Does *Hastings* matter for Consumer Protection?

Hastings v Finsbury Orthopaedics Ltd

[2022] UKSC 19; 2022 SC (UKSC) 43
UK Supreme Court
Lord Reed PSC, Lord Kitchin, Lord Stephens, Lady Rose, Lord Lloyd-Jones
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Consumer Protection, defectiveness, hip replacement, evidence

Unlike *O'Byrne v Aventis Pasteur*,[1] which addressed a narrow point of procedure, *Hastings v Finsbury Orthopaedics Ltd* provides the first substantive consideration by the UK apex court of the product liability regime constituted by Part I of the Consumer Protection Act 1987 (CPA).[2] Regrettably, however, given the attrition of legal issues as the case proceeded, and the approach ultimately taken by the Justices of the Supreme Court, only one question was addressed: what amounts to sufficient proof of defectiveness? Therefore, there was very little dispute about the law found in the CPA.[3] It was agreed, for example, that section 3 introduced a tailor-made strict liability regime for defective consumer products, which adopted an objective approach to the concept of 'defect', nor was there any debate about possible defences. The key legal issue was whether the Lord Ordinary (Lord Tyre) in the Outer House of the Court of Session was entitled to find that the pursuer had failed to prove that a hip replacement product was defective.[4] The Inner House refused the pursuer's reclaiming motion.[5] However, perhaps mindful of the general public importance of the claim, the Inner House granted permission to appeal to the UK Supreme Court. The Supreme Court may not have been so convinced of the claim's importance: its judgment focussed solely on the question of proof, sidestepping the wider questions raised by the pursuer about the CPA. Ultimately, the appeal was refused. This leaves us to wonder if there is much else to say, for this singular appeal decision does not offer any sustained analysis of section 3. Yet, arguably, there is; what is important is what people think *Hastings* represents rather than the specific contours of the appeal presented to the Supreme Court.

The legal question?

Although there may be more to *Hastings* than the judgment suggests, it is important to remember that the Supreme Court focussed solely on the question of proof and the assessment of evidence at first instance. At an interlocutory stage, both parties agreed that the Outer House should determine, following a proof, whether the inherent propensity of the hip prostheses to produce debris and cause injury to users was enough to render the product defective. Vitally, the defenders, Finsbury Orthopaedics Limited and Stryker UK Limited, admitted that there was a risk of injury and that the hip may shed metal pieces causing discomfort, further complications, and the need for additional medical intervention. The pursuer attempted to establish the product was defective in three ways. First, they emphasised design faults which should have made it evident to the defender that the product was unsafe. Second, they noted

[1] [2010] UKSC 23; [2010] 1 WLR 1412.
[2] [2022] UKSC 19; 2022 SC (UKSC) 43.
[3] ibid at [15].
[4] [2019] CSOH 96; 2019 SLT 1411 (OH).
[5] [2021] CSIH 6; 2021 SLT 187 (IH).

that general professional opinion was that the product was inadequate and led to unnecessary harm and further surgery. Third, they sought to draw an inference of defectiveness from the fact that the defender voluntarily withdrew it from market.

Sufficient evidence?

As formulated by Lord Lloyd-Jones, giving the unanimous judgment of the Supreme Court, the evidence establishing defectiveness should determine 'whether… the level of safety of [the defender's product] would not be worse, when measured by appropriate criteria, than existing… products [manufactured by alternative suppliers] that would otherwise have been used.'[6] Therefore, what a consumer is entitled to expect of a hip replacement is to be determined according to, *inter alia*, the safety of hip replacements available from other manufacturers. To determine this, the Lord Ordinary thought it necessary to measure the success of the pursuer's product in terms of longevity, ie how long before a revision was required, whereby the previous hip replacement is removed, and a replacement hip was installed, in comparison to competitor's products.[7] It was also necessary to examine how effective any subsequent revision of the hip replacement was when using the pursuer's product in contrast to others.[8] Neither the pursuer nor defender disputed this comparative approach; rather, they differed on what could be extrapolated from the evidence.

The Outer House took ten days to hear extensive and complex medical evidence. Expert consensus was that 'the best prostheses had a revision rate of 10% or less at ten years and that this should be regarded as the benchmark.'[9] Yet, from around 2008, evidence published by medical practitioners suggested that metal-on-metal prostheses was, in general, problematic. In 2012, a study claimed the defender's specific product had a revision rate of 23.7% at ten years. It was this figure which initially led the defender to withdraw the product from the market, and subsequently then, for warning notices to be issued by the Medicines and Healthcare products Regulatory Agency. The defender's anticipatory withdrawal was a key point in the pursuer's case: the voluntary withdrawal, along with the warnings, could be taken as an admission that the product was defective.

However, later evidence suggested that the 23.7% figure was unreliable, or at least the data was incomplete and suffered from important limitations. Such constraints suggested that it was not possible to use the comparative methodology as a means by which to reliably determine the safety of the product. If the data was informed by a closer examination of surgeons' own reports about revision rates, this figure could be as low as 14.3%. However, that evidence was only available some years after the 2012 report. The evidential picture presented to the court was, therefore, the full statistical picture (or at least what was available at the time of proof) which went beyond that which was available to the manufacturer or indeed patients at the point harm was suffered. It was with the benefit of hindsight that the effectiveness of the pursuer's product could be re-evaluated as being potentially more successful than first thought.

The Outer House concluded, therefore, that the product did not fall below the standard of safety that the public were entitled to expect, regardless of whether it was less successful than other products available.[10] The statistical evidence which underpinned the original concerns about the pursuer's products was unreliable or did not provide a sufficient basis upon which to conclude that the product was defective.[11] The Inner House refused the pursuer's

[6] *Hastings* (UKSC) at [19].
[7] *Hastings* (OH) (n 4) at [150].
[8] ibid at [157].
[9] *Hastings* (UKSC) at [23].
[10] *Hastings* (OH) (n 4) at [163].
[11] ibid at [155].

reclaiming motion, merely noting there might be some criticism – albeit unfounded – that Lord Tyre adopted a scientific rather than legal standard of proof when assessing the reliability of the data.[12] The Supreme Court was alive to this criticism but chose to frame it in different terms;[13] that is, they concluded, in the end, that the thrust of the pursuer's case was a direct attack on the Lord Ordinary's factual assessment of the evidence: 'this appeal is no more than an attempt to appeal against the Lord Ordinary's findings of fact'.[14] After stressing yet again that an appellate court cannot overturn a factual determination unless it was vitiated by an error in law or was plainly wrong,[15] the Supreme Court dismissed the appeal.

Consumer protection trumps innovation?

In adopting the comparative approach, Lord Tyre was expressly following *A v National Blood Authority (No. 1)*,[16] *Wilkes v DePuy International*,[17] and *Gee v DePuy International*.[18] The the Inner House did not question this approach; nor did either party dispute the relevance of these cases. In particular, *Wilkes* offered a comprehensive examination of the circumstances which can be considered by a court when assessing compliance with section 3. There, the High Court was sceptical that defectiveness could be determined by assessing whether the injury could have been avoided. When it comes to medical products, a better measurement of defectiveness was said to be conducted on a risk-benefit axis. Thus, along with the criteria set out in section 3, the High Court favoured asking 'the ease and extent to which a risk can be eliminated or mitigated', particularly regarding medical products which otherwise might aim to provide distinct and material benefits to users. Of course, this was just one of the criteria that Hickinbottom J suggested could be utilised by a court. Such an approach was followed in *Gee* and considered favourably by the Outer House in *Hastings*. It is notable that these decisions suggest that the Directive's main objective, and by consequence that of the CPA, is not only consumer protection but also to allow for safe innovation. There is a balance to be struck, with no presumption of benevolence towards consumers.

The appellant used *Hastings* — and, in particular, the method of Lord Tyre to evidential questions — as a springboard to question this approach. In the Supreme Court, three arguments were made to strategically push for a definitive statement from the Justices as to what they saw as the principal aims of the CPA. It may also be that such arguments sought to anticipate the changes to the Consumer Protection Directive proposed by the EU Commission, specifically on questions of what evidence may establish that a product is defective. [19] First, the pursuer argued in the Supreme Court that the approach taken by the Outer House makes it overly difficult for a consumer to prove their case. In effect, they argued that Lord Tyre's approach reduced everything to a scientific question which was contrary to the overriding consumer protection principle of the Act, and therefore infringed the EU law principle of effectiveness. Next, they sought to convince the Supreme Court that the Directive introduced a fairer apportionment of risks between consumer and manufacturer – which was undermined by Lord Tyre's scientific approach. Lastly, the approach of the Outer House was chastised as being overly rigid.

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[12] *Hastings* (IH) (n 5) at [78].
[13] *Hastings* (UKSC) at [32], [36] and [38].
[14] ibid at [65].
[15] ibid.
[16] [2001] EWHC 446 (QB); [2001] 3 All ER 289.
[17] [2016] EWHC 3096 (QB); [2018] QB 627.
[18] [2008] EWHC 1208 (QB); [2018] Med LR 347.
[19] Proposal for a Directive of the European Parliament and of the Council on liability for defective products COM(2022) 495 final. See European Commission, Press Release of 28 September 2022, https://ec.europa.eu/commission/presscorner/detail/en/ip_22_5807 (accessed 12 January 2023).

The court did not respond directly to these arguments, preferring to bring the focus back to what they perceived to be the legal question at hand: was the Lord Ordinary entitled to determine the pursuer had failed to *prove* their case? In that regard, the Supreme Court did not offer any definitive statement of the law but preferred to indicate, through its implicit endorsement of several key cases, that section 3 is about balancing several factors rather than solely ensuring consumer protection.[20] It would appear that when it comes to medical products the determination of defectiveness is a complex task; mere failure or recall is not indicative of defectiveness. This is only implicit in the ruling: the court did not directly consider what defectiveness means, only how to prove defectiveness. Nevertheless, sometimes a case is noteworthy not because of what is said but what it suggests.

Why care about Hastings?

Hastings has been greeted by commentators and other interested parties as a crucial case, which gives direction to litigators, manufacturers, and consumer bodies about the direction of travel in this area of law.[21] Hence, it will influence the provision of insurance, shape how investments are assessed, inform decisions about litigation funding, and guide internal compliance steps taken by manufacturers to ensure their products are CPA compliant. Specifically, it is important for manufacturers of medical products used in the UK and the procurement systems of the NHS. Nevertheless, questions remain.

For example, how should Annex I of the EU Medical Device Regulation, incorporated into UK law by the Medical Devices Regulations 2002,[22] continue to inform the application of the CPA? That is, how consistent is the UK product liability regime with the public regulation of medical products, which post-Brexit is closely tethered to the EU regime? There is a further policy question: if the Consumer Protection Directive is updated along the lines suggested by the EU Commission, should the UK follow suit and amend the CPA accordingly?

Furthermore, domestically, *Hastings* contributes to the very complex environment for medical practitioners following *Montgomery v Lanarkshire Health Board*.[23] Although decisions about which equipment and implants to employ remain within the domain of treatment, and rely on, *inter alia*, the approval by the MHRA, *Hastings* introduces an intricacy for medical practitioners when advising on the course to be taken by a patient. It appears that there was reasonable concern amongst the orthopaedic community about the effectiveness of metal-on-metal implants, yet in the end, regardless of this professional opinion, the defender's specific product was not found to be defective. This raises the question of how much discussion there should be about the effectiveness and safety of products being used. Should the patient, as a consumer, be introduced to the cost-benefit analysis of the proposed implant?

From a legal point of view, *Hastings* confirms that UK courts will be careful not to expect too much of medical product manufacturers. Arguably, it demonstrates how hard it is

[20] Hastings (UKSC) at [15].

[21] (1) https://www.hausfeld.com/en-gb/what-we-think/perspectives-blogs/the-first-supreme-court-product-liability-decision-hastings-v-finsbury-orthopaedics/; (2) https://products.cooley.com/2022/09/13/uk-supreme-court-rules-on-whether-a-product-is-defective/; (3) https://www.scotsman.com/news/opinion/columnists/hip-replacement-case-may-have-wider-implications-for-consumer-protection-law-fiona-mcewan-3700927; (4) https://www.lawgazette.co.uk/legal-updates/product-safety-and-entitled-expectation/5113541.article; (4) https://www.globalcompliancenews.com/2022/07/08/uk-supreme-court-rules-no-entitlement-for-consumers-to-an-absolute-level-of-safety-in-product-liability-case-05072022/; (5) https://www.cms-lawnow.com/ealerts/2020/02/court-rules-in-favour-of-manufacturers-in-first-metal-on-metal-hip-replacement-case-in-scotland?cc_lang=en

[22] SI 2002/618.

[23] [2015] UKSC 11, 2015 SC (UKSC) 63, [2015] AC 1430.

for a consumer of a medical product to be successful; indeed, *A v National Blood Authority* appears to be the only reported CPA case where compensation was awarded to consumers of medical products which caused injury.[24] It affirms the status quo, in many ways, by demonstrating that a court will be mindful of what is reasonable to expect within the circumstances of medical innovation drawing upon and examining complex evidence used by manufacturers. Crucially, it implicitly endorses the approach taken in *Wilkes v DePuy International*[25] whereby in determining defectiveness a UK court will cautiously weigh consumer protection against the needs of innovation and development. This means that product recalls, associated warnings, or subsequent improvements to a products safety are not necessarily indicative of the product's defectiveness. Rather, a court will assess defectiveness vigilantly, showing regard to the scientific evidence available at the time of proof and alert to the fact that section 3 does not compel complete safety from a product.[26] This also means that the evidential expectations of a pursuer are extensive, and potentially, in some instances, prohibitive. Indeed, from the perspective of pursuers, *Hastings* presents, together with the High Court decisions on the CPA, a formidable legal hill for an injured consumer of a medical product to climb if they are to receive compensation. Whether this was really the intention of the original Directive[27] is another question; and possibly now an irrelevant one.

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[24] (n 19).
[25] (n 20).
[26] *Hastings* (UKSC) at [15].
[27] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.