Product liability developments in 2013: what they mean for your business

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SARAH CROFT OF SHOOK, HARDY & BACON LLP looks back over some of the main European product liability cases of 2013 and examines the trends which may impact businesses going forward.

UK: CONSEQUENCES OF REJECTING A PROPOSAL TO MODIFY A DEFECTIVE PRODUCT

In *Manton Hire and Sales Ltd v Ash Manor Cheese Company Ltd* [2013], in May 2013 the Court of Appeal held that an innocent party may reject a breaching party's offer to remedy the breach if the offer does not include enough information to make a fully informed decision. Offers must be clear, detailed and well supported.

Manton supplied Ash with a forklift truck to use in its warehouses. Manton had recommended the truck, which was manufactured by a third party, after a representative from Manton visited the Ash warehouses and measured the racking arrangements. On delivery, Ash found the truck did not fit in the racking so rejected it as 'not fit for purpose'.

Manton suggested making the truck smaller, but their proposals were unclear and did not include drawings, specifications or details of who would do the work. Ash raised concerns in relation to driver safety compliance and these issues were not adequately addressed. Manton argued that in rejecting its proposal to resolve the issues with the racking, Ash had failed to mitigate its loss reasonably.

The Court of Appeal held that Ash was not required to ask for additional details of the proposal and had not closed the door on negotiations. Further, there was nothing preventing Manton from putting forward a more detailed proposal. The Court pointed out that if this had been the case, Ash would have rejected it 'at its peril'. As things stood, however, the Court concluded Ash was entitled to reject the proposal to modify and there was no failure to mitigate by Ash.

UK: CONCRETE BASE OF CRANE IS NOT A 'PRODUCT'

In *Aspen Insurance v Adana Construction* [2013], the insured company, Adana, constructed the concrete base of a tower crane which collapsed causing serious injury and damage to property. The insured claimed that the base was covered by its insurance policy with Aspen. In June 2013, Aspen Insurance sought a declaration in the High Court that it was not liable to indemnify the insured.

Expert evidence stated that the crane would have collapsed in any event because the crane was exposed to excessive loads by the main contractor. Accordingly, the Health and Safety Executive prosecuted the main contractor and designer but not the insured.

Adana Construction was joined in an action brought by the injured crane operator against the main contractor and the designer. The insured did not have public liability cover 'against liability arising... caused by any Product'. The insured had product liability cover for liability caused by any product unless liability arose in connection with the product's failure to fulfil its intended function. The insurer alleged that the base of the crane was a product and since liability was caused by a product failing to fulfil its intended function, it was not liable under the policy.

The High Court interpreted the terms of the insurance policy according to what a reasonable person, with all relevant background knowledge of the parties at the time the contract was made, would have understood them to mean. The policy was described as covering the full range of liabilities a building contractor was faced and it was held that a medium size private family company would expect such insurance to cover all liabilities it might expect to encounter. It was held that the base of the crane (concrete poured in situ) was not a 'product' – it was created on site pursuant to a design by the structural engineers (as opposed to being made in a factory) and was not one of a range of products sold by the insured. The judge stated that if this conclusion was incorrect, the intended purpose of the base was to transfer the load of the crane into its piles and this purpose was achieved because it emerged from the collapse intact.

GERMANY: BOILER WHICH EXPLODED WAS NOT DEFECTIVE WHEN INCORRECTLY FITTED

In February 2013, the German Federal Supreme Court issued a decision overturning the lower courts' rulings in favour of the plaintiff in a case where an

under-sink boiler had exploded after being incorrectly fitted (Case Zivilsenat VI ZR 1/12 (5 February 2013)). The plaintiff had claimed that the boiler was a defective product under the German Product Liability Act (which implemented the EU Product Liability Directive).

It was alleged that the boiler had been incorrectly fitted, and that this was the cause of the explosion. In the context of applying the consumer expectation test, the Supreme Court held that the consumer could not reasonably expect a product to be safely designed for inappropriate use. The incorrect fitting of the boiler in this case was found to be inappropriate use, and, as a consequence, the court ruled that the boiler was not defective.

THE NETHERLANDS: HEART VALVE NOT DEFECTIVE

In October 2013, the Dutch Supreme Court affirmed the lower courts' rulings in favour of the medical device manufacturer Medtronic BV (*LUMC v Medtronic BV* [2013]). The plaintiff had alleged that an implanted mechanical heart valve manufactured by Medtronic had leaked and was a defective product under the provisions of the Dutch Civil Code. The court found the valve was not defective because only a small number of patients had been affected by leakage, which indicated that there was not a general design fault in the product, and the leakage did not cause any clinical symptoms, so the product could not be considered unsafe.

FRANCE, GERMANY: PIP-TUV CASE

In November 2013, a French Court ordered a German company, TUV Rheinland, to pay compensation to hundreds of women who had been fitted with the defective breast implants manufactured by PIP. TUV Rheinland was responsible for awarding EU safety certificates to PIP. The company was sued for €50m (£42m) by six implant distributors and 1,700 affected women, who argued that anything more than a cursory inspection would have identified problems with the implants. There were also gaps in post-marketing surveillance and adverse event reporting. The plaintiffs were awarded an initial payment of 3,000 euros each to cover the costs of surgery to have the implants removed. It is reported that TUV will appeal this decision.

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EMERGING TRENDS

Traceability of medical devices

A significant practical issue in the PIP scandal in the UK was the lack of reliable data on the number of implants used, when, by whom and which women may have received the implants in question. Consequently it was very difficult to make an accurate assessment of increased rupture rate in PIP implants as against background rupture rates. NHS medical director Professor Bruce Keogh wrote that 'The PIP implant scandal... exposed woeful lapses in product quality, after care and record keeping' in his report reviewing the Regulation of Cosmetic Interventions published in April 2013. In the face of concern that 'a person having a non-surgical cosmetic intervention has no more protection and redress than someone buying a ballpoint pen', the report recommended a new legislative framework for surgical and non-surgical interventions to ensure that the products used are safe and that practitioners are appropriately skilled.

A full response to the review from the government is expected in early 2014 but has not been published at the time of going to press. However, in December 2013, the health minister Dr Dan Poulter announced that the government would be proposing reforms to the regulation of the cosmetic surgery industry including the introduction of a register to track every breast implant operation in England. He indicated that the register would be the subject of pilot projects in the NHS and certain private clinics before becoming compulsory for the whole of England. Health ministers in the remainder of the UK will decide whether to join the register.

The PIP scandal also added impetus to the EU's proposal for a new regulatory framework for medical devices and in vitro diagnostic medical devices which is in need of modernisation. The proposals will impose more stringent standards and are due to be adopted in 2014 and to be implemented gradually between 2015 and 2019.

Traceability and product recalls

Also related to traceability, there has been wide reporting throughout the year on the question of the effectiveness of recalls, with commentators highlighting that even the best run recalls may not reach all consumers with the product in question.

To illustrate the issues which can arise, in November 2012, Beko issued a safety notice warning that some of its tumble dryers sold between May and October 2012 were at risk of catching fire due to failure of an electrical component which could cause overheating. In November 2012, Beko implemented a recall of 32,000 products and in July 2013 it was reported that 25,000 (71%) of these products had been recalled and repaired. Beko acted swiftly on the tumble dryer recall and implemented an effective recall, helped by the fact that the products were new and the owners easier to trace than for older products. In October 2013 it was reported that group litigation proceedings on behalf of seven families affected by the recalled tumble dryers were to be commenced.

Market surveillance

The current Market Surveillance Regulation (EC) 765/2008 obliges EU member states to carry out market surveillance and empowers authorities to take action where a product is considered a 'risk'. The current market surveillance regime is scattered across three sources, causing inconsistency in the interpretation and evaluation of risk presented by a product. This will be merged into one source under a new Regulation proposed by the EU in 2013 and in time, the increased consistency in the interpretation of the market surveillance rules will reduce uncertainty

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for manufacturers. Another proposed benefit is a chronological explanation of the market surveillance procedure so the obligations of manufacturers are easier to follow.

In the medical device context the proposed EU regulatory framework will also include widening and clarifying the scope of devices which are regulated, strengthening the powers of independent assessment bodies to ensure thorough testing, improving traceability of products and requiring a manufacturer to appoint a qualified person to be responsible for regulatory compliance.

In February 2013, the EU proposed reforms to its current regime for regulating product safety and market surveillance to reduce the risk of unsafe products reaching consumers. These reforms are a significant development for manufacturing companies because they provide more coherent rules and better co-ordination of product safety checks. It is expected that these proposals will be discussed by the European Parliament during 2014 and that they will take effect on 1 January 2015.

The reforms will be implemented by new regulations for consumer products safety and market surveillance. The Consumer Products Safety Regulation will replace the existing General Product Safety Directive (2001/95/EC) and to enhance the safety of consumer products sold in the EU by specifying uniform rules for a general safety requirement, assessment criteria and obligations of economic operators (defined as manufacturers, importers and distributors). The obligations imposed upon manufacturers include to: ensure that their product is safe, carry out sample testing of products, investigate complaints, draw up technical documentation to analyse possible risks and the solutions adopted, provide means to identify a product and its manufacturer, provide instructions where necessary, take immediate corrective action against an unsafe product and to immediately inform market surveillance authorities in the member state in which they made the product available.

Claims where the manufacturer is insolvent

The growth in company insolvencies over the recent recession has had implications for claims where a manufacturer is insolvent. The issues that can arise were illustrated in the PIP context.

The company which manufactured PIP implants entered liquidation in 2011. Claims against it for compensation would have been pointless in the absence of the availability of insurance cover – to the extent that such cover would not have been denied in any event on the basis of fraud. In the UK, clinics which carried out surgery in which the implants were used were the next obvious target. In England, a group litigation order was granted in April 2013 allowing claims to be brought on behalf of hundreds of English women against various private clinics who had fitted the implants (*X Y Z v Various companies (PIP Breast Implant Litigation)* [2013]). One of the clinics, Harley Medical Group, went into administration in 2012. Transform Medical Group (CS) Ltd, a defendant in the UK group litigation was ordered by the High Court in November 2013 to provide details of their insurance in order to determine whether it is adequate to cover the litigation.

The unusual circumstances of the PIP scandal have forced potential plaintiffs to cast their nets wider in the search for compensation, such as the claim in France reported above against the company which issued safety certificates to PIP.

It has also been reported that women who paid for their breast implants by credit card have successfully obtained refunds from their credit card company under s75 of the Consumer Credit Act 1974. Under s75, if a consumer buys a product costing over £100 and pays for any of it by credit card, the credit card company is jointly and severally liable with the supplier in respect of misrepresentation or a breach of contract. Although in normal circumstances the manufacturer would be the target of product liability claims, the success of claimants identifying financially viable alternative targets may encourage similar claims in the future against a wider range of targets.

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Aspen Insurance UK Ltd v Adana Construction Ltd *[2013] EWHC 1568*

LUMC v Medtronic BV *ECLI:NL:PHR:2013:835*

Manton Hire and Sales Ltd v Ash Manor Cheese Company Ltd *[2013] EWCA Civ 548*

X Y Z v Various companies (PIP Breast Implant Litigation) *[2013] EWHC 3643 (QB)*

Zivilsenat VI ZR 1/12 (5 February 2013)