HENDERSON CHAMBERS

Alerter

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Alerter on Hastings v Finsbury Orthopaedics Ltd

By Noel Dilworth

1. The Supreme Court has, this week, handed down its judgment dismissing the claimant's appeal in ***Hastings v Finsbury Orthopaedics Ltd and anor*** [2022] UKSC 19. Mr Hastings had brought a claim under the Consumer Protection Act 1987 ("CPA") for personal injury damages allegedly sustained as a result of implantation in 2009 of a particular brand of prosthetic hip, the "MITCH-Accolade product", one of a number of available metal-on-metal ("MoM") total hip replacements ("THRs").

2. It was not in dispute at first instance that MoM THRs had an inherent propensity to shed metal debris through wear in use and that there was a risk that some patients may suffer an adverse reaction to such metal debris that may necessitate early revision.[1] The Claimant's case on defect had been that the MITCH-Accolade product gave rise to a greater risk of an adverse effect on the patient and so a greater risk of early failure, in comparison with non-MoM prostheses, and that design features of the product created a greater risk of early failure than with non-MoM prostheses, as well as a worse outcome after revision.[2] At first instance, two particular circumstances were relevant to the argument that the product fell short of the relevant standard under section 3 of the CPA, namely, what persons generally were entitled to expect: (1) the time to revision (also termed, the "survivorship" of the implant); and (2) the prospects of success of revision surgery. On appeal, it was only the first of these two aspects – the time to revision - which remained live.[3]

[1] Paragraph 14
[2] Paragraph 17
[3] Paragraph 20

3. The Lord Ordinary at first instance found that the time to revision did not give rise to a breach of an entitled expectation.[4] Crucial to that finding was the undisputed evidence of Professor Robert Platt, a Professor of Pharmacoepidemiology at McGill University, Canada, whose evidence, quoted at paragraph 27, included the following:

    1. "*…there are limited data available to reliably estimate the survivorship of the MITCH-Accolade and to compare its survivorship to other THR prostheses… I find no reliable evidence that the survivorship of the MITCH-Accolade is out of line with benchmarks as of the time the product was introduced to the market, as of the time the Pursuer's hips were implanted, and as of today.*"

4. Essentially, the Supreme Court deferred to the finding of fact made at first instance on a preliminary issue that the MITCH-Accolade product did not have a defect, within the meaning of section 3 of the CPA. As Lord Lloyd-Jones (giving the judgment with which all other Justices agreed) put it at paragraph 65:

    2. "*Ultimately, this appeal is no more than an attempt to appeal against the Lord Ordinary's findings of fact. As the Lord President observed… in order to reverse a determination of fact, the appellate court must be satisfied that the Lord Ordinary erred in law, made a finding without any basis in the evidence or demonstrably misunderstood, or failed to consider, relevant evidence. Otherwise, it can only interfere with the findings of fact if it concluded that the Lord Ordinary was plainly wrong, in the sense of his decision not being capable of being reasonably explained or justified. None of these requirements is satisfied in the present case and, accordingly, it is not open to this court to interfere with the Lord Ordinary's findings…*"

5. On its face, therefore, the judgment ends with something of a whimper. At one level, it does beg the question why the appeal reached the Supreme Court in the first place. For product liability specialists, however, there are at least four points of interest.

[4] Paragraphs 28 - 34

6. First, the Supreme Court endorsed the main statements of principle with respect to the concept of "defect", expressed in the judgments of Hickinbottom J in *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB) and Andrews J in *Gee v DePuy International Ltd, The DePuy Pinnacle Metal on Metal Hip Litigation* [2018] EWHC 1208 (QB), as well as the CJEU in *W v Sanofi Pasteur MSD SNC* (Case C-621/15) as follows (paragraph 15):

> "*(i) The Directive and the CPA have introduced a system of no-fault liability. The concept of "defect", introduced by the Directive and implemented by the CPA, is an autonomous one, defined in terms of failure of the product to meet an objective standard of safety that the court must evaluate.*
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> *(ii) The test of whether a product is defective is whether the safety of the product is not such as persons generally are entitled to expect. The test is not what is expected but one of entitled expectation. The test is an objective one. The standard of safety is measured by what the public at large is entitled to expect.*
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> *(iii) What persons generally are entitled to expect is assessed having regard to all the circumstances which are factually or legally relevant to the evaluation of safety, including the matters identified in section 3(2). This must be evaluated at the time when the product was supplied by its producer to another. The assessment of risks associated with a product, which might inform entitled expectations as to its safety, must be done at the time the product is supplied and not with the benefit of hindsight.*
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> *(iv) In determining whether a product met the level of safety persons generally were entitled to expect, the court is entitled to have regard to everything now known about it that is relevant to that enquiry, irrespective of whether that information was available at the time it was put on the market or has come to light subsequently.*
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> *(v) The burden of proof is on the consumer to establish a defect and a causal link to the injury. The standard and means of proof are matters for national law, subject to the principle of effectiveness.*"

7. Further, the Supreme Court endorsed the adjustment of the relevant expectation (applied by Andrews J in *Gee*) by reference to the fact that, for products like MoM THRs, there can be no entitlement to an absolute level of safety and that it is natural for a prosthesis to wear and to shed metal debris that can cause soft tissue damage, so that that propensity, in itself, cannot be a defect.

8. The second point of interest is that the principle of "effectiveness" which cropped up in articulating the burden of proof opened up the primary route of argument on appeal. Effectiveness is the term of art derived from ECJ jurisprudence used to describe the requirement that procedural rules should not make the protection or enforcement of rights which an individual derives from EU law practically impossible or excessively difficult (e.g. *Amministrazione delle Finanze dello Stato v SpA San Giorgio* (Case C-199/82) [1983] ECR 3595; *W v Sanofi Pasteur MSD SNC* (Case C-621/15), para 26). This argument was accompanied by the invocation of the policy objective of consumer protection underpinning the Directive[5] from which the CPA sprang (*Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt - Die Gesundheitskasse* (Joined Cases C-503/13 and C-504/13)) and an appeal to unfairness generally by dint of the fact that the impossibility of proving his case by statistics which were not available to him stemmed from the producer's actions in withdrawing the product from the market (see the summary, at paragraphs 37 to 40, of the grounds on which the appellant brought his appeal). These appeals fell on stony ground. There was to be no *Fairchild*-like relaxation or adjustment of the standard or quality of evidence necessary to meet the relevant test for "defect". The relevance of the withdrawal of the product from market was limited by reason of the finding at first instance that that it was motivated by commercial considerations.

9. Third, the aspect of perhaps greatest practical significance for the practitioner from this judgment is the importance of statistical evidence and of interrogating each aspect of the statistical evidence and, where appropriate, challenging or qualifying or limiting it. The Appellant had sought to argue that Professor Platt's analyses were "*neutral because no reliable statistical assessment of long-term survivorship can be*

[5] Directive of the Council of the European Communities, dated 25 July 1985 (No 85/374/EEC) on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products

made" (paragraphs 37 & 38). In one sense, they were correct; the Court was in no position whatsoever to give a decisive and scientifically authoritative or accurate answer to the question whether the MITCH-Accolade product underperformed relative to the market generally for THRs. However, at paragraph 62 of its judgment, the Supreme Court did not see fit to disturb the Lord Ordinary's approach, which involved prioritising the statistical analyses over the evidence of the expressions historically of concern by experts in the field and the history of medical device alerts and of field safety notices. Thus, the Lord Ordinary's approach was at least justified and reasonable. Whether or not it was correct is now a matter of limited interest for lawyers (although potentially an active one for pharmaco-epidemiologists). However, the impression left by the sheer weight of the statistical evidence provides a salutary lesson for practitioners for claimants and defendants in dealing with statistical evidence. It is always worth testing and reconsidering the statistical evidence with experts from another, perhaps related field of expertise.

10. Fourth, there is (currently) no (obvious) divergence in the foundations of consumer protection law between English law and EU jurisprudence. However, reform of the relevant Directive is under active consideration, with an impact assessment in 2021 specifically mooting the possibility of reversing the burden of proof and/or harmonising the use of presumptions (arising, for example, from the fact of withdrawal of a product from market). No decision has been made as yet as to whether those policy choices will be included in the reforms deemed necessary for the digital era. As to whether English law will remain aligned with any changes made by the Commission to the allocation of the burden of proof or the use of presumption, is likely to be, following the UK's exit from the EU, a question for Parliament, rather than the Courts.

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