Defective medical devices: the CJEU confirms that the purpose of notified bodies under the Medical Products Directive is to protect end users but leaves it to the national courts to decide if this creates a direct liability

Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH

By James Palmer & Chloe Campbell

In the latest development in the PIP breast implant litigation, the Court of Justice of the European Union (CJEU) on 16 February 2017 delivered a preliminary ruling in Case C-219/15 *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH* which confirms that the purpose of the role of a notified body under the Medical Products Directive 93/42 concerning Class III medical devices is to protect end users, and clarifies the obligations that arise in fulfilling that role, but ultimately bats the question of whether this gives rise to a direct liability to end users firmly back to the national courts.

Background

1. In 2008 Mrs Elisabeth Schmitt had silicone breast implants fitted in Germany which had been manufactured by the French company Poly Implant Prothèse ("PIP"). In 2010 the French authorities found that the company had been using low-grade industrial silicone to manufacture the implants and as a result Mrs Schmitt had her implants removed in 2012, and subsequently became one of the key litigants in this ever evolving medical products litigation.

2. The manufacturer became insolvent and Mrs Schmitt brought an action before the German courts against TÜV Rheinland LGA Products GmbH ("TÜV"), a German

company responsible for auditing the manufacturer's quality system for the purposes of EC certification in its capacity as the "notified body" under the Medical Devices Directive 93/42.

3. Mrs Schmitt claims €40,000 for non-material damage and a declaration that TÜV is liable for any future material damage, on the basis that it had not fulfilled its obligations satisfactorily as the notified body. Her case is that had TÜV carried out an adequate inspection of the delivery notes and invoices it would have been able to ascertain that the manufacturer had used industrial grade silicon rather than the approved form.

Approach of the national courts to date

4. These claims were rejected at first instance and by the appeal court on the basis that:

   (a) Whilst under German domestic law the duty to exercise due diligence under a contract may in certain cases extend to third parties, in this case the contract between the notified body and the manufacturer fell to be assessed exclusively by reference to private law and did not include Mrs Schmitt. This was because the appeal court considered that the purpose and the intention of TÜV's involvement was not to protect third parties but only to ensure compliance with the requirements for placing medical devices on the market, and the inclusion of a third party within the scope of the contract contrary to the intention of the parties and in the absence of any legitimate interest would have the effect of extending the notified body's liability indefinitely;

   (b) Whilst under German domestic law civil liability may be incurred for breach of a rule conferring legal protection, TÜV was not considered to be under any civil liability on the basis of the same reasoning that the purpose of TÜV's activity as the notified body was not to protect end users; and

   (c) In any event no fault was found as TÜV had made regular announced visits which the appeal court deemed sufficient in the absence of any suspicion of improper production practices.

5. It is worth noting that this decision follows another decision of the Paris Civil Court dated 29 September 2014, which had also excluded TÜV's liability.

6. When Mrs Schmitt appealed on a point of law to the Federal Court of Justice of Germany, the Bundesgerichtshof ("BGH"), it recognised that the resolution of the dispute under German law ultimately rested on the purpose under the Directive of the role of the notified body, clarification of its obligations in performing that role, and whether the Directive was to be regarded as intending that legal rights be conferred directly on end users in the event of any infringement of those obligations.

Questions referred to the CJEU

7. To clarify this issue, the BGH referred the following three questions to the CJEU:

   (i) Is it the purpose and intention of Directive 93/42 that, in case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance acts in order to protect all potential patients and may therefore, in the event of a culpable infringement of an obligation, have direct and unrestricted liability towards the patient concerned?

   (ii) Does it follow from Sections [3.3,4.3,5.3 and 5.4] of Annex II to Directive 93/42 that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance is subject to a general obligation to examine devices, or at least examine them where there is due cause?

   (iii) Does it follow from the aforementioned sections of Annex II to Directive 93/42 that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance is subject to a general obligation to examine the manufacturer's business records and/or to carry out unannounced inspections, or at least to do so where there is due cause?

The CJEU's findings on the obligations of the notified body

8. As to questions (ii) and (iii), which it considered first, the CJEU observed that notified bodies are required by the Directive to take specific action vis-à-vis both the audit of manufacturers' approved quality system and manufacturers' due compliance with that system. The CJEU appears to have recognised implicitly that Annex II sets out specific obligations as well as optional powers available to notified bodies to enable them to discharge these functions. The CJEU recognised that notified bodies should be allowed an appropriate degree of discretion as to how to discharge these functions, subject nonetheless to a general obligation to act with all due diligence.

9. From that it follows that a notified body has a duty to be alert, with the result that in the face of evidence that a medical device may not comply with the Directive, it must take all steps necessary to comply with its Article 16(6) responsibilities in relation to the withdrawal or restriction of any certificate of conformity, as well as complying with the requirements of the sections of Annex II identified in the referral.

10. The CJEU concluded that notified bodies are therefore not under a general obligation to carry out unannounced inspections, to examine devices and/or to examine manufacturers' business records. However, where evidence exists to suggest non-compliance of a particular device, the notified body's duty is to take all the steps necessary to ensure compliance with the Directive.

11. This appears somewhat circular, with the discretion to judge the necessity of certain steps, such as unannounced inspections, remaining in the hands of the notified body, but the steps required to comply with the obligation perhaps being more rigorous in the event of evidence of a non-compliant product.

The CJEU's findings on the purpose of the notified body and whether this gives rise to direct liability

12. Turning to question (i) the CJEU observed that the aim of the Directive was not just the protection of health *stricto sensu* but to protect the end users of medical devices. It noted that whilst it is incumbent on the manufacturer in the first place to ensure compliance, the Directive clearly also imposes obligations to that end on Member States and notified

bodies. It concluded that it is therefore apparent that the purpose of the notified body's involvement in the procedure relating to the EC declaration of conformity under the Directive is to protect the end users of medical devices.

13. But significantly it went on to observe, as it had previously stated (*Paul and Others* C-222/02), that:

> *"it does not necessarily follow from the fact that a directive imposes surveillance obligations on certain bodies or the fact that one of the objectives is to protect injured parties that the directive seeks to confer rights on such parties in the event that those bodies fail to fulfil their obligations, and that is the case especially if the directive does not contain any express rule granting such rights."*

14. The CJEU concluded that as the Directive mentions no such express rule,

> *"it cannot be maintained that the purpose of the directive is to govern the conditions under which the end users of medical devices may be able to obtain compensation for culpable failure by those bodies to fulfil their obligations."*

15. However it noted that it was well established (*Skov and Bilka,* C-402/03) that the existence of a Directive does not preclude the application of other systems of contractual or non-contractual liability.

16. Whether any direct liability arose in such circumstances is therefore to be left to the national courts to determine under their governing laws subject to the principles of equivalence and effectiveness.

17. The CJEU further commented that the mere fact that the Directive requires notified bodies to take out civil liability insurance is not sufficient for it to be concluded that Member States must confer on end users a right to look to those bodies for compensation.

18. In light of this finding that there is no direct and unrestricted liability towards end users conferred by the Directive, the CJEU did not find it necessary to answer the request made by Ireland that the temporal effects of the judgment be limited. It thereby side-stepped the rather controversial proposal set out by Advocate General Sharpston in her

Opinion to the court which preceded this judgment (15 September 2016), that the Directive should not be interpreted as imposing liability where that liability arose before the date of the judgment, except where that liability was already the subject of insurance cover. This proposition was curious given that Annex XI(6) imposes a mandatory duty on a notified body to take out civil liability insurance. Had this stood it would have created an extraordinary situation whereby a notified body complying with the insurance requirement could have found itself liable to pay compensation, whereas one that ignored the insurance requirement could be said to have no liability.

Summary of preliminary ruling

19. **In summary therefore the CJEU:**

- **Significantly confirms that the purpose of the notified body's involvement under the Directive is to protect end users of medical devices;**
- **Clarifies that in fulfilling its duties under the Directive there is no general obligation to carry out unannounced inspections, to examine devices and/or to examine the manufacturer's business records, but in the face of evidence that a product may not comply it must take all reasonable steps necessary to ensure it fulfils its obligations under the Directive;**
- **But notes that the Directive does not make any express provision that this confers rights on end users to bring direct action against notified bodies and therefore leaves it for the national courts to determine under their governing laws the circumstances in which culpable failure to fulfil those obligations may give rise to a direct liability to end users, subject to the principles of equivalence and effectiveness.**

Analysis and discussion

20. How the national courts apply this guidance under their own laws therefore remains to be seen. It remains for those national courts to determine:

(a) what will be taken to constitute satisfactory evidence that a medical device may not comply with the requirements of the Directive;

(b) the circumstances in which that evidence ought to or can be considered to have come to the attention of the notified body;

(c) whether in the face of such evidence the notified body took all steps necessary to fulfil its obligations under the Directive; and most significantly

(d) whether, in the event of culpable failure, liability arises on its part directly to end users of the product as a result of that failure under the governing national law.

21. In the event that culpability is established, the finding that the notified body's purpose is to protect the end user may well affect the national courts' approach when considering liability under their domestic laws:

(a) It may give rise to direct civil liability, in the German courts on the basis of the infringement of a rule conferring legal protection, or in our courts under general principles of negligence. In circumstances where the German appeal court in this case based its reasoning on its interpretation that under the Directive it was not the purpose or intention of TÜV's involvement to protect third parties, its position on civil liability may well be different in light of the CJEU's finding to the contrary.

(b) It is perhaps less likely to affect the interpretation of the right of the end user to claim as a third party under a contract, although it may give rise to arguments that the purpose of the contract can now be said to be to protect the end user.

22. Whilst the CJEU has clarified that the purpose of the notified body's role is to protect end users under the Directive, it therefore remains to be seen whether this provides enough of a hook for the national courts to hang direct liability upon. It will certainly open up new avenues of argument under domestic laws upon which claimants may be better able to establish a claim against a notified body, which of course will be particularly pertinent where the manufacturer is insolvent.

23. On the other hand, the somewhat restrictive approach as to the duties and liabilities of notified bodies taken by the national courts in France and Germany to date, could indicate

that the courts were mindful of the importance of such notified bodies as TÜV continuing to fulfil the vital function on which the protective regime established by the Directive relies. There is nothing in this CJEU judgment to disabuse the national courts of this approach. In fact, in confirming the vital purpose of the notified body in protecting end users, whilst at the same time noting that the Directive does not expressly confer rights on end users in the event of any failure to fulfil these obligations, it might be suggested that the CJEU could perhaps be seen to be affirming it.

24. We will simply have to keep a close eye on the German courts to see how the next chapter in this evolving story unfolds.

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A number of members of Henderson Chambers' product liability practice group represent various parties involved in the PIP breast implant litigation.