Liability of apparent manufacturer of a medical device

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March 09 2016 | Contributed by Preslmayr Attorneys at Law

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The Supreme Court recently clarified**(1)** the rather sparse jurisprudence in relation to the liability of apparent manufacturers according to Section 3 of the Product Liability Act, implementing the EU Product Liability Directive (85/374/EEC).

Facts

The defendant was part of a group of companies and distributed products manufactured by its sister companies. The defendant neither manufactured the products nor was it involved in the production process.

In 2006 the claimant was implanted with a hip prosthesis which consisted of four components in a clinic. The components had been supplied by the defendant to the clinic's consignment stock in separate packages. They were withdrawn from the consignment stock by the surgeon. Among these components was a ceramic femoral head produced by the defendant's French sister company. According to the instruction leaflet in the package, the French sister company was the only manufacturer. In addition, only the French sister company was listed on the packaging and accompanying stickers (for the implant passport). The ceramic femoral head showed no indication of the manufacturer. Further, only the French company was listed on the other three components.

Following the surgery, the claimant was provided with an instruction manual and an implant passport which had been provided to the clinic by the defendant. The passport's front page listed the defendant and its address, as well as the name 'Total Orthopaedic Solutions'. This passport was completed by the clinic with the stickers supplied with the four components.

In 2011 the implanted femoral head broke into pieces and had to be replaced.

The claimant sued the defendant for damages under the Product Liability Act on the basis that, according to the implant passport, the defendant was the manufacturer. There was no indication that the defendant had acted only as a retailer. In particular, the claimant argued that because the English name Total Orthopaedic Solutions was listed on the front page of the passport, there was an impression that the product was manufactured and supplied by the

defendant. Therefore, the defendant was responsible as the apparent manufacturer.

The defendant objected. The true manufacturer was mentioned on the stickers in the implant passport and the implant passport had been supplied to the clinic separately from the implant components. The defendant therefore denied liability as an apparent manufacturer.

Both lower courts dismissed the claim on the basis that the French company was clearly indicated as the manufacturer and the passport had been supplied separately; as such, there was a clear separation from the product and thus there was no impression that the retailer was the manufacturer. The appellate court granted leave to appeal to the Supreme Court, as the question of whether a retailer is liable as an apparent manufacturer based on an implant passport has far-reaching implications.

Decision

The Supreme Court ultimately dismissed the appeal.

Under Section 3 of the Product Liability Act, liability is placed on any person that presents itself as the manufacturer by putting its name, trademark or other distinguishing feature on a product. 'Distinguishing feature' is defined as anything that identifies an enterprise. The distinguishing feature must be put on the product by the apparent manufacturer, thus creating the impression on the public that it is the manufacturer of the product. This impression must exist when the product is put into circulation. Accordingly, the court had to consider whether the objective impression was that the prosthesis was manufactured by the defendant when the product was put into circulation. According to Section 6 of the Product Liability Act, a product is put into circulation when the power of disposition is passed to a third party or is given to a third party for the purposes of using the product. The shipping of a product is sufficient for this purpose. The essential point is the deliberate giving up of the power of disposition over the product.

The European Court of Justice (ECJ) has held on several occasions that the phrase "putting into circulation" as used by the EU Product Liability Directive – without further explanation– means that a product is put into circulation when it leaves the manufacturer's production and enters into the marketing phase by presenting it in a useable condition to the public.**(2)**

In another decision the ECJ held that a product is considered to be put into circulation when used in connection with a medical service related to the preparation of a human organ for transplant and the damage occurred in connection with the preparation.**(3)** This case concerned a defective rinsing fluid used for kidney transplants which had been produced by the pharmacy of another clinic of the same operator. According to the ECJ, it is irrelevant whether the product used for medical treatment is manufactured by the clinic or an affiliated unit or third party.**(4)**

However, according to the Supreme Court, the question of whether Section 6 of the Product Liability Act conforms to the EU Product Liability Directive was irrelevant in the case at hand, as the defendant had already put the product into circulation in accordance with the strict wording of Section 6. It was undisputed that the surgeon took the components from the consignment stock. As a result, the ceramic femoral head passed into the clinic's custody with the defendant's consent and consequently was put into circulation by the defendant at this point in time. When the surgeon removed the products, the stickers for each component were in the package. They were subsequently pasted into the implant passport by the clinic's personnel. The implant passport was separately delivered to the clinic by the defendant. Therefore, at the relevant point in time (ie, when the ceramic femoral head was put into circulation), no

connection to the defendant was established. The defendant neither appeared on the product itself nor on the packaging or accompanying documents.

Comment

This case centred on the question of whether there was an objective impression that the defendant was the manufacturer when the prosthesis was put into circulation. In accordance with ECJ precedents, the Supreme Court confirmed that a product is considered to be put into circulation when used in connection with a medical service related to the preparation of a human organ for transplant and the damage occurred in connection with the preparation.

Unfortunately, the Supreme Court failed to discuss what "putting [a name, trademark or other] distinguishing feature on the product" means. As such, the question of whether the implant passport – which is essentially a separate item from the product – is so close to the product that a reference to the distributing company in the passport can be considered to be "put on the product".

The Supreme Court also failed to address a comparable decision by the Koblenz Appellate Court.**(5)** In this judgment, the Koblenz Appellate Court denied a retailer's liability for an implant manufactured by its US parent company and imported by a Dutch sister company. As with the Austrian case, the implant passport contained the retailer's name and address. Like the Supreme Court, the German court denied liability, as the defendant was not mentioned on the product or the packaging itself, but only in the implant passport and the information brochure. In addition, the German defendant was not listed as the manufacturer in the printed materials and the documents did not create the general impression that the defendant had "influence on the quality and the manufacturing process". According to the Koblenz Appellate Court, the defendant's name and address identified it only as a point of contact for service needs. Interestingly, the German appellate court (as opposed to the Austrian appellate court) did not grant leave to appeal to the German Federal Court, because it considered the matter as an individual case without fundamental significance.

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Endnotes

(1) OGH June 10 2015, 7 Ob 82/15g; RdM 2015, 306.

(2) ECJ ruling of February 9 2006, C-127/04, *O'Byrne/Sanofi Pasteur MSD Ltd*.

(3) ECJ ruling of May 10 2001, C-203/99, *Veedfald/Århus Amtskommune*.

(4) ECJ C-203/99, Margin number 17.

(5) OLG Koblenz, July 24 2012, 5 U 299/12, VersR 2013, 1142.