



**Non-Contractual Liability of the EU for Damage  
Sustained by Women Who Received PIP Breast  
Implants**

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## **LIST OF ABBREVIATIONS**

AG – Advocate General

CEN – European Committee for Standardization

CFI – Court of First Instance

CJEU – Court of Justice of the EU

EC – European Community

ECJ – European Court of Justice

EEC – European Economic Community

EN – European Standard (fr *norme européenne*)

EU – European Union

ISO – International Organization for Standardization

MDD – Medical Devices Directive (Council Directive 93/42/EEC3 concerning Medical Devices)

PIP – Poly Implant Prothèse

TEC – Treaty Establishing the European Community

TEU – Treaty on European Union

TFEU – Treaty on the Functioning of the European Union



## DEFINITIONS

**CE Marking** indicates that a device is in conformity with the essential requirements referred to in Article 3 of the MDD.<sup>1</sup>

**Competent Authority** – a body appointed by the government of each Member State with authority to act on behalf of the Member State government to ensure that Member State government transposes requirements of Medical Device directives into national law and applies them.

**Conformity Assessment Procedure** – a procedure needed to be followed in order to affix CE-marking.<sup>2</sup>

**General Principle** – principles of law derived from common legal principles in the various EU Member States, or found in international law, or EU law, and applied by the CJEU and the national courts of the Member States when determining the lawfulness of legislative and administrative measures within the EU.

**Harmonised Standard**<sup>3</sup> – a voluntary European standard elaborated on the basis of a request<sup>4</sup> from the European Commission to a recognised European Standards Organisation<sup>5</sup> to develop a European standard that provides solutions for compliance with the essential requirements or other provisions of relevant EU harmonisation legislation. When references of Harmonised Standards are published in the Official Journal of the EU the Harmonised Standards have the capacity to

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<sup>1</sup> Directive 93/42/EEC, OJEC No L 169/1, 14 June 1993 (hereinafter MDD), art 17(1).

<sup>2</sup> Art 11(1) MDD.

<sup>3</sup> Such as EN Standards or EN ISO Standards (according to the Vienna Agreement signed by the European Committee for Standardization (CEN) in June 1991 with International Organization for Standardization (ISO) the same text is adopted as both an ISO Standard and a European Standard) – European Committee for Standardization <<http://www.cen.eu/cen/AboutUs/Pages/default.aspx>> accessed on 23 April 2013.

<sup>4</sup> Such a request provides guidelines which requested standards must respect to meet the essential requirements or other provisions of relevant EU harmonisation legislation.

<sup>5</sup> Such as European Committee for Standardization (CEN) <[www.cen.eu](http://www.cen.eu)> accessed on 17 January 2013; European Committee for Electrotechnical Standardization <[www.cenelec.eu](http://www.cenelec.eu)> accessed on 17 January 2013; European Telecommunications Standards Institute (ETSI) <[www.etsi.org](http://www.etsi.org)> accessed on 20 February 2013.



confer the presumption of conformity compliance with the essential requirements or other provisions of relevant EU harmonisation legislation.<sup>6</sup>

**Intended Purpose** means the use for which the device is intended according to the data supplied by the Manufacturer on the labelling, in the instructions and/or in promotional materials.<sup>7</sup>

**Manufacturer** means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name.<sup>8</sup>

**Medical Device** means any instrument, apparatus, appliance, material or other Article, whether used alone or in combination, including the software necessary for its proper application intended by the Manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.<sup>9</sup>

**Notified Bodies** are third independent bodies that the Member States have designated for carrying out the tasks pertaining to the Conformity Assessment Procedures referred to in Article 11 and the specific tasks for which the bodies have been designated.<sup>10</sup>

**Quality Assurance System** – a system set up by the Manufacturer where it declares that products, and the systems for checking the conformity of products, conform to the requirements of the MDD.<sup>11</sup>

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<sup>6</sup> European Standard, Harmonised Standards <<http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/>> accessed on 23 April 2013.

<sup>7</sup> Art 1(2)(g) MDD.

<sup>8</sup> Art 1(2)(f) MDD.

<sup>9</sup> Art 1(2)(a) MDD.

<sup>10</sup> Art 16(1) MDD; the Commission shall assign identification numbers to these bodies and publish a list of the Notified Bodies and ensures it is kept up to date (art 16(1) MDD).

<sup>11</sup> Annex II Section 1 MDD.



## INTRODUCTION

This Report has been prepared by the Amsterdam International Law Clinic on the request of Shanta Singh ('Client'), a lawyer representing twenty women who allegedly suffered injuries and damage as a result of receiving breast implants; primarily those manufactured by the French company Poly Implant Prothèse (PIP).

The case resulted from the 'PIP controversy,' which concerns the discovery that thousands of CE certified PIP breast implants had been fraudulently manufactured using industrial grade silicone.<sup>12</sup> Council Directive 93/42/EEC ('MDD'),<sup>13</sup> enacted in order to regulate the Medical Devices market, introduced a system of certification ('CE marking') requiring that Medical Devices (such as breast implants) conform to certain criteria in order to be assigned the CE Marking necessary for entry onto the European market. These criteria were determined at European Union ('EU') level and elaborated on in the MDD and its accompanying Annexes. The MDD also made provisions for the monitoring of conformity with these criteria, requiring such monitoring to be undertaken by independent Notified Bodies, assigned by the Competent Authorities at a national level. Despite the fact that the breast implants manufactured by PIP did not conform to the necessary criteria set out in the MDD and its Annexes, they slipped through the regulatory net designed to avoid such devices becoming available for use within the EU.

In response to this controversy, the European Commission gave a mandate to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to provide a common risk assessment with regard to PIP breast implants based on information provided by the EU Member States. SCENIHR confirmed the concerns about the safety of PIP silicone breast implants in a 2012 report, stating that the possibility of health effects could not be ruled out.<sup>14</sup>

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<sup>12</sup> J Lister, 'Controversy Over Breast Implants Spreads Across Europe' (2012) *Covering Health International: Association of Health Care Journalists*, accessible at <[www.healthjournalism.org/blog/2012/02/controversy-over-breast-implants-spreads-across-europe](http://www.healthjournalism.org/blog/2012/02/controversy-over-breast-implants-spreads-across-europe)> accessed on 14 July 2013.

<sup>13</sup> Directive 93/42/EEC, OJEC No L 169/1, 14 June 1993.

<sup>14</sup> Scientific Committee on Emerging and Newly Identified Health Risks, 'The Safety of Poly Implant Prothèse (PIP) Silicone Breast Implants' (1 February 2012) <[http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_o\\_034.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_034.pdf)> accessed on 23 April 2013.



In a final report of the Expert Group set up by the UK National Health Service (NHS) the issue was summarised as follows:

PIP implants are significantly more likely to rupture or leak silicone than other implants, by a factor of around 2-6, and this difference is detectable within five years of implantation. In a proportion of cases, failure of the PIP implant results in local reactions but these are readily detected by outward clinical signs – ‘silent’ ruptures (ruptures which come to light only on explantation) are not generally associated with these local reactions.<sup>15</sup>

Of the twenty women represented by the Client, approximately ten had PIP implants. The others received either Allergan or Mentor (Siltex) implants. All suffered from various injuries allegedly resulting from the increased and premature rupturing of their implants and the consequential oozing of silicone, likely, in the case of the PIP implants, a result of their fraudulent manufacture.<sup>16</sup> The aim of the claim directed by the Client is to compensate the women for the damage that they have suffered, which can be divided into three categories: personal injury; pure economic loss; and non-material damage attributable to physical and mental suffering.

Considering the available information, this Report will address issues arising from the use of PIP implants specifically. If it is possible to hold the EU liable for the damage suffered by these women, whether such liability can be extended to cover the damage suffered by the women who received alternative implants can then be considered. The fact that the PIP breast implants found their way onto the European Medical Devices market suggests failings at the European institutional level to provide an adequate framework to achieve the harmonisation of the internal market, whilst also ensuring a high level of health protection to EU citizens. Thus, this Report aims to establish whether, based on the non-contractual liability of the EU as set out in Article 340 of the Treaty on the Functioning of the European Union (‘TFEU’),<sup>17</sup> the EU can be held liable for the damage caused to the women, represented by the Client, as a result of PIP breast implants.

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<sup>15</sup> MHRA, PIP Breast Implants, Background and Chronology (30 July 2012) <<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice-A-F/Breastimplants/PIPbreastimplants/BackgroundinformationonPIPimplants/index.htm>> accessed on 23 April 2013.

<sup>16</sup> *ibid.*

<sup>17</sup> Treaty on the Functioning of the European Union, OJEU 2008/C 115/01, 13 December 2007.



The scope of this Report will be limited to the issue of EU non-contractual liability (Article 340 TFEU); it will not cover the possibility of establishing Member State ('MS') liability flowing from a breach of EU law, or any possibilities arising from the rules concerning consumer protection. The first part of the Report will establish the criteria that must be fulfilled in order to establish the non-contractual liability of the EU. The second part will discuss the regulatory framework for Medical Devices within the EU. The third part will analyse the case in light of the previously discussed conditions for EU liability and the Medical Devices regulatory framework, and will assess the possibility of holding the EU liable under Article 340 TFEU. The fourth and final part draws conclusions from the analysis.





## 1 CRITERIA FOR NON-CONTRACTUAL LIABILITY OF THE EU

The non-contractual liability of the EU can be found in Article 340 TFEU,<sup>18</sup> which states that ‘[t]he EU shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its institutions or by its servants in the performance of their duties.’ However, the Treaties contain no further elaboration on this principle, leaving to the EU Courts<sup>19</sup> the competence (Article 268 TFEU) to rule on the liability of the EU in accordance with the General Principles common to the laws of the MS (Article 6 TEU).

Article 340 TFEU provides that the EU shall make good damage *caused* by its institutions, and thus acts must be attributable to the EU institutions for the EU to incur liability.<sup>20</sup> Therefore, the EU Courts will first assess whether an act is capable of such an attribution. An ‘act’ for these purposes has been defined as a ‘measure or conduct attributable to a community institution or body.’<sup>21</sup> Thus the CJEU has determined that primary EU law cannot give rise to claim as such laws do not constitute ‘acts’ of the institutions.<sup>22</sup> However, other acts or measures taken by the EU, as well as the conduct of the institutions and joint conduct of the EU institutions and MS can all constitute ‘acts’ for these purposes. Such acts have included the enactment of an improper EU measure, breach of the requirement of proportionality, discrimination, breach of legitimate expectations, and invocation of the misuse of powers doctrine.<sup>23</sup> Additionally, the case of *Richez-Parise v Commission*<sup>24</sup> established that wrongful omissions could constitute acts for the purposes of establishing EU liability, and other case law supports the proposition that liability will not be precluded by reliance on an omission as an act.<sup>25</sup> However, this principle is not unlimited. In

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<sup>18</sup> Non-contractual liability was first established in Art 215 EEC, Art 228 EC, now Art. 340 TFEU. See for an in-depth analysis: P Aalto, *Public Liability in EU Law Brasserie, Bergaderm and Beyond* (Hart Publishing 2011), 1.

<sup>19</sup> Hereinafter the term ‘EU Courts’ refers to the Court of First Instance (‘CFI’)/General Court (after the Treaty of Lisbon) and the Court of Justice of the EU (‘CJEU’), formerly known as ECJ.

<sup>20</sup> A H Türk, *Judicial Review in EU Law* (Edward Elgar Publishing 2009) 241.

<sup>21</sup> Case T-250/02 *Autosalone Ispra v EAEC* [2005] ECR II 5227 [42] as discussed in Türk (n 20) 241.

<sup>22</sup> Case T-113/96 *Edouard Dubois v Council and Commission* [1998] ECR II-125 [41]; Türk (n19) 241.

<sup>23</sup> Aalto (n 18) 112-121.

<sup>24</sup> Case C-40/71 *Richez-Parise v Commission* [1972] ECR 00073.

<sup>25</sup> Case T-137/07 *Portela v Commission* [2008] ECR II-00329; C-85/09 *P Portela v Commission* [2009] I-00178; Case T-304/01 *Abad Pérez and Others v Council and Commission* [2006] ECR II-04857; Case T-138/03 *É.R. and Others v Council and Commission* [2006] ECR II-04923.



*KYDEP v Council and Commission*<sup>26</sup> and *Area Cova*,<sup>27</sup> the CJEU held that the EU institutions could only be held liable for omissions in circumstances where they had breached a legal duty resulting from a provision of EU law.<sup>28</sup> Thus in circumstances where the institutions have a wide discretion as to the nature and form of their action, it is unlikely that an action to establish liability for an omission will succeed, as the existence of a legal duty must be established.<sup>29</sup>

The EU Courts have developed a set of criteria for establishing the existence of liability under Article 340 TFEU, which they will apply following a determination that an act is capable of being attributed to an EU institution. The current test for EU liability was established in *Bergaderm*,<sup>30</sup> influenced by the conditions for MS liability developed in *Francovich*<sup>31</sup> and *Brasserie du Pêcheur*.<sup>32</sup> To establish liability under Article 340 TFEU, three criteria must be satisfied: 1) the rule infringed must have intended to confer rights on individuals; 2) the nature of the breach must be sufficiently serious; and 3) there must be a direct causal link between breach of the obligation and the damage sustained. Following this structure, this Report will now discuss how each of these criteria can be satisfied.

## 1.1 RULE INTENDED TO CONFER RIGHTS ON INDIVIDUALS

The concept of ‘right’ is considered amorphous and difficult to capture in EU law,<sup>33</sup> due to the gradual development of the concept through the case law of the CJEU. It has been suggested that the existence of an individual right can only be established if a legal rule refers to *a specific right* granted to a *private party* that, together with other conditions, gives rise to a right and accompanying remedy for compensation in respect for harm sustained.<sup>34</sup> Of central importance then is the condition laid down in *Bergaderm*, which states that for 340 TFEU liability there must

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<sup>26</sup> Case C-146/91 *KYDEP v Council and Commission* [1994] ECR I-04199 [58].

<sup>27</sup> Case T-196/99 *Area Cova SA and Others v Council and Commission* [2001] ECR II-3597 [84].

<sup>28</sup> *ibid*; and see *Türk* (n 20) 241.

<sup>29</sup> See J Shaw, *Law of the European Union* (3<sup>rd</sup> edn, Palgrave 2000) 542; see also Case T-572/93 *Odigitria AAE v Council and Commission* [1995] ECR II-02025 [34]-[35].

<sup>30</sup> Case C-352/98 *Bergaderm and Groupil v Commission* [2000] ECR I-5291.

<sup>31</sup> Case C-6/90 and C-9/90 *Francovich and Bonifaci* [1991] ECR I-5357.

<sup>32</sup> Cases C-46 & 48/93 *Brasserie du Pêcheur SA v Germany and R v Secretary of State for Transport, ex p Factortame Ltd (Factortame III)* [1996] ECR I-1029; see also *Aalto* (n 18) 82-91.

<sup>33</sup> See *Aalto* (n 18) 131.

<sup>34</sup> See W van Gerven ‘Of Rights, Remedies and Procedures’ (2000) CMLR 501, 507.



be a violation of ‘a rule of law granting rights to individuals.’<sup>35</sup> This ‘rights language’, introduced with *Bergaderm*, coincided with the adoption of the EU Charter of Fundamental Rights in 2000 (‘Charter’), which became primary Union law with the adoption of the Lisbon Treaty,<sup>36</sup> and its significance will be further illustrated below in chapter 3.

In the current case it would be necessary to establish, by reference to the case law, in which situations the EU Courts have recognised that certain rights could be granted to individuals. As a matter of clarification, the concept of ‘rights’ does not necessarily fully coincide at EU and national level: In the case of the latter it is usually expressed in the Treaties or in secondary EU legislation, whilst EU liability is mostly related to breaches of principles.<sup>37</sup> We would need to show that the norm infringed was especially designed to protect the interests of those who were injured or of the group to which they belonged (i.e., the so-called ‘*Schutznorm*’). The principle stems from German and Italian law but is also known in the other MS so it has found its way into EU law as a ‘general principle of law.’<sup>38</sup> Nevertheless, the EU Courts has not given a strict interpretation.

In the *Kampffmeyer* case<sup>39</sup> the Court established that for the purposes of Article 340 TFEU it is sufficient to show that the rule infringed is for the protection of individuals generally, and it is not necessary for the applicant to be ‘directly and individually concerned’ in the technical sense of the annulment procedure of Article 263 TFEU.<sup>40</sup> Thus, it can be argued that it is sufficient that the rule infringed has been adopted in the interest of individuals, even if it pursues other aims.<sup>41</sup> Recent case law supports this position.<sup>42</sup> Therefore, the threshold appears to be lower in order to

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<sup>35</sup> A Ward, *Judicial review and the Rights of Private parties in EU Law* (OUP 2007) 54-58.

<sup>36</sup> Charter of Fundamental Rights of the European Union, OJ 200/C 364/01, European Union, 71 December 2000 (‘Charter’). The Charter became primary law with the coming into force of the Treaty of Lisbon on 1 December 2009 (Art 6 TEU).

<sup>37</sup> Although claims based on breaches of legislation are more frequent nowadays before the EU Courts than earlier; see *Aalto* (n 18) 111.

<sup>38</sup> See AG Toth, ‘The Individual and European Law’ (1975) 24 ICLQ 659, 692.

<sup>39</sup> Joined cases 5, 7, 13-24/66 *Kampffmeyer and others v Commission* [1967] ECR 317; the case concerned a series of German grain dealers who wanted to import maize from France and the relevant provisions of EC law required the applicants to obtain permits from the German authorities.

<sup>40</sup> *Becher v Commission*, 30/66 (1968) CMLR 169, 181-182; *Kampffmeyer* (n 39). See also A Biondi and M Farley, *The Right to Damages in European Law* (Kluwer 2009) 109.

<sup>41</sup> See also *Türk* (n 20) 261.

<sup>42</sup> See Case T-309/03 *Camos Grau v Commission* [2006] ECR II-1173 [102], regarding an investigation by the European Anti-Fraud Office into the conduct of Commission employees; here, the requirement of impartiality, apart



establish the conferral of individual rights for EU non contractual liability. It appears that for this determination the Courts have adopted a case-by-case approach, depending on the objectives to be achieved by the rule in question.<sup>43</sup> However, it must be stressed that the criterion is still difficult to fulfil, as it will be demonstrated below. For the purposes of the present Report, EU environmental law case-law in the context of MS liability appears instructive as certain parallels can be drawn.<sup>44</sup> It must be noted, however, that as well as this case law being rather limited, interests are diffuse and individual rights are difficult to identify.<sup>45</sup>

Many environmental directives impose obligations on MS without creating any rights for individuals. However, some directives, whilst their main aim is the protection of the environment, are also intended to protect human health and safety. This can be seen in the language used in their preambles. Thus, according to the CJEU, they can actually create rights for individuals that must be protected by the relevant courts.<sup>46</sup> Also, illuminating in this regard was the Opinion of AG Mischo in *Commission v Germany* where he stated that ‘[t]here are *individual ordinary citizens who derive the right to ensure that the air they breathe conforms to fixed standards of quality against (...) that in addition to the protection of the environment, they envisage the protection of man’s health and the quality of life (...)*’.<sup>47</sup>

The case of *San Pedro*<sup>48</sup> also revolved around the ‘conferral of individual rights’ issue. Here the CFI elaborated on the test for individual protection by stating that a violated norm constitutes a

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from intending to ensure that the public interest is respected, was found to confer a right on individuals to see that the corresponding guarantees are complied with.

<sup>43</sup> See Case T-271/04 *Citymo v Commission* [2007] ECR II-1375, where the CFI (GC post-Lisbon) ruled that in this circumstances the principle of good faith could be regarded as a rule protecting individuals who were in a position to negotiate with the Commission and that by failing to advise the applicant immediately of its decision not to award the contract, the Commission had breached this principle. (The case concerned negotiations between the Community public authority and a tenderer in a public tendering procedure).

<sup>44</sup> For example, these issues have been addressed by national courts: Case C-188/89, *Foster v British Gas* [1990] ECR 3343.

<sup>45</sup> M P Granger, ‘National applications of Francovich and the construction of a European administrative *ius commune*’ (2007) 32 ELR 157, 177.

<sup>46</sup> Case C-131/88, *Commission v Federal Republic of Germany* [1991] ECR I-0825 [7]; A C Geddes, *Protection of Individual Rights under EC Law* (Buttersworths 1995) 12.

<sup>47</sup> Joined case C-361/88 and C-59/89, *Commission v Germany* [1991] ECR I-2567 [23], Opinion of AG Mischo; the case concerned the correct implementation in national law of the Directives 80/779 and 82/884 (on air quality limit values and the limit value of lead in air respectively) (emphasis added).

<sup>48</sup> Case T-415/03 *Cofradia de pescadores de “San Pedro” de Bermeo and Others v Council of the EU* [2005] ECR II-4355 [86]; this case concerned the Common Fisheries Policy, and in particular the allocation of fishing quotas per



*Schutznorm* in the following circumstances:<sup>49</sup> when it has direct effect;<sup>50</sup> when it protects individuals' interests;<sup>51</sup> when it creates an advantage in the form of a vested right;<sup>52</sup> and, when the right is implicit but sufficiently identifiable.<sup>53</sup> Thus, the CFI reformulated the *Kampffmeyer* rule and interpreted it in line with CJEU's rulings under MS liability.<sup>54</sup> Accordingly, this Report will illustrate the specific conditions under which the criteria are satisfied.<sup>55</sup>

### 1.1.1 Direct Effect of Directives

The notion of direct effect can be narrowly defined in terms of the capacity of a Union legal provision to confer rights on individuals, enforceable before the courts.<sup>56</sup> When it comes to directives, in *Van Duyn* the CJEU held that their provisions enjoy vertical direct effect (between individuals and the MS), as long as they are sufficiently clear, precise, and unconditional,<sup>57</sup> and the existence of discretion left to the state does not necessarily preclude such a directive from being directly relied upon by an individual.<sup>58</sup> In the context of the present Report, the question arises as to whether any provision of the MDD fulfils these three conditions.

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MS, which limits catches. Spanish vessels owners and associations of owners brought an action for annulment of Council Regulations allowing the Portuguese fleet to fish in a particular ICES area, which was rejected as inadmissible by the CFI. However, Spain brought, successfully, an action for annulment against these Regulations before the ECJ. Then 98 ship-owners and 11 fishermen associations brought an action for damages under Art 340 TFEU.

<sup>49</sup> See also TMC Asser Instituut, 'Tort Liability of the European Community', available at <[http://www.asser.nl/upload/eel-webroot/www/documents/cms\\_eel\\_id183\\_1\\_Tort%20liability%20of%20the%20European%20Community.pdf](http://www.asser.nl/upload/eel-webroot/www/documents/cms_eel_id183_1_Tort%20liability%20of%20the%20European%20Community.pdf)> accessed on 23 April 2013, where it is suggested that this is a non-exhaustive list.

<sup>50</sup> See *Brasserie du Pêcheur* (n 32) [54].

<sup>51</sup> Joined Cases 83/76, 94/76, 4/77, 15/77 and 40/77 *HNL and Others v Council and Commission* [1978] ECR 1209 [5].

<sup>52</sup> See, to that effect, Case T-113/96 *Dubois et Fils v Council and Commission* [1998] ECR II-125 [63]-[65].

<sup>53</sup> Joined Cases C-178/94, C-179/94, C-188/94 to C-190/94 *Dillenkofer and Others* [1996] ECR I-4845 [22].

<sup>54</sup> TMC Asser Instituut (n 49). However, see Case C-222/02 *Peter Paul and Others v Deutschland* [2004] ECR I-09425 [14]; under this MS liability case, prior though to *San Pedro* (n 48), the ECJ ruled that conferring rights on individuals under EU law *must be express*.

<sup>55</sup> In this regard, this Report will concentrate on the first two criteria, regarding the third as irrelevant for the purposes of this Report and the fourth as subsumed under direct effect.

<sup>56</sup> Direct Effect was first established by the CJEU in Case 26/62 *Van Gend en Loos* [1963] ECR 1; P Craig, G de Burca *EU Law Text Cases, and Materials* (OUP 2011) 182.

<sup>57</sup> Case 41/74, *Van Duyn v Home Office* [1974] ECR 1337 [12].

<sup>58</sup> Case C-72/95, *Kraaijeveld* [1996] ECR I-5403 [59].



### 1.1.2 A Provision Designed to Protect Individuals: Breach of General Principles

Since EU liability is most likely established when there is a breach of a general principle of EU law designed to protect an individual, this section will focus on the principles invoked in the framework of Article 340 TFEU before the CJEU. In the majority of cases, general principles are invoked when they serve to protect legitimate expectations.<sup>59</sup> Any individual in regard to whom *an institution has given rise to justified hopes* may rely on this principle.<sup>60</sup> However, in *Emesa Sugar* the CFI noted that traders cannot have a legitimate expectation that an existing situation which is capable of being altered by the EU institutions in the exercise of their discretion will be maintained.<sup>61</sup> Similarly, a more restrictive interpretation of the principle of legitimate expectations was given in *Citymo*,<sup>62</sup> where the CJEU concluded that the right to rely on the principle exists only when the assurances given are ‘[p]recise, unconditional and consistent information from authorized and reliable sources.’<sup>63</sup>

The duty of diligence is another general principle that has been found to grant rights to individuals, usually in conjunction with other rules.<sup>64</sup> The CFI has noted that the duty of diligence is breached if an irregularity is found which in comparable circumstances would not have been committed by a normally prudent and diligent administration.<sup>65</sup> Another principle that could potentially come into play in the current case is the precautionary principle, which is integrated, *inter alia*, into EU public health policy.<sup>66</sup> In *Artogodan* the CFI stated that the principle is

[a] general principle of Community [Union] law *requiring the Competent Authorities to take appropriate measures to prevent specific potential risks to public health* (...) by giving precedence to the requirements related to the protection of those interests over economic interests (...) the Community [Union] institutions

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<sup>59</sup> See *Aalto* (n 18) 112.

<sup>60</sup> Joined Cases C-104/89 and C-37/90 *Mulder v Council and Commission* [1992] ECR I-3061 [15].

<sup>61</sup> Case T-43/98 *Emesa Sugar v Council* [2001] ECR II-3519 [87], concerning sugar imports from overseas countries in the framework of an EC Decision.

<sup>62</sup> *Citymo* (n 43).

<sup>63</sup> *ibid* [7].

<sup>64</sup> Case T-178/98 *Fresh Marine Company SA v Commission* [2000] ECR II-3331 [3].

<sup>65</sup> Case T-212/03 *MyTravel v Commission* [2008] ECR II-1967 [49]-[50], [132]. The case concerned a Commission decision declaring a concentration of two companies incompatible with the common market, annulled earlier by the CFI. Moreover, in this case the breach had been established in a successful procedure for annulment, however, it was not considered sufficiently serious for the purposes of art 340 and the claim was subsequently rejected.

<sup>66</sup> *Craig and de Burca* (n 56) 549.



are responsible, in all their spheres of activity, for the protection of public health... *Prior to the enshrinement in case-law of the precautionary principle, on the basis of the Treaty provisions, that principle was implicitly applied in the review of proportionality.*<sup>67</sup>

Although there is considerable controversy over the meaning, and most significantly, the application of this principle,<sup>68</sup> the legal and factual background of the MDD calls for an assessment of the role of the precautionary principle in the present case.<sup>69</sup> However, as the principle has so far been used in the context of legality review,<sup>70</sup> it is uncertain whether and to what extent individuals can rely upon it for the purposes of Art 340 TFEU.

### 1.1.2.1 The Right to Health as a General Principle of EU Law

It remains questionable whether the right to health care as enshrined in Article 35 of the Charter has the quality of individual justiciability,<sup>71</sup> despite incorporation of the Charter into primary Union law with the Lisbon amendments (Article 6 TEU). The Charter sets out an ‘unfortunate distinction’ between principles and rights (Art 52(2) Charter).<sup>72</sup> This means that the rights under the Charter that may be interpreted as ‘mere’ principles do not create any directly enforceable rights. With respect to the right to health, scholars have suggested that it can be categorised as *a pure objective* instead of a clear individual right or even a right that the EU ‘recognizes and respects’.<sup>73</sup> Moreover, the legal commentary of Article 35 of the Charter refers to the right to health as ‘principles’ which, in the legal context of the Charter, implies that article 35 does not entail any individual rights. Thus, for the purposes of the present section Article 35 of the Charter alone cannot serve as a legal basis for a claim by EU citizens against the EU institutions.

Yet, Article 35 refers to the obligation of ensuring a ‘high level of human health protection [...] in the definition and implementation of all Union policies and activities’. Thus, it can be seen as a

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<sup>67</sup> Cases T-74, 76, 83-85, 132, 137, and 141/2000 *Artegodan GmbH v Commission* [2002] ECR II-4945, [184]-[185] (emphasis added).

<sup>68</sup> N de Sadeleer ‘The Precautionary principle in EC Health and Environmental Law’ (2006) 12 ELJ 139; J Corkin, ‘Science, Legitimacy and the Law: Regulating Risk Regulation Judiciously in the European Community’ (2008) 33 ELRev 359.

<sup>69</sup> The MDD deals with scientific data and scientific evaluation.

<sup>70</sup> Art 263 TFEU; Craig and de Burca (n 56) 550; P Craig, *EU Administrative Law* (OUP 2012) ch 21.

<sup>71</sup> G De Burca, B D Witte, *Social Rights in Europe*, (OUP 2005) 317.

<sup>72</sup> See S Douglas-Scott, ‘The European Union and Human Rights after the Treaty of Lisbon’, (2011) 11 HRLR 645, 652.

<sup>73</sup> B Hepple ‘The EU Charter of Fundamental Rights’ (2001) 30 ILJ 225, 228.



‘touchstone against which Community [Union]... action can be tested.’<sup>74</sup> Indeed, the EU institutions are required to have regards to this right when legislating; thus it could be argued that the EU has the obligation to protect public health, as contained in the second sentence of Article 35 of the Charter.<sup>75</sup> This obligation is not necessarily tempered by the need for further implementing legislation; its content is clear, and it is directed specifically at the EU institutions. When read alongside Article 168 TFEU and Article 9 TFEU, which set out the competences of the EU in relation to the protection of public health, it requires both the EU institutions and MS to ensure a high level of human health protection in the context of Union law.

Another possibility is that Article 35(2) of the Charter, in combination with a directly enforceable right, could be construed as a right in terms of the Charter. Support for this proposition can be gleaned from cases in which positive obligations on public authorities have been deemed justiciable with regards to public health in the Council of Europe/European Court of Human Rights (‘ECtHR’) context. Indeed, these cases could provide a useful background from which to interpret Article 35. Of particular importance in this context is the prevention of loss of life. It has been accepted that it is possible, in certain circumstances, to interpret the right to life as placing an obligation on public authorities to take steps to prevent avoidable loss of life. In this respect, the general position of the ECtHR is that the right to life ‘must be interpreted in a way which does not impose an impossible or disproportionate burden on the authorities.’<sup>76</sup> However, the ECtHR has also acknowledged in a more recent case that the right to life would impose a positive obligation on states to prevent human life being avoidably put at risk. In this case, UK military personnel were exposed to dangerous levels of radiation, which was considered to put their offspring at risk.<sup>77</sup> The case was brought by the daughter of an affected member of the forces who had developed childhood leukemia as a consequence of her father’s exposure to the radioactive material. Although the application was rejected due to a lack of evidence regarding the link between childhood leukemia and exposure to radiation, it is not unthinkable following

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<sup>74</sup> Laenaerts and Foubert ‘Social Rights in the Case-Law of the European Court of Justice: The Impact of the Charter of Fundamental Rights of the EU on Standing Case-Law’ (2001) 28 LIEI 267, 271.

<sup>75</sup> Note that art 168 TFEU and art 35 of the Charter incorporate provisions that relate both to health care and public health protection, and both articles make a distinction between the two.

<sup>76</sup> ECtHR, *Osman v United Kingdom* [1998] EHRR 101, 28 October 1998.

<sup>77</sup> ECtHR, *L.C.B. v the United Kingdom* (1998-III, no. 76) *Reports of Judgments and Decisions* 1998-III, 9 June 1998.





this case that, with regards to taking preventive measures, the EU could be held liable for not ensuring the right to health.<sup>78</sup> The EU is in charge of numerous surveillance and response mechanisms that enable the trade of products that may have possible public health risks, including medical devices.

A relevant preventive measure that the EU may be obliged to undertake considering the right to health in conjunction with the right to life, is to warn the general public of any public health risks. The case of *Oneryildiz v Turkey* is informative in this respect.<sup>79</sup> This case involved the death of thirteen members of the Oneryildiz family who perished as a result of a methane-gas explosion on a municipal rubbish tip that caused a landslide to bury ten dwellings, killing thirty-nine people in total. The ECtHR accepted that the right to life includes an obligation on the part of the public authorities to warn the public of public health risks:<sup>80</sup>

The Court therefore arrives at the conclusion that in the present case the administrative authorities knew or ought to have known that the inhabitants of certain slum areas of Ümraniye were faced with a real and immediate risk both to their physical integrity and their lives on account of the deficiencies of the municipal rubbish tip. The authorities failed to remedy those deficiencies and cannot, moreover, be deemed to have done everything that could reasonably be expected of them within the scope of their powers under the regulations in force to prevent those risks materializing. Furthermore, they failed to comply with their duty to inform the inhabitants of the Kazım Karabekir area of those risks, which might have enabled the applicant – without diverting State resources to an unrealistic degree – to assess the serious dangers for himself and his family in continuing to live in the vicinity of the Hekimbaşı rubbish tip.<sup>81</sup>

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<sup>78</sup> ECtHR, *L.C.B. v the United Kingdom* (1998-III, no. 76) *Reports of Judgments and Decisions* 1998-III, 1403, [36], 9 June 1998; *Calvelli and Ciglio v Italy*, [GC], no. 32967/96, [48], ECHR 2002-I; *Eriksson v Italy* (dec.), no. 37900, 26 October 1999, unreported; and *Leray and Others v France* (dec.), no. 4461/98, 16 January 2001.

<sup>79</sup> ECtHR, *Oneryildiz v Turkey*, Application no 48939/99, Judgement of 18 July 2002

<sup>80</sup> See further for this argument: A de Ruijters, 'Uncovering European Health Law' (forthcoming thesis 2013) University of Amsterdam, Faculty of Law 2013.

<sup>81</sup> *Oneryildiz v Turkey* (n 78) [87]. See also [63]: 'Although not every presumed threat to life obliges the authorities, under the Convention, to take concrete measures to avoid that risk, the position is different, *inter alia*, if it is established that the authorities knew or ought to have known at the time of the existence of a real and immediate risk to the life of an individual or individuals and that they failed to take measures within the scope of their powers which might have been expected to avoid that risk'.



All the above clearly reinforces the position that the right to health protection, as set out in Article 35 of the Charter, read alongside Article 168 TFEU and Article 9 TFEU, could be regarded as constituting an individual right, which EU institutions have to respect when legislating for internal market purposes. Additionally, Article 35 of the Charter, coupled with a substantive right, such as the right to life, could be interpreted as conferring rights on individuals in the present case, especially when taking into consideration the key objectives in the preamble of the MDD: The *maintenance* or *improvement* in the protection of health of patients and third parties.

## 1.2 SUFFICIENTLY SERIOUS BREACH

In relation to the requirement that the breach be sufficiently serious, the CJEU stated in *Bergaderm* that ‘...the decisive test for finding that a breach of Community [Union] law is sufficiently serious is whether the Member State or the Community [Union] institution concerned manifestly and gravely disregarded the limits on its discretion.’<sup>82</sup> Under this test, discretion is the key element when assessing whether a breach is sufficiently serious. The wider the discretion of the institution involved, the more difficult it will be to establish a breach.<sup>83</sup> Conversely, where there is little or no discretion involved, a mere infringement of EU law may be enough to establish a sufficiently serious breach.<sup>84</sup> It will be for the claimant to show the serious breach.<sup>85</sup>

In *Brasserie du Pêcheur*,<sup>86</sup> the CJEU elaborated on the test for finding that a breach of EU law was sufficiently serious. Although this case concerned MS liability for a breach of EU law, it is likely that these factors will also guide the EU Courts in cases concerning EU liability, as it has been an aim of the EU to harmonise the criteria for non-contractual liability of the EU and the MS.<sup>87</sup> Thus, when determining whether a breach is sufficiently serious, the EU Courts may consider the following:

- i) The clarity and precision of the rule breached;

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<sup>82</sup> *Bergaderm* (n 30) [43].

<sup>83</sup> *Aalto* (n 18) 134-151; *Bergaderm* (n 30) [44].

<sup>84</sup> *ibid.*

<sup>85</sup> Case T-16/04 *Arcelor v Parliament and Council* [2010] ECR II-00211 [134] as discussed in Craig and de Burca (n 56) 563.

<sup>86</sup> *Brasserie du Pêcheur* (n 32).

<sup>87</sup> See *Aalto* (n 18) 85; *Bergaderm* (n 30) [41].



- ii) the measure of discretion left by these rules to the national or EU authorities;
- iii) whether the infringement and the damage caused was intentional or involuntary;
- iv) whether any error of law was excusable or inexcusable;
- v) whether the position taken by a EU institution may have contributed towards the omission;
- vi) the adoption or retention of national measures and practices contrary to EU law.<sup>88</sup>

Nevertheless, mere errors of judgement in the exercise of discretion by the institutions will not constitute ‘illegal’ acts.<sup>89</sup> In this context, ‘illegality’ has been construed fairly narrowly in order to avoid compromising the capacity of the EU institutions to regulate any given field.

[T]he concept of a sufficiently serious breach does not comprise all errors or mistakes which, even if of some gravity, and not incompatible with the normal conduct of an institution responsible for overseeing the application of competition rules, which are complex, delicate and subject to a considerable degree of discretion.” To do otherwise would “risk compromising the capacity of the Commission fully to function as regulator of competition, a task entrusted to it by the EC treaty...<sup>90</sup>

The CJEU further elaborated on this point in *Bayerische*, where it noted that

In this type of legislative field [wide discretion], the court will not substitute its own solution for that adopted by the community institutions. Providing that legislation is adopted in pursuance of the stated objective and is within the rule of law, the court will not interfere with the measure. It is only if it can be shown that the community institutions have acted in disregard of their powers, in that the measure was not appropriate for the achievement of the objective being pursued and cannot be justified, or, if they acted erroneously without excuse, the liability may be engaged.<sup>91</sup>

Thus, for the current case we need to take into consideration that in an area where the EU institutions have wide discretionary powers, ‘proving an obligation to act in a particular way rather than that adopted will be difficult.’<sup>92</sup>

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<sup>88</sup> See *Brasserie du Pêcheur* (n 32) [56].

<sup>89</sup> *MyTravel* (n 65) [40].

<sup>90</sup> *ibid.*

<sup>91</sup> *HNL and others* (n 51); J Wakefield, *Judicial Protection through the Use of Article 288(2) EC* (Kluwer Law International 2002) 90.

<sup>92</sup> Wakefield, *ibid.*, 91.



### 1.3 DAMAGE

To hold the EU non-contractually liable under Article 340 TFEU, the presence of a direct causal link between the breach of EU law and the damage sustained is required. In order to assess the existence of this link, the damage element must be analysed. According to Black's Law Dictionary, damage can be described as '[l]oss, injury, or deterioration, caused by the negligence, design, or accident of one person to another, in respect of the latter's person or property.'<sup>93</sup> The general objective when awarding compensation for loss in the context of non-contractual liability is to place the victim in the situation that would have been pertained if the wrong had not been committed.<sup>94</sup> Although Article 340(2) TFEU states that the duty of the EU is to make good "any damage", loss will be recoverable only if it is certain and specific, proven and quantifiable.<sup>95</sup> Damage must also be direct,<sup>96</sup> but this is a matter of causation,<sup>97</sup> and will be discussed below in section 1.4.

#### 1.3.1 General Characteristics of Damage

In order to determine compensation, damage claimed must be *certain*, or in other words, actually sustained. The consequence of this condition is that hypothetical loss or a mere risk of a future loss is insufficient.<sup>98</sup> However, while the damage claimed must in general be certain, the CJEU held in *Kampffmeyer* that it is possible to maintain an action 'for imminent damage foreseeable with sufficient certainty even if the damage cannot yet be precisely assessed'.<sup>99</sup> It is also required that the damage sustained must be serious not only slight, as otherwise the disregard of the

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<sup>93</sup> Black's Law Dictionary Free Online Legal Dictionary (2nd Ed) <<http://thelawdictionary.org/damage/>> accessed on 16 April 2013.

<sup>94</sup> *Mulder* (n 60) [34]; *Cofradia* (n 48) [110]; Joined Cases T-3/00 and T-337/04 *Pitsiorlas v Council and ECB* [2007] ECR II-4779 [293], [319]-[320].

<sup>95</sup> Toth, in Craig and de Burca (n 56) 573.

<sup>96</sup> Cases 9 and 12/60 *Société Commerciale Antoine Vloeberghs, SA v High Authority* [1961] ECR 197, Opinion of AG Roemer [240]; Case 25/62 *Plaumann v Commission* [1963] ECR 95, Opinion of AG Roemer in J Wakefield (n 91) 216.

<sup>97</sup> Wakefield (n 91) 216.

<sup>98</sup> *Pitsiorlas* (n 94) [293]; D Chalmers, G Davies & G Monti, *European Union Law Cases and Materials* (2<sup>nd</sup> edn, Cambridge University Press 2010) 437.

<sup>99</sup> *Kampffmeyer* (n 39) [711], [741]; Case 44/76 *Milchkontor v Council and Commission* [1977] ECR 393 [8]; Case T-99/98 *Hameico Stuttgart and others v Council and Commission* [2003] ECR II-2915 [63]; Case T-79/96 *Camar and Tico v Commission and Council* [2000] II-02193, [207]. Immediate action is necessary in order to prevent even greater damage; Craig and de Burca (n 56) 573.



discretion of the EU institutions could not be ‘manifest and grave’.<sup>100</sup> The condition that the damage suffered must be *specific* means that it must affect the applicant’s interests in a special and individual way.<sup>101</sup>

Reparation sought by the applicant must be set out explicitly,<sup>102</sup> and the burden of proof to show that the damage occurred and that the injury was actually sustained lies on the injured party.<sup>103</sup> Moreover an application seeking compensation for damage caused by an EU institution or any other EU body or agency must state, amongst other things, the nature and extent of the damage, and provide relevant admissible evidence.<sup>104</sup> The damage must also be *quantifiable* if the applicant is to succeed,<sup>105</sup> meaning that it is capable of being assigned a monetary value. As long as sufficient evidence of damage is provided, the damage need not be quantified and can be assessed at a later stage,<sup>106</sup> especially in complex cases.<sup>107</sup> The EU Courts have jurisdiction to assess the just quantum of damage; in *Mulder*<sup>108</sup> the Court ruled that the amount of compensation payable should correspond to the damage which is caused.<sup>109</sup> For example, loss of earnings are to be calculated as the difference between what could have been earned but for the breach of law and the sum actually earned, including that earned from “replacement activities”.<sup>110</sup> In order to decide whether damage is quantifiable for compensation, it is necessary to ascertain the types of damage that are recoverable.<sup>111</sup>

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<sup>100</sup> *Mulder* (n 60) [12]-[17].

<sup>101</sup> Case 26/74 *Roquette Frères v Commission* [1976] ECR [677], [694].

<sup>102</sup> Art 21 of the Statute of the CJEU, art 120(d) Rules of Procedure of the Court of Justice of the European Union (4 July 1991) OJ L 176, entered into force 1 September 1991.

<sup>103</sup> *Roquette Frères* (n 101) (AG Trabucchi) [677], [694].

<sup>104</sup> Case T-461/08 *Evropaïki Dynamiki - Proigmena Systemata Tilepikoinonion Pliroforikis kai Tilematikis AE v European Investment Bank (BEI)*, Judgment of the General Court (Fourth Chamber) of 20 September 2011 (not yet published in ECR) [80].

<sup>105</sup> *Cofradia* (n 48) [110]; Cf also Art 138(1)(c) of the Rules of Procedure of the CJEU (n 102).

<sup>106</sup> Cases T-195 and T-202/94 *Quiller and Heusmann v Council and Commission* [1997] ECR-II 2247 [144]-[145].

<sup>107</sup> Case 29/63 *Laminoirs de la Providence and Others v High Authority* [1965] ECR 01123, 941.

<sup>108</sup> *Mulder* (n 60).

<sup>109</sup> *Mulder* (n 60) [34]; AG Toth ‘The Concepts of Damage and Causality as Elements of Non-Contractual Liability’ in T Heukels and A McDonnell (eds), *The Action for Damages in Community Law*, (The Hague/London/Boston, 1997) 179, 187.

<sup>110</sup> *Mulder* (n 60) [59].

<sup>111</sup> *Craig and de Burca* (n 56) 573.



### 1.3.2 Recoverable Types of Damage

In *Ireks-Arkady*,<sup>112</sup> AG Capotorti set out the types of loss which may be recovered, namely material loss, i.e. a reduction in a person's assets, and also loss of profit, i.e. the loss of an increase in those assets, which would have occurred if the harmful act had not taken place.<sup>113</sup> The CJEU's view on recoverable types of damage is broad;<sup>114</sup> it will grant damages for loss actually sustained as well as, exceptionally, for non-material damage<sup>115</sup> such as anxiety, hurt feelings<sup>116</sup> and slurs of professional reputation.<sup>117</sup> It is willing, in principle, to give damages for lost profits, but apart from some exceptions<sup>118</sup> it has been reluctant to do so in practice.<sup>119</sup>

From the point of view of this Report, the relevant types of damage derive from physical injuries and are either in the form of material loss *strictu sensu* or non-material damages suffered as a result of the injury. Loss of profit is not of relevance here because the injuries were sustained by the women as natural persons as opposed to business entities (juridical persons) engaging in business activities with the aim of making profit. Cases involving personal injury are rare in the jurisprudence of the EU Courts, as the EU institutions have very little *physical* contact with the citizens. Although they do occasionally occur, the majority have concerned EU staff.<sup>120</sup>

Bodily harm to a person may give rise to several types of loss. In *Grifoni*,<sup>121</sup> a worker injured in an EU building due to the Commission's failure to take the safety measures prescribed by Italian legislation was awarded compensation for medical expenses (and expenses related to the treatment and recovery) caused by the accident to the extent they were proven by original receipts and other admissible evidence, as well as for partial temporal incapacity and permanent

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<sup>112</sup> Case 238/78 *Ireks-Arkady v Council and Commission* [1979] ECR 2955, 2998-2999.

<sup>113</sup> *ibid.*

<sup>114</sup> Chalmers, Davies & Monti (n 98), 436.

<sup>115</sup> Case T-84/98 *C v Council* [2000] ECR IA-113 [98]-[103]; Case T-307/01 *Jean-Paul Francois v Commission* [2004] ECR II-1669 [107]-[111]; Case T-48/01 *Francois Vainker and Brenda Vainker v European Parliament* [2004] ECR II-197 [180]; Case T-309/03 *Grau v Commission* [2006] ECR II-1173 [162].

<sup>116</sup> Case 110/63 *Williame v Commission* [1965] ECR 649, 667.

<sup>117</sup> Case T-48/05 *Franchet and Byk v Commission* [2008] ECR II-1585 [400]-[411].

<sup>118</sup> Eg see *Kampffmeyer* (n 39) and *Mulder* (n 60) [26]-[34].

<sup>119</sup> *Kampffmeyer* (n 39) [266]-[267]; Case T-160/03 *AfCon Management Consultants v Commission* [2005] ECR II-981, [112]-[114]; Case 74/74 *CNTA v Commission* [1975] ECR 533.

<sup>120</sup> *Türk* (n 20) 289.

<sup>121</sup> C-308/87 *Grifoni v EAEC* [1990] ECR I-01203 and [1994] ECR I-00341.



invalidity. If the parties do not reach an agreement, the Court can order an expert medical report to be relied upon. In *Adams*, substantial compensation was awarded for the endured mental anguish and economic loss.<sup>122</sup>

#### 1.4 CAUSATION

Finally, the second paragraph of Article 340 TFEU refers to the principles common to the laws of the MS. However, these cannot be relied upon to oblige the EU to make good every harmful consequence attributable to the conduct of its institutions, such as those that are remote. Consequently, the sustained damage must be causally linked to the wrongful action or omission of the EU institutions.<sup>123</sup>

The causal link is established where there is direct damage and exclusive causation, i.e. the damage is the direct consequence of the wrongful act in question,<sup>124</sup> and there are no ‘intervening circumstances or acts which prevent the relationship of cause and effect between this initial act and subsequent damage from being established with certainty’.<sup>125</sup> For establishing that damage is direct and exclusive, the Court uses a ‘but for’ test. ‘Wrongful or illegal conduct found by the Court is hypothetically removed and the situation reconsidered to discover whether the damage would have been sustained (...) “but for” the wrongful conduct of the EU institution.’<sup>126</sup> The test

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<sup>122</sup> Case 145/83 *Adams v Commission* [1985] ECR 3539. Mr Adams had provided the European Commission with evidence about his employer’s, Hoffmann-La Roche & Co, anticompetitive business activities. Mr Adams was arrested, detained, tried and convicted in Switzerland for disclosing business information and breaching business confidentiality. The Commission wrongfully had not kept the identity of Mr Adams in secrecy or warned him against the risk of arrest in Switzerland. The CJEU thus awarded Mr Adams compensation *inter alia* for mental anguish suffered as a result of the imprisonment. However, the responsibility was apportioned equally between the Commission and Mr Adams since Mr Adams had himself acted negligently.

<sup>123</sup> C-433/10 P *Volker Mauerhofer v European Commission* Order of the Court (Fifth Chamber) of 31 March 2011 (not yet published in ECR) [127] citing Joined Cases 64/76, 113/76, 167/78, 239/78, 27/79, 28/79 and 45/79 *Dumortier and Others v Council* [1979] ECR 3091 [21]; Joined Cases C-363/88 and C-364/88 *Finsider and Others v Commission* [1992] ECR I-359 [25]; and Case C-419/08 P *Trubowest Handel and Makarov v Council and Commission* [2010] ECR I-02259 [53].

<sup>124</sup> Case T-149/96 *Confederazione Nazionale Coltivatori Diretti (Coldiretti) and 110 Farmers c Council and Commission* [1998] ECR II-3841 [101]; *Fresh Marine* (n 64) [118]; Case T-561-08 *Jürgen Gutknecht v European Commission*, Judgment of the General Court (Second Chamber) of 18 October 2011 (not yet published in ECR) [30], citing Case C-331/05 P *Internationaler Hilfsfonds v Commission* [2007] ECR I-5475 [23], and Case C-497/06 P *CAS Succhi di Frutta v Commission* [2009] ECR I-00069 [59].

<sup>125</sup> *Plaumann* (n 96), Opinion of AG Roemerin, in Wakefield (n 91) 216.

<sup>126</sup> Case T-7/96 *Perillo v Commission* [1997] ECR II-1061 [43]; Case 33/82 *Murri Frères v Commission* [1985] ECR 2759 [30] in J Wakefield (n 91) 217.



is satisfied if the damage would not have occurred. In the case of a wrongful or illegal omission ‘the Court will reconsider the facts to discover whether, “even if” the EU institution had acted properly, the damage would still have been sustained. If it would have, the wrongful or illegal conduct will be irrelevant to determinations of causation’; i.e. there is no causal link between the omission and the damage.<sup>127</sup> It is emphasised that the ‘but for’ test alone is insufficient; the alleged loss must be a *sufficiently* direct consequence of the conduct complained of and such a causal link must be the *determining cause of the loss*.<sup>128</sup>

The requirement of exclusivity precludes multiple causes, whether simultaneous or successive, from giving rise to liability of the EU institutions. The CJEU will consider the circumstances in which the illegal measures arose.<sup>129</sup> In *Lütticke*<sup>130</sup> the AG Lamothe opined that, in a legislative context, where an institution had discretion, it would not be possible to show causation because the outcome of the legislative choice would be uncertain.<sup>131</sup> A similar position was taken by the CFI in *Dubois*,<sup>132</sup> where the Court considered that

if the unlawful act complained of concerns a legislative measure, the liability of the Community [Union] can be incurred only if there has been a breach of a higher-ranking rule of law for the protection of individuals. Moreover, if the institution has adopted the measure in the exercise of a broad discretion, the Community [Union] cannot be rendered liable unless the breach is clear, that is to say, if it is of a manifest and serious nature.<sup>133</sup>

Causation must also be immediate.<sup>134</sup> In addition to showing that the EU action or inaction caused the loss, the applicant must show that the causal chain has not been broken by the MS or the applicant.<sup>135</sup> The CJEU has held that the EU is no longer liable where the loss arises from an independent or autonomous act by the MS.<sup>136</sup> However, in such a case, an illegal failure by the

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<sup>127</sup> *ibid.*

<sup>128</sup> *Evropaïki Dynamiki* (n 104) [209].

<sup>129</sup> Wakefield (n 91) 218.

<sup>130</sup> Case 4/69 *Alfons Lütticke GmbH v Commission* [1971] ECR 325.

<sup>131</sup> *Lütticke* (n 127) (AG Duheillet de Lamothe) 346-7, in Wakefield (n 88) 218.

<sup>132</sup> *Dubois* (n 51).

<sup>133</sup> *Dubois* (n 51) [59], in J Wakefield (n 88) 218.

<sup>134</sup> Toth (n 109) 192.

<sup>135</sup> See A-G van Gerven in *Mulder* (n 60) [38].

<sup>136</sup> Case 132/77 *Société pour l'Exportation des Sucres SA v Commission* [1978] ECR 1061, 1072-1073; Case T-571/93 *Lefebvre v Commission* [1995] ECR II-2379 [65].





Commission to exercise its supervisory powers will be considered to be the cause of damage.<sup>137</sup>

AG Toth has also emphasised that

[t]he fact that a Community [Union] act or omission is one only of several such circumstances may not in itself be sufficient to establish a causal connection entailing non-contractual liability. For that purpose, the causality must be ‘direct, immediate and exclusive’ which it can be only if the damage arises directly from the conduct of the institutions and does not depend on the intervention of other causes, whether positive or negative.<sup>138</sup>

The difficulties of proving a causal link are reflected in the Court’s case law.<sup>139</sup> In *É.R. and Others* the Court stated that ‘where the conduct which allegedly causes the damage pleaded consists in refraining from taking action, it is particularly necessary to be certain that that damage was actually caused by the inaction complained of and could not have been caused by conduct separate from that alleged against the defendant institutions.’<sup>140</sup> This means that the inaction on the part of the institution of the EU must be a *conditio sine qua non* (a necessary prerequisite) for the damage to occur.

The burden of proof of such a causal link rests on the applicants.<sup>141</sup> Therefore, an application seeking compensation for damage caused by an EU institution must provide evidence of the alleged conduct. It must also explain the reasons for which the applicant considers there to be causal link between the conduct and the damage, and set out the nature and extent of that damage.<sup>142</sup>

However, even where a direct causal link is established between the loss suffered and the illegal act, the applicant might still not recover full compensation. Firstly, according to the doctrine of contributory negligence, where the applicant is considered to have contributed to the damage as a result of a failure to take due care, the claim might be defeated or the awarded damages reduced.<sup>143</sup> Secondly, the applicant is obliged to mitigate any loss suffered, and a failure to do so

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<sup>137</sup> *Vloeberghs* (n 96) [216], [240]; *Lütticke* (n 127) [336]-[338].

<sup>138</sup> Toth (n 109) 192.

<sup>139</sup> *Dumortier* (n 123) [21].

<sup>140</sup> *É.R. and Others* (n 25) [134].

<sup>141</sup> *Evropaïki Dynamiki* (n 104) [209].

<sup>142</sup> *ibid* [80]; Case T-19/01 *Chiquita Brands and Others v Commission* [2005] ECR II-315 [79], [65].

<sup>143</sup> *Adams* (n 122) [53]-[55]; *Grifoni* (n 121) [15]-[18].



will result in the compensation being reduced.<sup>144</sup> It has also been held that if the individual ought to have foreseen the possibility of certain events which might cause loss, then the damages claim will be diminished or lost. Finally, compensation will be reduced if there is evidence that the applicant has, or could have, passed the loss on to somebody else.<sup>145</sup>

## 1.5 INTERIM CONCLUSION

To establish liability under Article 340 TFEU, three criteria must be satisfied: 1) the rule infringed must have intended to confer rights on individuals; 2) the nature of the breach must be sufficiently serious; and 3) there must be a direct causal link between breach of the obligation and the damage sustained. To satisfy the first of these criteria, it is necessary to show that the norm infringed was especially designed to protect the interests of those who were injured or of the group to which they belonged.<sup>146</sup> Although it is sufficient that the rule infringed has been adopted in the interest of individuals whilst pursuing other aims, the EU Courts treat this issue on a case-by-case basis, and as individual rights are often difficult to identify, this requirement is hard to satisfy.<sup>147</sup> Nonetheless, individual rights have been established based on general principles of EU law in a number of cases, and it is arguable that the right to health in conjunction with the right to life could constitute an individual right on which we could rely in the present case.

In order to fulfil the second criterion and establish a sufficiently serious breach, it must be shown that ‘the Member State or the Community [Union] institution concerned manifestly and gravely disregarded the limits on its discretion.’<sup>148</sup> Discretion will be key to this assessment; the wider the discretion of the institution involved, the more difficult it will be to establish a breach. Conversely, the narrower the discretion of the institution, the easier it will be to establish breach.<sup>149</sup>

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<sup>144</sup> *Mulder* (n 60) [32]-[33].

<sup>145</sup> *Ireks-Arkady* (n 112) [13]-[17].

<sup>146</sup> *Becher v Commission*, 30/66 (1968) *CMLR* 169, 181-182; *Kampffmeyer* (n 39). See also *Biondi and Farley* (n 40) 109.

<sup>147</sup> See also *Türk* (n 20) 261.

<sup>148</sup> *Bergaderm* (n 30) [43].

<sup>149</sup> *Aalto* (n 18) 134-151; *Bergaderm* (n 30) [44].



Regarding the third criterion, damage will be recoverable only if it is certain and specific, proven and quantifiable. Damages deriving from physical injuries, including economic loss and non-material damages for mental suffering are in principle recoverable. However, sustained damage must be causally linked to the wrongful action or omission of the EU institutions. The threshold for establishing causality requires direct damage and exclusive causation, i.e. the damage must be a sufficiently direct consequence of the wrongful act or omission, and there may not be any intervening circumstances. The burden of proof of such a causal link rests on the applicant.

## **2 REGULATORY FRAMEWORK FOR MEDICAL DEVICES**

In order to determine whether the EU may be held liable under Art 340 TFEU it is necessary to assess the framework in place for the regulation of Medical Devices.

### **2.1 DIRECTIVE 93/42/EEC: THE MEDICAL DEVICES DIRECTIVE**

The MDD was adopted by the Council under the Treaty of the European Economic Community (EEC 1992),<sup>150</sup> having particular regard to Article 100a, as a measure adopted in the context of the approximation of the laws of the MS and functioning of the internal market.<sup>151</sup> At the time the MDD was adopted, competences concerning regulation of the internal market and public health belonged to the category of competences shared between the EEC and the MS. However, the Council had, and still has, wide discretion in deciding which measures to adopt and what form they should take when regulating Medical Devices' access to the internal market.<sup>152</sup>

According to its recitals, the MDD has two main aims: 1) to ensure the functioning of the internal market, and 2) to ensure a high level of protection of human health and safety, which it seeks to achieve through the approximation of the laws of the MS. The MDD requires MS to take all necessary steps to ensure that devices may be placed on the market and put into service as long as they do not compromise the health and safety of users when properly installed, maintained and

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<sup>150</sup> Art 2 EEC [now art 3 TEU].

<sup>151</sup> Art 100a EEC [now art 14 TFEU].

<sup>152</sup> Art 189 EEC [now art 288 TFEU].



used in accordance with their intended purpose.<sup>153</sup> Additionally, the MDD imposes obligations on Notified Bodies, the bodies designated by the MS to conduct assessments and issue certifications of Medical Devices in line with the MDD, and on manufacturers of Medical Devices, through implementation of national legislation by the MS.

For the purpose of this Report, the obligations of the EU in relation to the aim of ensuring a high level of protection of human health and safety are significant. Thus, this Report will now give an overview of the responsibilities of the EU in the field of public health within the regulatory framework of the Medical Devices, namely the essential requirements for Medical Devices and the Conformity Assessment Procedure.

## 2.2 ALLOCATION OF OBLIGATIONS UNDER THE MEDICAL DEVICES DIRECTIVE

By means of the MDD, the EU set up a framework to regulate the conditions of entry for Medical Devices' access to the internal market. As previously discussed, the MDD was enacted under the internal market competences of the EU rather than those specifically relating to health, as health matters within the EU have remained to a large extent a matter of national competence.<sup>154</sup> Nevertheless, the MDD is a prime example of the extent to which EU regulation in other policy fields can impact on national health policies;<sup>155</sup> whilst its primary objective is harmonisation of the internal market, the nature of the subject matter addressed has obvious implications for public health and health care. Indeed, the MDD itself alludes to this in its preamble, where it states that *maintenance or improvement* in the protection of patients and third parties is one of the *essential* objectives of the MDD.

The importance of the protection of public health is well recognised within the EU, despite the limited legislative competences of the EU institutions in this field. The Treaty of Maastricht first introduced the concept of the 'mainstreaming' of public health. The concept finds its place post-

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<sup>153</sup> Art 2 MDD.

<sup>154</sup> Due to the potential economic and ethical impact of regulation; see Riitta-Maija Hämäläinen, Meri Koivusalo, Eeva Ollil, 'EU Policies and Health' (2004) National Research and Development Center for Welfare and Health, Themes from Finland 1/2004 (Stakes), 1, 1.

<sup>155</sup> For example, regulation to ensure the free movement of people, services and goods has affected the movement of health care professionals, pharmaceuticals, and Medical Devices and equipment within the EU. Hämäläinen, Koivusalo and Ollil (n 154) 1.



Lisbon in Art 9 TFEU, which states that ‘[i]n defining and implementing its policies and activities, the EU shall take into account requirements linked to the promotion of a *high level* of (...) protection of human health.’<sup>156</sup> Although a broad principle, it is tempered by the principle of subsidiarity. This principle requires that the EU only act if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the MS.<sup>157</sup>

The obligation to protect health follows directly from the legal basis of the directive (Article 114 (3) TFEU) and is also contained in Article 35 of the Charter. Art 51(1) read alongside Art 6(2) TEU suggests a ‘*positive obligation* on the EU to take *full account* of the Charter when performing their legislative tasks.’<sup>158</sup> Thus when performing their functions, the EU institutions must take account of the right to health contained in Article 35 of the Charter. As noted above, this is supported by the wording of Article 35 itself, which states in the second paragraph that ‘[a] *high level* of human health protection shall be ensured in the definition and implementation of all EU policies and activities.’<sup>159</sup> However, the practical implications of Article 35 rights in EU litigation are so far unclear, as the EU Courts have yet to address the issue.<sup>160</sup> Thus, in enacting the MDD, the EU was required to have regard to the EU’s wider obligations concerning the protection of public health,<sup>161</sup> with the Commission obliged to take a *high level* of protection as a base for its actions, and, additionally, take account of any new developments based on scientific facts as required by Article 114(3) TFEU.

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<sup>156</sup> Art 9 TFEU (emphasis added).

<sup>157</sup> Contained generally in Art 5 TEU, and more specifically with regards to public health and health care in Art 168(7) TFEU. The implications of the principle of subsidiarity for holding the EU liable in damages will be discussed further below.

<sup>158</sup> Jean McHale, ‘Fundamental Rights and Healthcare’ in Jean McHale, *Health Systems Governance in Europe: The Role of European Union Law and Policy* (Cambridge University Press 2010) 282 (emphasis added).

<sup>159</sup> Art 6(2) TEU (emphasis added).

<sup>160</sup> McHale (n 158) 304-308.

<sup>161</sup> Art 9 TEU.



## 2.2.1 Essential Requirements for Medical Devices and the Conformity Assessment Procedure

According to Article 3 MDD, devices must meet the relevant essential requirements as set out by the Council in Annex I, taking account of the intended purpose of the devices concerned. The basic requirement contained in Annex I requires that

[t]he devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a *high level* of protection of health and safety.<sup>162</sup>

Whether a medical device meets the essential requirements is determined by a Conformity Assessment Procedure. Medical Devices are allocated into risk Classes I, IIa, IIb and III in accordance with Annex IX, with Class I reserved for the lowest risk devices, and Class III for the highest risk devices.<sup>163</sup> This classification determines which Conformity Assessment Procedure the Manufacturer must follow.<sup>164</sup> The assessment procedures are carried out by *independent* third parties designated for this purpose by the MS, namely the Notified Bodies.<sup>165</sup>

Until 2003, breast implants were classified as Class IIb devices, along with all implantable devices and long-term surgically invasive devices, bar a few exceptions.<sup>166</sup> Devices in this category were required to undergo verification of the Manufacturer's quality system in line with Annex II, and thus the involvement of the Notified Body was fairly limited.<sup>167</sup> In 2003, on the request of France and UK, breast implants were reclassified as Class III devices – the highest risk devices – by Commission Directive 2003/12/EC.<sup>168</sup> Therefore, since 1 September 2003 (or since 1 March 2004 regarding breast implants already on the market), the Conformity Assessment

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<sup>162</sup> Annex I art 1(1) MDD (emphasis added).

<sup>163</sup> Art 9 MDD.

<sup>164</sup> MEDDEV, 6.

<sup>165</sup> Art 16(1) MDD (except for Class I devices following only the conformity procedure laid down in Annex VII).

<sup>166</sup> Annex IX, rule 8, MDD.

<sup>167</sup> For details, see discussion of conformity assessments for Class III devices below at section 2.2.1.1.

<sup>168</sup> Commission Directive 2003/12/EC on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices, OJEU L28/43, 4 February 2003.



Procedure required for entry, and continued entry to the market for breast implants has been in line with that required by the MDD for Class III devices discussed below.

The easiest way for Manufacturers to demonstrate compliance with the requirements of the MDD is to comply with the voluntary Harmonised Standards.<sup>169</sup> Compliance with Harmonised Standards provides a presumption of conformity with the corresponding requirements of harmonisation legislation.<sup>170</sup> EN ISO 14607:2009<sup>171</sup> sets the particular requirements for breast implants to comply with the essential requirements of the MDD and EN ISO 13485: 2012<sup>172</sup> the requirements for the quality management systems in order to comply with those foreseen in the MDD.<sup>173</sup>

#### *Conformity Assessment Routes for Class III Devices*

There are two routes to certification for Class III devices from which the Manufacturer can choose before a CE mark can be affixed:

1) A Notified Body must carry out either an Annex II audit of the full Quality Assurance System,<sup>174</sup> plus the Manufacturer must submit the design dossier to the Notified Body for approval under Annex II;<sup>175</sup> or 2) An Annex III type-examination must be conducted, plus either a) examination and testing of each product or homogenous batch of products (Annex IV); or b) Audit of the production Quality Assurance System (Annex V).<sup>176</sup> Once the Manufacturer has

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<sup>169</sup> See definition under Definitions.

<sup>170</sup> European Standard, Harmonised Standards (n 6).

<sup>171</sup> EN ISO 14607:2009 Non-active surgical implants - Mammary implants - Particular requirements (ISO 14607:2007), superseding EN ISO 14607:2007.

<sup>172</sup> EN ISO 13485:2012 Medical Devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003), superseding EN ISO 13485:2003.

<sup>173</sup> European Standards, Medical Devices, < [http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/index_en.htm) > accessed on 23 April 2013.

<sup>174</sup> Art 11 MDD (In line with ISO13485:2003: CE Marking Consulting Service, Medical Devices <<http://www.ce-marking.com/medical-devices-class-III.html>> accessed on 23 April 2013.

<sup>175</sup> Annex II Section 4 MDD. This is an additional requirement solely intended for Class III devices subject to Annex II Conformity Assessment Procedures: see Annex II Section 7.

<sup>176</sup> Art 11 MDD In line with ISO13485:2003 (excluding Design), CE Marking Consulting Service, Medical Devices <<http://www.ce-marking.com/medical-devices-class-III.html>> accessed on 23 April 2013.



received certification from the Notified Body the CE mark can be attached to the products and the devices may be placed on the market.<sup>177</sup>

Although at first glance these procedures, particularly under Annex III, indicate rigorous assessment procedures and full involvement of the Notified Bodies, an analysis of the processes with reference to the criteria laid down in the relevant annexes suggests otherwise.

### **2.2.1.1 Option 1- Annex II: Full quality assurance**

The full quality assurance procedure requires the Manufacturer to set up a Quality Assurance System where it declares that products, and the systems for checking the conformity of products, conform with the requirements of the MDD.<sup>178</sup> The Notified Body is required to audit this system, which involves onsite inspection of the systems, but no testing of the actual products.<sup>179</sup>

Additionally, the *Manufacturer* is required to lodge an application for examination of the design dossier by the Notified Body.<sup>180</sup> This application describes the design, manufacture and performance of the product.<sup>181</sup> The Notified Body must examine the application to see whether the product conforms, and it may require further tests for proof, but this is not an essential requirement.<sup>182</sup> Therefore no examination of the actual product is required. If the Notified Body is satisfied, based on the application, that the product conforms, it issues a design examination certificate.<sup>183</sup> Any changes in design must receive further approval from the Notified Body wherever the changes could affect the conformity of the product with the essential requirements of the MDD.<sup>184</sup> The obligation to inform the Notified Bodies of any changes falls solely on the *Manufacturer*, and no independent action is required on the part of the Notified Body to ensure that Manufacturers comply with this obligation.<sup>185</sup>

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<sup>177</sup> Art 11 MDD.

<sup>178</sup> Annex II Section 1 MDD.

<sup>179</sup> Annex II Sections 3-5 MDD.

<sup>180</sup> Annex II Section 4 MDD.

<sup>181</sup> Annex II Section 4.2 MDD.

<sup>182</sup> Annex II Section 4.3 MDD.

<sup>183</sup> Annex II Section 4.2 MDD.

<sup>184</sup> Annex II Section 4.4 MDD.

<sup>185</sup> *ibid.*





### 2.2.1.2 Option 2- Annex III: Type-examination

Under the type-examination procedure, the Notified Body ascertains and certifies that a representative sample of the production covered fulfills the relevant provisions of the MDD.<sup>186</sup> The sample and accompanying documentation<sup>187</sup> is *provided by the Manufacturer*.<sup>188</sup> The Notified Body must then examine this *documentation* (rather than actual product) and verify that the type is, according to those documents, in conformity with the MDD.<sup>189</sup> If this is the case, the Notified Body issues an EC type-examination certificate. The *Manufacturer* must inform the Notified Body of any changes to the product, which must receive further approval from the Notified Body (a supplement to the initial EC Type-examination).<sup>190</sup>

Similarly to the procedure in Annex II, the Annex III procedure does not require the Notified Body to actually test the product. The Notified Body audits information provided solely by the Manufacturer, and therefore relies wholly on the integrity of the Manufacturer. However, if Manufacturers choose the Annex III route, the procedure must be coupled with either examination and testing as required by Annex IV, or a production quality assurance in line with the requirements of Annex V.

### 2.2.1.3 Option 2a- Annex IV: Examination and testing

The examination and testing procedure requires *either* that every product to be tested, or, that a statistical verification is carried out.<sup>191</sup> This statistical verification consists of the testing of a random sample from homogenous batches *provided by the Manufacturer*.<sup>192</sup> As such, the Manufacturer can control which batches of products undergo examination and testing.

### 2.2.1.4 Option 2b- Annex V: Declaration of conformity (production quality assurance)

The declaration of conformity procedure requires the *Manufacturer* to ensure and declare that everything is in line with the *Manufacturer's own quality system* and that the products meet the

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<sup>186</sup> Annex III Section 1 MDD.

<sup>187</sup> Which must allow understanding of the design, manufacture, and performance: Annex III Section 3 MDD.

<sup>188</sup> Annex III Section 2 MDD.

<sup>189</sup> Annex III Section 4 MDD.

<sup>190</sup> Annex III Section 6 MDD.

<sup>191</sup> Annex IV Section 4 MDD.

<sup>192</sup> Annex IV Section 6 MDD.



provisions of the MDD.<sup>193</sup> The Notified Body must audit the *system* to determine whether it meets the requirements of Section 3.2.<sup>194</sup> The Manufacturer is required to inform the Notified Body of any changes proposed to the products, or the system.<sup>195</sup> The Notified Body must carry out inspections and assessments to make sure Manufacturer applies the approved quality system.<sup>196</sup> The Notified Body *may* also pay unannounced visits to the Manufacturer, although this is not an essential requirement.<sup>197</sup>

Once certification is issued by the Notified Body, the Manufacturer must affix the CE Marking in accordance with Article 17 MDD and draw up a written declaration of conformity.<sup>198</sup> By issuing a declaration of conformity, the Manufacturer, who fulfils the obligations imposed by Section 1 Annex II, ensures and declares that the products concerned meet the relevant provisions of the MDD.<sup>199</sup> To summarise, there are a number of potential routes, as specified in the Annexes to the MDD, that lead to CE certification for medical devices. The appropriate route is determined on the basis of device class, which is assigned by the Commission. There are four classes of device under the MDD: Class I, II(a), II(b) and III. Breast implants have been classified as Class III devices since 2003. There are two possible certification routes for Class III devices: The full quality assurance and the type-examination, the latter of which requires an assessment of a representative sample of devices. The manufacturer has the discretion to decide which certification route to follow in order to satisfy the requirements necessary to have products placed on the market.

### **2.2.2 Surveillance and supervision of the MDD**

Under the MDD, rights and obligations are distributed between various authorities. However, it is notable that no direct control is exercised at EU level in respect of many key aspects of the procedure for surveillance and supervision of the MDD; no direct European level management

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<sup>193</sup> Annex V Section 1 MDD.

<sup>194</sup> Annex V Section 3.3 MDD: this includes audit on the Manufacturer's premises.

<sup>195</sup> Annex V Section 3.4 MDD.

<sup>196</sup> Annex V Section 4.3 MDD.

<sup>197</sup> Annex V Section 4.4 MDD.

<sup>198</sup> Annex V Section 2 MDD.

<sup>199</sup> *ibid.*



system was set up to oversee the implementation of the MDD or the functioning of the framework, and broad discretion was left to the MS in this area.<sup>200</sup>

For example, in relation to pre-market supervision, surveillance of the Notified Bodies is carried out by the *national* notifying authorities, who have authority to withdraw or modify the notification if the conditions of notification fail to be satisfied. The MS concerned must immediately inform the other MS and the Commission of the withdrawal or modification of the notification.<sup>201</sup> It could be argued that the EU exercises indirect control over this procedure (and thus over the Notified Bodies and also Competent Authorities), through monitoring of the MS application of EU law.<sup>202</sup> In the field of food and product safety, consumer rights, or public health, this is done by the Directorate General of Health and Consumers.<sup>203</sup> If the Commission considers that a MS has failed to fulfil an obligation under the Treaties,<sup>204</sup> it *may* initiate infringement proceedings against that MS before the EU Courts.<sup>205</sup> Nevertheless, the EU is not liable where it does not bring proceedings (Article 258 TFEU) against a MS that is in breach of EU law.<sup>206</sup> The CJEU in *Star Fruit Company v Commission*<sup>207</sup> emphasised that the Commission has discretion, rather than a duty, to commence proceedings. Although individuals can file a complaint against the MS in breach, they cannot require the Commission to take action.

Similar discretion is left to MS at post-market surveillance stage, where the MDD also places considerable responsibility on the Manufacturers to instigate supervisory procedures. Once devices are on the market, Manufacturers must notify the relevant national Competent Authority about any *severe* incidents that occur, and must investigate these incidents and take any necessary corrective action. In its application for assessment of its quality system the manufacturer must undertake to notify the Competent Authorities of ‘any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for

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<sup>200</sup> For example, competence on matters such as the designation of Notified Bodies, the supervision of clinical investigations, the investigation of vigilance cases, and the supervision of devices on the market.

<sup>201</sup> Art 16(3) MDD.

<sup>202</sup> Art 17 TEU.

<sup>203</sup> Supported by SANCO: European Commission: Health and Consumers

<[http://ec.europa.eu/dgs/health\\_consumer/about\\_us/who\\_we\\_are\\_en.htm](http://ec.europa.eu/dgs/health_consumer/about_us/who_we_are_en.htm)> accessed on 23 April 2013.

<sup>204</sup> This includes implementing and applying directives, Art 4 TEU and Art 288 TFEU.

<sup>205</sup> Art 258 TFEU.

<sup>206</sup> Case T-571/93 *Lefebvre v Commission* [1995] ECR II-2379 [60]-[61] in J Shaw (n 29) 550.

<sup>207</sup> Case 247/87 *Star Fruit Company v Commission* [1989] ECR 291 [11].



use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health'.<sup>208</sup>

National Competent Authorities must follow specific procedures laid down in the legislation when they consider that an unsafe Medical Device must be withdrawn from the market (safeguard clause) or when a CE Marking is either unjustifiably affixed to a device, or missing (wrongly affixed CE Marking). Where a MS has ascertained that a Medical Device bearing the CE Marking (or a custom made Medical Device that meets the necessary conditions when correctly installed, maintained and used for their intended purpose) may compromise health and (or) safety, and has subsequently taken the appropriate measures and informed the Commission as mandated by Article 8 MDD, the Commission must enter into consultation with the parties concerned as soon as possible. If, after such consultation, the Commission finds that the measures taken by the MS are justified, it must immediately so inform all MS. Where the MS concerned took the measure(s) due to shortcomings in the standards themselves, the Commission shall, after consulting the parties concerned, bring the matter before the Committee on Standards and Technical Regulations and shall initiate the procedures referred to in Article 6 MDD within two months if the MS which took the measures intends to maintain them.<sup>209</sup>

Although this system seems to provide a framework to avoid the introduction and continued circulation of unsafe devices on the market, the broad discretion of MS to oversee the Notified Bodies has resulted in discrepancies in levels of control, which in turn has led to discrepancies in Notified Body control over Manufacturers (particularly in relation to the performance of conformity assessments procedures). Without EU level oversight, this has resulted in different standards of control being present within different MS, which has lead not only to market fragmentation, but to uneven levels of patient/user protection.<sup>210</sup> Additionally, it has caused significant variations in the levels of incident reporting between MS, which has magnified the

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<sup>208</sup> Annexes of MDD (e.g. Annex II Section 3.1(i)).

<sup>209</sup> Art 10 MDD.

<sup>210</sup> Commission Staff Working document, 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 *Impact Assessment on the Revision of the Regulatory Framework for Medical Devices*, Part II Annex 1, 14.



problem.<sup>211</sup> Although much discretion was left to the MS to supervise implementation under the MDD, no EU level mechanism was introduced to check whether the appropriate coordination between MS occurred.

Similarly, high levels of MS discretion were not accompanied by clear and precise legal standards for MS to follow. This problem was identified by the Commission, who stated that ‘the minimum requirements laid down in the current Medical Devices directives (...) are very vague,’<sup>212</sup> and is relevant with regards to the obligations incumbent upon MS, National Competent Authorities, Notified Bodies, and Manufacturers. The standards by which the Competent Authorities are required to designate and supervise the Notified Bodies provide a particularly good example of this.<sup>213</sup> The coordination group of MS’ Competent Authorities issued a ‘Designating Authorities’ Handbook’ in an attempt to compensate for these deficiencies, but it has no legal status and as such, adherence is at the discretion of the individual Competent Authority.<sup>214</sup> Additionally, there is no mechanism to ensure that Competent Authorities carry out supervision in accordance with any commonly agreed criteria.<sup>215</sup> The vague and imprecise terms of the MDD regarding incident reporting in the post market surveillance stage not only led to a lack of uniformity in the way MS shared information amongst themselves, but also with regards to the assessment criteria used by Manufacturers to report incidents to the Competent Authorities.<sup>216</sup>

### **2.2.3 Interim Conclusion**

Through the approximation of the laws of the MS the MDD aims to ensure the functioning of the internal market, and a high level of protection of human health and safety. The national laws of the MS harmonised by the MDD should require the Manufacturers to ensure that the Medical Devices, including breast implants, comply with the essential requirements regarding the safety of their performance in order to have access to the market. The quality systems and design

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<sup>211</sup> Arguably a result of the lack of provisions for a central system for incident reporting.

<sup>212</sup> Commission Staff Working document (n 210) Part 1, 15.

<sup>213</sup> *ibid.*

<sup>214</sup> *ibid.*

<sup>215</sup> *ibid.*

<sup>216</sup> *ibid.*



dossiers of the Manufacturers are assessed by the Notified Bodies, which are under the surveillance of *national* Competent Authorities.

However, the MDD leaves wide discretion to the MS and the manufacturers themselves for achieving these aims, and the role of the EU institutions (the Commission) is relatively minor and dependent on previous actions of the MS, as is clear from the provisions of the safeguard clause described above.<sup>217</sup> Similarly, it is arguable that the Conformity Assessment Procedures require too little from the Notified Bodies, placing far too much responsibility on the Manufacturers and too much reliance on their integrity. This Report will now assess whether any action of the EU institutions or indeed any inaction on their part, in regulating the Medical Devices field by way of the MDD can form the basis of EU liability as provided for by Article 340 TFEU.

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<sup>217</sup> Section 2.2.2.



### 3 ANALYSIS OF THE CASE

Reiterating the *Bergaderm* test,<sup>218</sup> to establish liability under Article 340 TFEU, three criteria must be satisfied: 1) the rule infringed must have intended to confer rights on individuals; 2) the nature of the breach must be sufficiently serious; and 3) there must be a direct causal link between breach of the obligation and the damage sustained. Following this structure, this Report will now analyse whether EU liability can be established with regards to the damage suffered by the women who received PIP breast implants.

#### 3.1 CONFERRAL OF INDIVIDUAL RIGHTS

According to the *Kampffmeyer* rule, for the purposes of Article 340 TFEU it is sufficient that the rule infringed has also been adopted in the interest of individuals, even though it pursues other aims.<sup>219</sup> This position is reinforced by the conclusions drawn from case law for state liability with regards to environmental directives; since in addition to the protection of the environment their preambles envisage the protection of human health, it is possible that they do grant enforceable rights to individuals. Additionally, the EU Courts have adopted a case-by-case approach based on the objectives to be achieved by the rule in question. As such, it can be argued that, since the underlying objective of the MDD is the general protection of the health of the users of Medical Devices,<sup>220</sup> the MDD was adopted in the interest of individuals, despite being primarily aimed at approximation of the laws of the MS. This is even more the case if the right to health is read in conjunction with the right to life, which may create a positive obligation on EU institutions to warn and provide information to the individuals regarding risks to their health.

Although in *Peter Paul*<sup>221</sup> the Court demanded that the relevant directives contain an *express grant* of rights to individuals, it observed that the preamble of the directive in question *clearly precluded liability of the relevant authorities to depositors*.<sup>222</sup> This fact appears to be an element that distinguishes this case from the Client's case, since no similar provisions can be found in the

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<sup>218</sup> *Bergaderm* (n 30).

<sup>219</sup> *Kampffmeyer* (n 39); See also *Türk* (n 20) 261.

<sup>220</sup> As clearly stipulated in the MDD preamble.

<sup>221</sup> See n 54.

<sup>222</sup> *Peter Paul* (n 54) [31].



MDD. Nevertheless, it is debatable whether the above-mentioned distinguishing factor is enough to preclude the CJEU from applying the *Peter Paul* principle to the Client's case. *Inter alia*, in *Peter Paul* the Court recognized the inherent complexity of banking supervision and the need to protect a plurality of interests, including the overall stability of the financial system.<sup>223</sup> A series of factors in our case appear comparable to *Peter Paul*; the absence of an express grant of rights to individuals in the MDD, the need to protect a particularly large group of individuals including virtually all users of the breast implants at question in the EU, and the complexity of the field subject to the applicable legislation (the Medical Devices market). On this basis, it is possible but unlikely that the MDD would be found to confer individual rights on the women in our case. In other words, it is unlikely that the Court would expose the EU to individual claims such as the above where the number of individual claimants could potentially be quite significant.

### 3.1.1 Direct Effect of the MDD provisions

As already discussed,<sup>224</sup> three prerequisites must be met for a directive provision to enjoy vertical direct effect; if an MDD provision is sufficiently clear, precise and unconditional, these women can derive enforceable rights. Article 3 of the MDD provides the most viable basis for deriving direct effect, as it can be argued that it establishes responsibility of the EU vis-a-vis the users/patients as their beneficiaries, thus possibly satisfying the first two criteria of direct effect.<sup>225</sup> However, it is doubtful whether they can qualify as unconditional; the conditions for application set out in the Article seem too broad to enable them to qualify as complete provisions on which these women could rely upon. Most importantly however, Article 2 assigns responsibility to the MS for the *placing into the market* of the devices, and to their subsequent failure to conform to the requirements, which is the case here. Hence, it is difficult to identify

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<sup>223</sup> *ibid*, [44].

<sup>224</sup> See section 1.1.1.

<sup>225</sup> According to art 3, devices must meet the relevant essential requirements as set out by the EU institutions in Annex I, taking account of the Intended Purpose of the devices concerned. The basic requirement contained in Annex I (art 1.1) requires that '[t]he devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will *not compromise the clinical condition or the safety of patients, or the safety and health of users* or, where applicable, other persons, *provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.*'





provisions in the MDD that could confer individual rights from the EU level to the women in our case.

### **3.1.2 A Provision Designed to Protect Individuals: Breach of General Principles**

Of the principles discussed above, legitimate expectations offer a possible basis for a claim for damages. Although its use has so far been restricted to purely economic contexts, there is nothing to suggest a bar to a claim founded on breach of legitimate expectations in the context of health protection. In *Emesa Sugar*, discussed above,<sup>226</sup> the CFI noted that traders cannot have a legitimate expectation that an existing situation which is capable of being altered by the EU institutions in the exercise of their discretion will be maintained.<sup>227</sup>

However, in the present case it could be argued that when it comes to the users of the implants, they have reason to rely on the fact that when the EU undertook to regulate this area of the internal market, the respective legislation would take sufficiently into account their interests by ensuring a high level of health protection for them and their right to life. This is even more so, when considering that the protection of the health of users and patients is one of the ‘essential objectives’ of the MDD. Indeed, the rationale behind the ruling in *Emesa Sugar* is that traders are bound to accept harmful effects arising from their participation in sectors falling within the economic policy of the EU,<sup>228</sup> and therefore action for damages against the EU institutions will be precluded when loss has been caused by this participation. Nevertheless, this case can be distinguished from the Client’s case since it would be rather unreasonable to demand that implant users accept a lower level of protection when it comes to their health and life. Indeed, with the obligation to protect health of central importance within EU policy – an obligation contained in primary law – it seems reasonable that EU citizens could expect the EU to ensure that the market that it facilitates is compatible with maintaining a high level of public health protection.

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<sup>226</sup> See section 1.1.2.

<sup>227</sup> *Emesa Sugar* (n 61) [87].

<sup>228</sup> Case T-483/93 *Antillean Rice Mills v Commission* [1995] ECR II-2305 [299], affirmed in Case C-390/95 *P Antillean Rice Mills NV v Commission* [1999] ECR I-769.



### 3.1.2.1 The Right to Health as a General Principle of EU Law

The above conclusion becomes significant when Article 35 of the Charter comes into play. First, it has been argued above that Article 35 of the Charter, coupled with Article 168 TFEU and Article 2 of the Charter on the right to life, could constitute a General Principle granting a specific right to these women with respect to their health protection.<sup>229</sup> On this basis, it can be argued that the MDD regulatory framework created a legitimate expectation that the health and safety of the users of Medical Devices was guaranteed. Such an approach could be adopted by the CJEU in assessing damages liability of the EU institutions for alleged breaches in the context of the present case.<sup>230</sup>

## 3.2 SUFFICIENTLY SERIOUS BREACH

The competences of the EU institutions to regulate the internal market are highly discretionary. As discussed above, when employing the *Bergaderm*<sup>231</sup> test to determine EU liability, discretion is measured on a sliding scale; the more discretion an institution has, the less likely an act will be found to constitute a sufficiently serious breach.<sup>232</sup> As such, in order to determine whether there has been a sufficiently serious breach of the type required to establish EU liability, this part of the Report will focus on the obligations of the institutions with regards to the protection of public health. Previous analysis<sup>233</sup> has shown that, even in the context of legislative measures taken to regulate the internal market, the EU has an obligation to ensure ‘[a] high level of human health protection (...) in the definition and implementation of all EU policies and activities.’<sup>234</sup> The Charter and Article 168 and 9 TFEU are primary law, and for establishing a breach of law, it must be demonstrated that the EU institutions acted contrary to these provisions. As discussed above,<sup>235</sup> the failure to protect public health contained in Article 168 TFEU - coupled with the obligation now also contained in Article 35 and Article 2 of the Charter - arguably constitutes such a serious breach. As such, if a sufficiently serious breach of the EU obligation to protect

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<sup>229</sup> A Ward, ‘Damages under the EU Charter of Fundamental Rights’, ERA Forum (2012) 12:589–611.

<sup>230</sup> Ward (n 35) 21.

<sup>231</sup> *Bergaderm* (n 30).

<sup>232</sup> *Bergaderm* (n 30) [43]; See also section 1.2.

<sup>233</sup> See section 2.2.

<sup>234</sup> Art 168 TFEU.

<sup>235</sup> See section 3.1.2.



health can be established, this limb of the *Bergaderm*<sup>236</sup> test may be satisfied. This is also true with regards to establishing a breach of the general principle of legitimate expectations based on a breach of the obligations contained within Article 35 of the Charter.<sup>237</sup> Thus this Report will now analyse whether such a breach has occurred.

Following *Bergaderm*, whether a breach of a sufficiently serious nature has occurred depends on whether the institutions involved ‘manifestly and gravely disregarded the limits of its discretion.’<sup>238</sup> Thus the discretion afforded to the institutions to regulate the Medical Devices market and related public health concerns must be analysed. Under Article 4 TFEU, regulation of the internal market and common safety concerns in public health are areas of shared competence, as is the protection and improvement of human health.<sup>239</sup> Consequently, either the EU or the MS may legislate and adopt legally binding acts in the area.<sup>240</sup> The EU has specified competences in relation to the above mentioned fields.<sup>241</sup> Once the EU has decided to exercise its competence, the scope of this competence will be determined by detailed rules that govern the particular area.<sup>242</sup> In the area of public health, once the scope of EU competences are determined by reference to the rules governing the area, the EU has some discretion to determine the measures necessary for the protection of public health.<sup>243</sup> Regarding the present case, the fact that the EU had no direct supervisory role, instead sharing competence with the Member States, whilst also having discretion as to how public health was to be ensured,<sup>244</sup> makes it unlikely that a serious breach by the EU institutions could be established.

Nevertheless, the problems with the MDD, many of which were identified above in section 2.2, show failures on the part of the institutions to pay due regard to their obligations to ensure a high level of protection of public health within the EU that arguably go past mere error or illegality.<sup>245</sup>

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<sup>236</sup> *Bergaderm* (n 30).

<sup>237</sup> See section 1.1.2.1.

<sup>238</sup> *Bergaderm* (n 30) [43].

<sup>239</sup> Whereas art 6 TFEU envisages a supportive role for the EU on this matter, the caveat contained in art 168(4) modifies this competence to ‘shared’ in respect of the regulation of medical devices.

<sup>240</sup> Art 2 TFEU.

<sup>241</sup> Craig and de Burca (n 56), 84.

<sup>242</sup> *ibid* 85.

<sup>243</sup> See generally *Artegoda* (n 67); C-221/10 P *Artegoda and Others v Commission* [2012] ECR 0000.

<sup>244</sup> Subject to arts 9, 168 TFEU and art 35 Charter, which require that health protection be in some way ensured.

<sup>245</sup> As identified in *MyTravel* (n 65).



The furore surrounding the PIP controversy generated a wealth of criticism directed at the MDD, the inadequacy of which was recognised by the EU Parliament in its Resolution of 14 June 2012, where it noted that the controversy has ‘brought to light a malfunction at the European and national levels,’ and called for the Commission ‘to develop an adequate legal framework to guarantee the safety of breast implants and medical technology in general.’<sup>246</sup>

Although the factors already discussed make establishing sufficiently serious breach difficult,<sup>247</sup> they do not necessarily make it impossible,<sup>248</sup> and the fact that the EU in its supervisory structure did not provide the protection of health that is promised to Europeans by the primary treaties and in Article 2 and 25 of the Charter may be deemed serious and grave enough to attach liability to the EU.<sup>249</sup> As such, the following analysis attempts to distinguish, by reference to the failures inherent in the MDD, sufficiently serious breaches of the institutions’ obligation to legislate in accordance with the obligation to protect health, taking account of the factors set out in *Brasserie du Pêcheur*,<sup>250</sup> which may guide the court in such a determination.

As discussed above, the MDD left discretion to the MS on a number of key aspects of the supervision of the MDD.<sup>251</sup> The Council and the European Parliament are, however, also obliged to ensure the protection of public health when legislating; and it is arguable that, considering the health implications of the aspects of the MDD over which MS retained broad discretion, the institutions overlooked their obligation to ensure a *high* protection of public health when enacting the MDD. In an area concerned with both internal market harmonisation and the protection of public health – both issues on the European agenda – that the Commission has acknowledged as being characterised by fast technological development, the fact that the MDD afforded such broad discretion to MS whilst providing little opportunity for EU level oversight was misguided.

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<sup>246</sup> European Parliament, *Resolution of 14 June 2012 on defective silicone gel breast implants made by French company PIP* (2012/2621(RSP)).

<sup>247</sup> See *Area Cova and others* (n 27); Case T-155/99 *Diekmann and Hansen v Commission* [2001] ECR II-3143 [82].

<sup>248</sup> See Case T-285/03 *Agraz and others v Commission* [2005] ECR II-1063.

<sup>249</sup> *Craig and de Burca* (n 56) 564.

<sup>250</sup> *Craig and de Burca* (n 56) 564.

<sup>251</sup> For example, competence on matters such as the designation of Notified Bodies, the supervision of clinical investigations, the investigation of vigilance cases, and the supervision of devices on the market.



The institutions failed to sufficiently consider the health implications of the power allocations set by the MDD. This is particularly apparent considering the lack of clarity and precision with which the MDD defined the obligations contained therein. The fact that the MDD requires no input from medical professionals, which could have enabled the EU to keep up with technological advancements in the medical devices market, emphasises this error of judgement.<sup>252</sup> No mechanisms were implemented to monitor whether the MDD enabled an appropriate level of harmonisation to secure sufficient levels of patient safety. As such, it can be argued that the institutions have breached their obligation to ensure a *high* level of public health protection within the EU when enacting the MDD. However, it must be noted that, precisely due to the level of discretion left to MS on these issues, and considering the second *Brasserie du Pêcheur* criterion, the EU Courts may not hold the EU responsible under Article 340 TFEU.

Problems with respect to discretion also exist regarding the Conformity Assessment Procedures laid out under the MDD, and the insufficiency of these legal standards to accommodate the realities of Medical Devices regulation. For example, as discussed above, the Conformity Assessment Procedures arguably require too little from MS and Notified Bodies and place far too much responsibility on the Manufacturers and their integrity. Neither the conformity assessment for Class IIb devices (as breast implants were previously categorised) or either of the conformity assessment routes mandated for Class III Devices *require* the Notified Bodies to conduct independent testing (ie not reliant upon information or product samples provided for the purposes of testing by the Manufacturer) of the products it is certifying. Although, following the Annex III procedure coupled with either Annex IV or V, the Notified Bodies are given the opportunity to conduct such testing; they are under no obligation to do so. Therefore, it is left to the discretion of the Notified Bodies whether or not to conduct such tests. If they decide against doing so, the Conformity Assessment procedures, on the basis of which certification is issued, rely wholly on the honesty and integrity of the Manufacturer to provide true and honest product samples and documentation. As such, the framework set up by the MDD to regulate the Medical Device market within the EU was insufficient to deal with cases like that of PIP, where dishonesty,

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<sup>252</sup> Commission Staff Working Document (n 210) Part II Annex 1.



misrepresentation and fraud were involved.<sup>253</sup> This proposition is lent support by the revision of the regulatory framework for Medical Devices currently being undertaken by the Commission,<sup>254</sup> and discussions and resolutions of the European Parliament that led to proposals for such a revision.<sup>255</sup>

What is of particular relevance for the purposes of this Report in relation to the problems with the Conformity Assessment procedures is that, despite the discretion left to MS, Competent Authorities, and Notified Bodies as to how to conduct themselves in line with the MDD, the standards by which they were to do so were set at EU level by the institutions, which differentiates this issue from the others discussed in this part. As such, the relevant question in determining whether failures to provide a sufficient framework in this area constitute a breach of the obligation to ensure a high level of protection of public health is whether the institutions could have, or should have foreseen the shortfalls of the Conformity Assessment procedures. Although this question is difficult to answer in relation to the initial drawing up of the MDD, it is arguable that subsequent problems with Medical Devices<sup>256</sup> should have highlighted the deficiencies of the procedures and the EU should have remedied the problems in line with their obligation to ensure a high level of health protection. For example, between 1999 and 2005 the US Food and Drug Administration (FDA) conducted a number of inspections of PIP, noting ‘major deficiencies’ regarding the quality system and manufacturing of the PIP saline-filled

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<sup>253</sup> See Lister (n 12)

<sup>254</sup> See generally the Commission Staff Working Document (n 210).

<sup>255</sup> European Parliament: News ‘PIP scandal: "stricter rules" needed on breast implants’, <<http://www.europarl.europa.eu/news/en/headlines/content/20120120STO35900/html/PIP-scandal-stricter-rules-needed-on-breast-implants>> accessed on 23 April 2013; European Parliament resolution on the petitions declared admissible concerning silicone implants (Petitions Nos 470/1998 and 771/1998) (2001/2068(INI)), available at <<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P5-TA-2001-0331+0+DOC+XML+V0//EN;>> accessed on 23 April 2013; European Parliament resolution of 14 June 2012 on defective silicone gel breast implants made by French company PIP (2012/2621(RSP)), available at <<http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2012-262;>> accessed on 23 April 2013.

<sup>256</sup> For example, subsequent to UK’s Medical Device Alert 2000(07) of December 2000 regarding PIP hydrogel breast implants <<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/MedicalDeviceAlerts/Devicealerts/CO-N008915>> accessed on 23 April 2013, when possible problems with PIP implants first became apparent, or considering the on-going problems with hip replacement devices: see *Medical Devices: On-going problems with metal-on-metal hip devices*, BMJ (2012) 344 e1349.



breast implants, and subsequently banned them from the US market.<sup>257</sup> The FDA alerted EU MS to the problems, even making available a ‘warning’ letter in which they state that PIP implants were ‘adulterated.’<sup>258</sup> It could be argued that, based on this information and considering the close relationship between Manufacturers quality systems and Conformity Assessment procedures under the MDD, the failures of the EU to act on this publicly available information and remedy the problems inherent in this part of the MDD constituted a breach of their obligation to ensure a *high* level of health protection and the right to health of the woman that received these implants. Additionally, it is arguable that this failure constitutes a breach of the principle of due diligence. The FDA, in comparable circumstances to those at the time of the PIP controversy in Europe, addressed the irregularity in a normally prudent and diligent manner, which, even after being alerted to the problems, the EU failed to do.

These shortcomings all contributed to the failure of the MDD to provide adequate safeguards to protect against the health risks involved in any actual or potential failure in the system. As noted by the European Parliament, ‘*the desire to provide swift access to new Medical Devices for patients must never take precedence over the need to ensure patient safety.*’<sup>259</sup> However, in attempting to harmonise the market by removing obstacles to trade and failing to provide a sufficient alternative framework to account for the health risk factors, the institutions allowed that situation to occur, and in doing so, it is arguable that they failed in their obligation to ensure a high level of protection of human health.

As the previous assessment of the EU institutions’ obligation to ensure a high level of protection of public health demonstrated, it is possible to defend the right to the protection of public health in relation to the right to life as an individual right. Therefore, it can be argued that enacting the MDD without due regard to this obligation—as evidenced from the discussion above—constituted a sufficiently serious breach of a General Principle of EU law, as required by the *Bergaderm* test to establish EU liability. Following from this, it is also arguable that the

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<sup>257</sup> Commission Staff Working document (n 210) Appendix 11, 14.

<sup>258</sup> Department of Health & Human Services, Warning Letter (22 June 2000) <<http://www.fda.gov/downloads/ICECI/EnforcementActions/WarningLetters/2000/UCM068539.pdf>> accessed on 23 April 2013; Kim Willsher, ‘French implants firm was criticised by US inspectors in 2000’ <<http://www.guardian.co.uk/world/2011/dec/27/french-implants-us-inspectors-2000>> accessed on 11 January 2013.

<sup>259</sup> European Parliament: News ‘PIP scandal: “stricter rules” needed on breast implants’ (n 255).



institutions breached the general principle of legitimate expectations by failing to take due regard of the obligation to protect health contained in the Charter.<sup>260</sup>

As a final note however, it must be stressed that the weight put on the *Brasserie*<sup>261</sup> criteria in assessing the serious nature of these apparent breaches will be determinative, and considering the uncertain nature of the right to a high level of health protection, and the discretion left to both national and EU authorities, it is by no means clear that the conduct of the institutions will be adjudged *sufficiently* serious for the purposes of establishing EU liability.

It is possible that circumstances may arise where damage flows from a lawful EU act, or an act that is merely ‘tainted’ with illegality.<sup>262</sup> In the event that a sufficiently serious breach of a rule of EU law cannot be established, it may be possible to challenge a valid legislative act in a claim for compensation. However, it must be noted from the outset that, although challenges have been mounted on this basis, none have so far succeeded. This is due, in particular, to the difficulties in establishing causation in the context of such actions.<sup>263</sup> Nevertheless, *Dumortier*<sup>264</sup> and *Tillack*<sup>265</sup> are illustrative in that although the actions were unsuccessful, the possibility of liability in such circumstances was recognised.

### 3.3 EXISTENCE OF DAMAGE

The women involved in this case have sustained damage in the form of personal injury<sup>266</sup> as a result of their decision to receive PIP breast implants. They have also sustained damage in the form of pure economic loss as a result of medical expenses incurred in relation to personal injury, loss of income suffered in relation to personal injury, and non-material damage due to physical and mental suffering. Evidence of this economic loss can be adduced from medical bills and salary statements, as well as witness statements from doctors and psychologists.

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<sup>260</sup> Art 35 Charter; art 168 TFEU.

<sup>261</sup> *Brasserie du Pêcheur* (n 32) [56].

<sup>262</sup> *Craig and de Burca* (n 56) 596.

<sup>263</sup> *ibid* 571-573.

<sup>264</sup> *Dumortier* (n 123).

<sup>265</sup> Case T-193/04 *Tillack v Commission* [2006] ECR II-3996.

<sup>266</sup> E.g., loss of function, capsular contraction, and other health problems caused by leaking and rupture.





As to the criteria for establishing loss or damage, this damage appears to fulfil the criteria of certainty,<sup>267</sup> having already been sustained. The women have suffered serious damage, as they are suffering both physically and mentally, which in turn has led to high medical expenses and losses in income.<sup>268</sup> The damage suffered also appears to fulfil the criteria of specificity,<sup>269</sup> as it affects the women's interests in a special and individual way. By receiving substandard breast implants these women were unknowingly in a higher risk group. Despite the fact that a group of women has suffered from injuries due to having PIP breast implants, each woman has suffered in an individual way. As mentioned above, evidence of loss can be adduced in support of the damages claimed by the women affected. Thus the damage sustained is also quantifiable.<sup>270</sup>

As to the recoverable nature of the damage, pure economic loss was recognised as recoverable damage with respect to the non-contractual liability of the EU in *Grifoni*<sup>271</sup> and *Adams*.<sup>272</sup> In *Adams*, the CJEU also recognised the recoverability of non-material damage.<sup>273</sup> Therefore, the damage suffered by the women is in principle of recoverable nature.

However, in the end, the EU Courts have jurisdiction to assess the just quantum of compensation, which should ideally correspond to the damage which is caused.<sup>274</sup> Interest can be awarded on damages payable by the EU following the rules common to the MS, under which interest is generally awarded from the date of the judgment.<sup>275</sup>

### 3.4 EXISTENCE OF A CAUSAL LINK

In order to fulfil this final criterion, a sufficiently direct and exclusive causal link must be established between the alleged breach of an EU rule and the damage sustained by the women.<sup>276</sup> Therefore, a sufficiently direct causal link must be established between the breach of the EU

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<sup>267</sup> *Kampffmeyer* (n 39); *Milchkontor* (n 99) [8]; *Hameico Stuttgart and others* (n 99) [63]; *Camar and Tico* (n 99) [207].

<sup>268</sup> See *Mulder* (n 60) [12]-[17], for threshold of severity necessary to constitute 'serious damage'.

<sup>269</sup> See *Roquette Frères* (n 101) [677], [694].

<sup>270</sup> *Cofradia* (n 48) [110]. Cf also art 38(1)(c) Rules of Procedure of the CJEU (n 102).

<sup>271</sup> See *Grifoni* (n 121).

<sup>272</sup> See *Adams* (n 122).

<sup>273</sup> *ibid.*

<sup>274</sup> *Toth* (n 109) [18]; *Mulder* (n 60) [34].

<sup>275</sup> Case C-152/88 *Softimport v Commission* [1992] 1990 I-2477 [32].

<sup>276</sup> *Coldiretti and 110 Farmers* (n 124) [101]; *Fresh Marine Company* (n 64) [118]; *Jürgen Gutknecht* (n 124) [30].



obligation to take into account a *high* level of protection of human health and the subsequent loss the women sustained as a result of receiving substandard PIP breast implants that slipped through this inadequate regulatory framework.<sup>277</sup>

When it comes to human health, the existence of a causal link between conduct and damage must be established from an analysis of the conduct that could be required of the institutions on the basis of the state of scientific knowledge at the time.<sup>278</sup> Indeed, the precautionary principle requires the EU institutions to take appropriate measures to prevent specific potential risks to public health.<sup>279</sup> As discussed above, it might be true that at the time of first adopting the MDD the risk assessments were in compliance with the available scientific data. However, the MDD remained unrevised for many years, even though technical developments would have rendered revision inevitable sooner. The information provided by the FDA to the MS<sup>280</sup> that arguably contributed to the state of scientific knowledge at the time should have triggered the adoption of a precautionary approach. That such an approach was apparently not adopted cannot be mitigated by the assertion that abnormally high rupture rates of PIP breast implants were not officially known to the EU until 2010 and not scientifically confirmed until 2012, as the idea of the precautionary approach is to mitigate *potential* risk prior to scientific confirmation.<sup>281</sup> As such, the EU thus should have adopted the approach once the above-mentioned factors alerted them to the potential risk of health problems, regardless of the lack of official confirmation.

In order to prove that damage is direct and exclusive the EU Courts employ a type of ‘but for’ test.<sup>282</sup> In case of omission, as can be argued here, a higher threshold must be met. It is necessary to establish that even if the EU institutions had adopted an adequate regulatory framework for the Medical Devices by fulfilling their obligation to take into account a *high* level of protection of health, the damage would not have been sustained.<sup>283</sup>

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<sup>277</sup> A causal link between the fraudulent PIP breast implants and the damage sustained by the women is required. However, this would require a medical expertise performed by a professional.

<sup>278</sup> *É.R. and Others* (n 25) [133].

<sup>279</sup> *Artegodan* (n 67) [184]-[185].

<sup>280</sup> See section 3.2.

<sup>281</sup> *Artegodan* (n 67); and see *Sadeleer* (n 68); *Corkin* (n 68).

<sup>282</sup> *Perillo* (n 126) [43]; *Case 33/82 Murri Frères* (n 126) [30], in *J Wakefield* (n 91) 217.

<sup>283</sup> *J Wakefield* (n 91) 217; *Perillo* (n 126) [43].



However, in the same vein, as reasoned in *É.R. and Others*,<sup>284</sup> it is not possible to conclude with adequate certainty that even if the EU institutions had adopted sufficient legislation in the area of Medical Devices, the fraudulent PIP breast implants would not have slipped through the regulatory net or that the women would not have suffered personal injuries. The ‘ideal’ level of protection of users from injuries resulting from ruptures of breast implants would require a total absence of breast implants with the risk of rupture. However, the rupture risks of breast implants cannot be eliminated unless all breast implants are banned from the market.

Moreover, in the present case the regulatory measures adopted by the institutions depended particularly for their effectiveness on action by the MS, who have not always been rigorous enough in ensuring that the rules concerning Medical Devices were strictly applied.

As noted by AG Toth, the fact that an EU act or omission is one of several circumstances contributing to the damage may not in itself be sufficient to establish a causal connection entailing non-contractual liability.<sup>285</sup> The causality must be ‘direct, immediate and exclusive’ which is the case only if the damage arises directly from the conduct of the institutions and does not depend on the intervention of other causes, whether positive or negative.<sup>286</sup>

The responsibility for the actual monitoring of the application of Medical Devices legislation lies principally with the MS. The CJEU has held that where loss arises from an independent or autonomous act by the MS, the EU is no longer liable.<sup>287</sup> The omissions on the part of the MS when implementing the MDD thus break the chain of causation between the actions or omissions of the EU institutions and the damage sustained by the women. Crucially for the present case, it is likely that the Kingdom of the Netherlands is in breach of its obligations under the MDD, particularly in relation to Article 10 MDD, thus breaking the chain of causation as described.<sup>288</sup>

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<sup>284</sup> *É.R. and Others* (n 25) [134].

<sup>285</sup> Toth (n 109) 192.

<sup>286</sup> *ibid.*

<sup>287</sup> *Société pour l’Exportation des Sucres SA* (n 136) 1072-1073.

<sup>288</sup> This is an alternative route being explored by the client falling out of the scope of the present Report. Although still to be litigated, so as yet uncertain, the Client informs us that it is likely that the Netherlands will be found in breach of its obligations under the MDD.



Consequently, due to the lack of causal nexus between the alleged omissions on the part of the EU institutions and the damage sustained by the women, it is unlikely that the EU could be held liable under Article 340 TFEU.



## CONCLUSION

The aim of this Report was to assess whether the EU institutions could be held liable under Article 340 TFEU for the damage sustained by the women represented by the Client, who received PIP breast implants. In order to establish non-contractual liability of the EU institutions it is necessary to prove that a rule intended to confer rights on individuals was breached, in a sufficiently serious manner, and that this breach caused damage to the individuals concerned.

This Report has reasoned that despite difficulties in establishing a rule intended to confer rights in this case, general principles of EU law, and in particular the protection of health in combination with a right to life, legitimate expectations, and due diligence, could be read as conferring such rights to the ten women represented by the Client. Moreover, it is arguable that it is possible to establish a breach of these rights in respect of omissions on the part of the EU institutions in relation to the MDD. However, it is questionable whether these breaches would be regarded by the EU Courts as sufficiently serious, considering the relative discretion of the EU and Member States on public health matters.

Damages are in principle available for personal injury, economic loss, and non-material damage. However, it is difficult to establish a causal link in the present case. It is unclear whether more thorough and sufficient regulation of the market could have averted the introduction of the fraudulently produced PIP implants onto the market, thereby avoiding damage sustained by the women represented by the Client. Additionally, since it is arguable that MS conduct contributed to the series of events that allowed the PIP implants entry to the market, it is unlikely that EU Courts would establish the causal link between Union inaction and the damage sustained that is required to hold the EU institutions liable. As a result, the authors of this Report consider that it would be difficult to hold the EU institutions liable for the damage suffered by these women who received PIP breast implants.



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