Legal Implications of Defective Hip Implants

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Introduction

Over the past years the media have reported repeatedly on defective prostheses such as DePuy replacement hips and silicone implants made by PIP. These implants may have the necessary legal implications for patients as well as doctors and hospitals implanting those prostheses. Dr. Thomas Joyce, prominent expert in biomedical engineering even went so far as to call the DePuy hip affair: ‘the biggest disaster in the history of orthopaedics’.

This article will set out the facts at issue in the DePuy replacement hips affair, and then discuss DePuy's product liability as well as the liability of orthopaedic surgeons, considering aspects of private international law as well as the court having jurisdiction.

Facts

Between 2003 and 2010 UK-based DePuy International Ltd. manufactured and sold 93,000 hip replacements under the brand name DePuy ASR and DePuy ASR XL. The metal-on-metal design makes these hip replacements more flexible than the earlier versions of hip implants. 8,000 patients in England were fitted with DePuy hips, 35,000 in the United States and 5,500 in Germany. We do not know how many prostheses were supplied to the Netherlands, but probably several thousands.

Research shows that the metal-on-metal design of these hip replacements might cause metal poisoning, and that there was an uncommonly high premature failure rate. When it became clear that there was an increased need for premature reoperation DePuy took action in March 2010, sending out a written notice to orthopaedic surgeons warning them of a higher risk of prosthesis failure. While pointing out the technical defects and the manner of implantation DePuy did not mention the risk of metal poisoning other than cautioning against implantation in young women because of the possible harmful effects of increased metal concentrations during pregnancy on the foetus.

On 22 April 2010 the MHRA (UK Medicines and Healthcare products Regulatory Agency) issued a device alert that a small group of patients may develop progressive soft tissue reactions to the metal debris, without showing any symptoms. A second device alert followed on 25 May 2010. Both DePuy ASR and

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3 DePuy claims studies showed that five years after implantation about 12% of the patients fitted with the ASR Hip system and 13% of the patients fitted with total ASR hip replacements required revision surgery. See also http://www.depuy.com/netpatient. (A recent study, however, revealed this percentage to be much higher, i.e. 49%) within six years.)
DePuy ASR XI were recalled by the end of August 2010, by means of a voluntary recall. DePuy advised orthopaedic surgeons to stop implanting DePuy ASR and ASR XI and to inform patients who had already been fitted with the hip replacement about the recall and invite them to a follow-up consultation. DePuy also advised on treatment.

In the United States several class action lawsuits have been filed against DePuy. Closer to home, in England, several renowned law firms are also preparing a class action.

**Product Liability of DePuy**

Under Article 6:185 of the Dutch Civil Code the manufacturer is liable for damage caused by a defect in the product marketed by this manufacturer. This is a risk liability that arises as soon as the product displays a defect.

Article 6:186 Dutch Civil Code implements Council Directive 85/374/EEC of 25 July 1985. This Article defines the term ‘defect’ as follows. A product is defective if it does not provide the safety that may be expected considering all circumstances and in particular the presentation of the product, the reasonably expected use and the time when the product was put into circulation. Also relevant is the manufacturer’s awareness of possible side effects of a product, the existence of harmless alternatives and the extent to which the manufacturer informs the consumer. The words ‘all circumstances’ do not refer to the actual use by an individual consumer. Therefore, injured parties seeking a declaratory decision in a class action to the effect that DePuy is liable towards them need not expand on their individual circumstances concerning the implantation of a DePuy hip replacement.

Given the facts it could be argued – also in court – that the prosthesis was defective as defined in Article 6:185 et seq. Dutch Civil Code so that in principle DePuy could be held liable for the damage. DePuy, after all, placed the hip replacements on the market, although this product did not provide the safety that may be expected. DePuy at least took responsibility in the sense that it offered to pay for further treatment and reoperations. However, DePuy is also known for dismissing liability on the ground that orthopaedic surgeons did not implant the prostheses properly. That defence could be countered by reliance on Article 6:185 Dutch Civil Code or Article 8.1 of the Directive respectively, which stipulates that the producer’s liability is not reduced when the damage is caused both by a defect in product and by the act or omission of a third party.

**Limitation Period**

Under Article 6:191 Dutch Civil Code any patient claims against DePuy based on product liability will be extinguished upon expiry of three years from the date following the day on which the injured party became aware or should have become aware of the damage, the defect, and the identity of the producer. The

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5 DES ruling, Supreme Court, 9 October 1992, NJ 1994,535
7 Halcion ruling, Supreme Court 30 June 1989, NJ 1990, 652
8 Vioxx ruling, Court of Appeal, 11 January 2011, NBP 2011/11
10 Asser/Hartkamp 2006 (III), no. 211a
claim against DePuy will extinguish upon expiry of ten years from the date following the day on which the producer has put the product into circulation.

More specifically, this means that this claim would extinguish in 2013 at the earliest. Please note that any patient claims would not be exhausted, as patients could still demand compensation for damage arising from an unlawful act under Article 6:162 Dutch Civil Code or breach of contract under Article 6:74 Dutch Civil Code.11

The five-year limitation period stipulated by Article 3:310.1 Dutch Civil Code for any recourse action under Dutch law by hospitals does not commence until the day following the date on which compensation has become payable, also if it was known before that damage would be sustained and who the liable party is.12

Liability Hospitals

Besides the general articles regarding unlawful act and breach of contract doctor’s liability can be based on the following:

- Article 6:77 Dutch Civil Code: defective device.13 Under this Article doctors are liable if in the execution of the agreement an unsuitable product is used. No liability applies if by common opinion it would be unreasonable to hold the doctor liable. Parliamentary history explicitly includes liability of the producer. It is up to the doctor to prove such unreasonableness. However, for now the doctrine assumes that there is insufficient ground to assume that liability of healthcare professionals for devices is unreasonable as a rule if they were not aware of a defect. Healthcare professionals are, after all, not in a position different from that of other contractors. The doctrine also postulates that the viewpoint taken at the time by the legislator, i.e. that hospitals as a rule are not liable for defective devices, should be regarded as outmoded. While the Court of Breda has adopted this viewpoint,15 the Court of Den Bosch disagrees but for now the hospital’s liability appears to be ‘extended significantly’.17 This does not imply, however, that the hospital is automatically liable. This depends in part on the defence raised and the circumstances of the specific case.

- Article 7:448 Dutch Civil Code: informed consent. In assessing the possible liability of hospitals for damage sustained by patients two periods can be distinguished. First, the period between 2003 and March 2010 when doctors could not reasonably have known the possibly harmful effects of the DePuy hip. Second, the period after that. Doctors should inform their patients about the normal, foreseeable risks of treatment.18 Doctors, of course, cannot inform their patients about risks of which they are not or could not have been aware. In March 2010 DePuy sent out a first warning about the increased risk of the prostheses’ malfunctioning. Prostheses implanted before that date are subject to doctors’ usual duty of information. To prostheses fitted after that date a more stringent duty of information

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11 Article 6:193 Dutch Civil Code. This arises from the supplementary character of part 3.
12 Supreme Court 5 April 2012, Lijn BU3784 and Supreme Court 10 October 2003, Lijn AF9416, NJ 2003/680
13 Also see: Broekema-Engelen, "Verbintenissenrecht" Article 77 Dutch Civil Code
14 Parliamentary History Book 6, p. 270-272 and Explanatory Memorandum 21561 no. 3 to Article 7:462 Dutch Civil Code
15 Court of Breda 3 January 2011, Lijn BO9631 with reference to Asser 7-IV, no. 456
16 Court of Den Bosch 21 July 2012, L&S 2011, 125
17 See De Ridder, TvGR 2011, page 682 and the literature mentioned there
18 Supreme Court 23 November 2002, NJ 2002, 386 and 387
appears to apply, on the assumption that reasonably competent orthopaedic surgeons, acting reasonably, at that time should have been aware of the increased risks. However, neither DePuy nor the MHRA issued explicit warnings about the risks of metal poisoning. They merely pointed out that there might be metal debris in the weak tissue, in connection with possible risks in case of reoperation. In our opinion the more stringent duty of information then merely relates to the risks of the prosthesis' premature failure and not to the risk of metal poisoning. Of course this is different if the orthopaedic surgeon could and should have learned about the risk of metal poisoning otherwise, for instance from professional literature.

If the claim is allowed the hospital in turn can seek recourse against the manufacturer, DePuy. DePuy is expected to raise a defence where possible.\(^{19}\)

**Court Having Jurisdiction**

As mentioned earlier the hip implants were made by DePuy, a manufacturer based in the UK. Patients or hospitals seeking recourse or insurers wishing to initiate proceedings against DePuy should first find out which court has jurisdiction. On the assumption that there is no agreement designating a court that has jurisdiction, EC Regulation no. 44/2001\(^{21}\) gives patients a choice to either start proceedings in the country in which DePuy is domiciled\(^{22}\), i.e. England, or in the country in which the harmful event has occurred\(^{23}\).

The question is whether the harmful event occurred in the Netherlands or in England. England, as this is where the defective hip implants were manufactured, or the Netherlands, as this is where the damage was sustained? According to the European Court of Justice in its ruling in *Mines de Potasse*\(^{24}\) the 'place where the harmful event occurred' as referred to in Article 5.3 refers to both the place where the damage occurred (*Erfolgsort*) and the place of the event giving rise to the damage (*Handlungsort*). This means that Article 5.3 gives Dutch patients a choice to sue DePuy in a Dutch or in an English court.

A class action for damages is being prepared in England. As Dutch patients may litigate in England, they could join this class action.

**Applicable Law**

If proceedings are initiated in the Netherlands, the Dutch Court will apply Dutch private international law, testing the case against the Hague Products Liability Convention of 1973\(^{25}\). Pursuant to this Convention Dutch law applies\(^{26}\), as Article 5 stipulates that the applicable law will be the law of the State of the habitual residence of the person suffering damage if that State is also the place where the product was acquired.

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\(^{19}\) See section on Product Liability of DePuy.

\(^{20}\) Article 23 Brussels I entitles parties to make an agreement designating a court that will have jurisdiction.

\(^{21}\) Council Regulation (EC) No. 44/2001 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters; Brussels, 22 December 2000 (Brussels I)

\(^{22}\) Article 2 Brussels I stipulates that a defendant may be sued in the member state in which he is domiciled.

\(^{23}\) Article 5.3 Brussels I

\(^{24}\) European Court of Justice 30 November 1976, zk 21/76 NJ 1977,494


\(^{26}\) Article 5b Hague Products Liability Convention 1973
If patients were to decide to initiate proceedings in England, the English court would use English private international law to determine which law governs their claims. If the harmful event occurred after 11 January 2009 the English court would apply the Rome II Regulation\textsuperscript{27, 28}. In that case Dutch law would be applied both to the question whether DePuy is liable\textsuperscript{29} and to determine compensation\textsuperscript{30}. If the damage event giving rise to the damage occurred before 11 January 2009 the English court would apply English private international law as in effect at the time. A distinction would be made between the law governing the question whether DePuy is liable and the law governing the determination of the damage.

To assess liability the English court is likely to apply English law. It would not make a big difference whether Dutch or English law is applied as in both countries the European directive of 1985 on liability for defective products\textsuperscript{31} applies.

It does make a difference, however, to the determination of damages. Under English law loss assessment forms part of procedural law\textsuperscript{32}. Applying English procedural law the English court must determine the loss under English law as well, on the understanding that the English court would not award damages for items of loss that are not demandable under Dutch law\textsuperscript{33}. As a rule English compensation law is much more favourable for patients than Dutch law, as it awards substantially higher non-economic damages than in the Netherlands\textsuperscript{34}.

**Conclusion**

In conclusion, patients who have been fitted with a DePuy implant could hold DePuy liable for any harmful effects. Given the facts it could be argued – also in court – that the prosthesis is defective as defined in Article 6:185 et seq. Dutch Civil Code as DePuy put the hip implants into circulation although they did not provide the security that could be expected. Patients could further hold hospitals liable pursuant to Article 6:77 or 7:448 Dutch Civil Code. Should that claim be allowed, hospitals could seek recourse against DePuy. As DePuy is domiciled in England patients could litigate in the Netherlands or in England, as could hospitals seeking recourse.

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\textsuperscript{28} Under Article 31 the regulation applies to events giving rise to damage which occur after its entry into force. Rome II entered into force on 11 January 2009 (also see Homawoo v GMF Assurances, ECJ SA C-412/10)

\textsuperscript{29} Article 5.1 a Rome II

\textsuperscript{30} Article 15 Rome II

\textsuperscript{31} OJ EC 7 October 1985, no. L.210/29

\textsuperscript{32} See also Harding v. Wealands (2006) A All ER1 (House of Lords)

\textsuperscript{33} For instance, damages for surviving dependants.

\textsuperscript{34} Also see Guidelines for the assessment of general damages in personal injury cases