. Stijns & R. Van Ransbeeck, Knelpunten in het buitencontractueel aansprakelijk- heidsrecht (Die Keure, 2013) 21-54.

on the ground of Articles 1382-1383 BCC if the certifier's behaviour on which the claim is based also constitutes a breach of a general duty of care.[209]

Not every breach of a contractual obligation automatically results in a violation of a general duty of care.[210] However, some contracts can also impose a general duty of care towards third parties, especially when a professional's violation of the contract also endangers the safety of the wider public.[211] In this regard, it has already been mentioned that decisions dealing with the liability of classification societies illustrated that violation of the general duty of care can occur when a certificate has been given to a vessel with major shortcomings in its construction.[212] For instance, the issuance of a certificate to a vessel whose water pipe is heavily corroded is a professional fault (contractual setting), which also constitutes a breach of the society's general duty of care (extra-contractual setting).[213] Therefore, classification societies do not only have a contractual duty of care towards the shipowner under the certification agreement but can also be held to have a general duty of care towards everyone who can be affected by their services. This includes parties to whom classification societies are not contractually bound.[214]

It is conceivable that the same reasoning applies to notified bodies. The violation of a contractual duty of care towards the manufacturer of the devices might thus also constitute a violation of a notified body's general duty of care. This especially seems

[209] Court of Cassation, AR C.08.0546. N, 22 June 2009, (2011-2012) Rechtskundig Weekblad, 1003; Court of Cassation, AR C.12.0079.F, 25 October 2012, (2012) Arr. Cass., 2332 and (2013-2014) Rechtskundig Weekblad, 934; H. Bocken, I. Boone with cooperation of M. Kruithof, Inleiding tot het schadevergoedingsrecht (Die Keure, 2014) 41-42; H. Vandenberghe, 'Contractuele en delictuele aansprakelijkheid-Co-existentie' (2011) 2 Tijdschrift Privaatrecht, 650-651.

[210] H. Bocken, I. Boone with cooperation of M. Kruithof, Inleiding tot het schadevergoedingsrecht (Die Keure, 2014) 42; H. Vandenberghe, 'Contractuele en delictuele aansprakelijkheid-Co-existentie' (2011) 2 Tijdschrift Privaatrecht, 650 with further references; J. Limpens, 'Responsabilité du contractant envers les tiers du chef de la violation du contrat' (1954) Revue de droit international et de droit comparé, 101-102.

[211] An example is the duty of care owed by elevator installers-repairers to third parties: Court of Appeal Ghent, 8 March, 1983, (1986) Rechtskundig Weekblad, 32; Court of Appeal Ghent, 15 May 1995, (1996) Tijdschrift voor aannemingsrecht, 369; H. Bocken, I. Boone with cooperation of M. Kruithof, Inleiding tot het schadevergoedingsrecht (Die Keure, 2014) 42.

[212] Court of Appeal Antwerp, 10 May 1994, (1995) Rechtspraak Haven van Antwerpen, 313-317.

[213] Court of Appeal Antwerp, 14 February 1995, (1995) Rechtspraak Haven van Antwerpen, 321-329.

[214] J. De Bruyne, 'Liability of Classification Societies: Cases, Challenges and Future Perspectives' (2014) 45 Journal of Maritime Law & Commerce, 194.

to be the case when certifiers have a so-called 'public role'. In this regard, Belgian courts already took into account the public role and position of auditors (another type of certifier, next to classification societies and notified bodies) when deciding on their third-party liability.[215] A decision of the Brussels Court of First Instance, for example, focuses on the public role of the auditor[216] to deduct conclusions regarding the latter's liability towards investors. The auditor performs a legal duty, namely the certification of the annual account, for which it has a monopoly. This influences the liability towards third parties.

The auditor does not solely act in the interest of the audited company but also in the interest of the general public. If the auditor issues an unqualified opinion, a third party may assume that the certified accounts comply with the applicable legal provisions and fairly reflect, in all material aspects, the economic position of the company. If it later turns out that the auditor, for whatever reason, fails to make a reservation regarding the annual accounts and by doing so does not draw the attention to bookkeeping irregularities or illegal acts, he commits a wrongful act (*faute*) towards third parties.[217] Arguably, notified bodies also have such a public role. They do not only act in the interest of their clients, the manufacturers of medical devices, but also have to take into account that third parties will rely on certificates to make decisions. Such a public role is not only identified in the applicable legislation[218]but also acknowledged in the ruling of the ECJ in the PIP case.[219]

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[215] See for more information: K. Aerts, Taken en aansprakelijkheden van commissarissen en bedrijfsrevisoren (Larcier, 2002) 62-70; N. Thirion & C. Balestra, 'De burgerrechtelijke aansprakelijkheid van de commissaris' in C. Balestra, L. Dupont, N. Thirion, B. Tilleman & S. Van Dyck, De aansprakelijkheid van de bedrijfsrevisor, (Studies I.B.R., Recht, 2003) 14-17; A. Benoit-Moury, 'Les pouvoirs et les responsabilités des commissaires' (1986) Revue pratique des sociétés, 43; P.A. Foriers & M. Von Keugelgen, 'La responsabilité civile des reviseurs et experts comptables' (1992) 26 Revue de Droit ULB, 43-44; A. Van Oevelen, 'De rol en de civielrechtelijke aansprakelijkheid van de commissaris-revisor' in M. Storme, E. Wymeersch & H. Braeckmans, Handels- economisch en financieel recht (Mys & Breesch, 1995) 273.

[216] The auditor's public role has also been accepted by several scholars: P.A. Foriers & M. Von Keugelgen, 'La responsabilité civile des reviseurs et experts comptables' (1992) 26 Revue de Droit ULB, 21-23; K. Aerts, Taken en aansprakelijkheden van commissarissen en bedrijfsrevisoren (Larcier, 2002) 9-10.

[217] Court of First Instance Brussels, 12 December 1996, (1997) Tijdschrift voor Rechtspersoon en Vennootschap, 41-42.

[218] The Regulation on Medical Devices as well as Recommendation 2013/473 on Unannounced Audits stipulate that the proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizen's confidence in the regulatory system.

[219] See the discussion *infra* in part 4.

With regard to the required causal link between the notified body's wrongful act and the damage incurred by women, in accordance with the generally accepted theory, Belgian law adheres to the doctrine of equivalence of conditions (*théorie d'équivalence des conditions*). Under this theory, a court has to accept causality if it has been established that the fact was necessary in the given circumstances for the damage to occur (the so-called *conditio sine qua non* or 'but for' test).

The fact that *in concreto* was necessary for the harm to occur constitutes a cause even if a later intervening fact was also necessary.[220] The existing cases dealing with the liability of classification societies can be used to examine how the court evaluates causality in the context of certifiers. In the *Spero* case, the causal link between the damage to the plaintiff and the classification society's negligent act was established as the issuance of the class certificate allowed the vessels to be retained in maritime transport.[221] In the *Paula* case, a similar conclusion was reached. The society's negligence and issuance of a certificate made it possible for the shipowner to continue using the vessel for maritime activities. The certificate created a false appearance of safety. The commercial use of the vessel depended on the existence of a class certificate.[222] Against this background, a causal link between a notified body's wrongful act and the harm suffered by women that purchased the defective breast implants can be established to the extent that the issuance of a certificate by the body was a necessary condition for the device to be marketed.[223]

5.2. The Liability of the Notified Bodies- Private International Law Aspects

In the European Union, the Brussels I Recast Regulation (also known as the Brussels *Ibis* Regulation) regulates the competence of the EU courts in civil and commercial cases.[224] It has replaced the Brussels I Regulation as of 10 January 2015.[225] The basic

[220] See in this regard: M. Kruithof, 'Tort Law' in M. Kruithof & W. De Bondt (eds.), Introduction to Belgian Law (Kluwer Law International, 2017) 273-275 with references to case law.

[221] Court of Appeal Antwerp, 14 February 1995, (1995) Rechtspraak Haven van Antwerpen, 329.

[222] Court of Appeal Antwerp, 10 May 10 1994, (1995) Rechtspraak Haven van Antwerpen, 314.

[223] See more extensively: J. De Bruyne, Third-party certifiers: an inquiry into their obligations and liability in search of legal mechanisms to increase the accuracy and reliability of certification, Doctoral Dissertation, Ghent University Faculty of Law and Criminology, 2018, 353-361.

[224] Regulation 1215/2012 of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, OJ L 351.

[225] Regulation 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, OJ L 12.

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. Pursuant to Article 63.1 Brussels *Ibis* 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 the Brussels *Ibis* Regulation as it has its domicile within the European Union. The overview of German case law illustrates 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 *Ibis* 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 *Ibis* 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 European Court of Justice established the rule of the double forum, which states that Article 5.3 Brussels I Regulation (now Article 7.2 Brussels *Ibis* 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*).[226]

In other words, under Article 7.2 Brussels *Ibis* 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 *Ibis* Regulation is often far more complex when it concerns third-party certifiers.

In this regard, it should 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

[226] C-21/76, Handelskwekerij GJ Bier BV v Mines de potasse d'Alsace SA, 30 November 1976, paragraph 25.

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 *Ibis* Regulation.

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, Germany. It is there that it applied the rules in force to the material findings and subsequently approved the CE marking.[227]

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 authorisation.[228]

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 unauthorised silicone gel. It would,

[227] 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' (2014) 20 Journal of International Maritime Law, 116-117.

[228] Commercial Court Toulon, 14 November 2013, n° RG 2011F00517, n° 2013F00567, 139.

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.[229] 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 European Union will be validated in that regard as Article 7.2 Brussels *Ibis* Regulation only gives jurisdiction to the courts of EU Member States.[230]

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 the authors' opinion, the connecting 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 women's domicile. The place of the operation, therefore, also contributes to the Brussels *Ibis* Regulation's objective of providing predictable jurisdictional rules.[231] 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. Such a woman has perhaps taken the decision to trust PIP implants – inspired by TüV Rheinland's conformity evaluation and subsequent approval – in her domicile and has continued to rely upon the German certifier's green light during her stay abroad to undergo surgery.

[229] See for a contrasting view on this matter: S. Fulli-Lemaire, 'Affaire PIP: Quelques réflexions sur les aspects de droit international privé' (2015) 1 Revue Internationale de Droit Economique, 117.

[230] 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.

[231] See in this regard Recital (15) of Regulation 1215/2012.

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.

6. Concluding Remarks

Through a discussion of the global PIP breast implant scandal, this article demonstrated the complexity of the liability of notified bodies, both in terms of substantive law, as well as in terms of private international law considerations. The recent European Court of Justice ruling in the PIP case underlines the importance of national law to settle questions surrounding this liability. The article used a Belgian law perspective to attempt to lay bare the most prevalent issues by drawing comparisons with other certifiers such as classification societies and auditors, has shown that the outcome of domestic courts' analysis remains unpredictable. Equally, with regard to the international jurisdiction of courts dealing with similar cases, it remains to be seen how the appropriate grounds of jurisdiction will be interpreted in the future.