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Product liability: the evidential burden

Hastings v Finsbury Orthopaedics Limited and another (Scotland) (2022) UKSC 19

This appeal concerned a metal–on–metal ("MoM") prosthetic hip called the MITCH-Accolade product. The MITCH–Accolade product was manufactured by the respondents. The appellant, Mr Hastings, underwent a total hip replacement using the MITCH–Accolade product in 2009. The appellant claimed that the replacement hip used in that operation was defective. He sought damages under the Consumer Protection Act 1989 (the "CPA"). At first instance, the issues in this case were limited to the question of whether the product used in the appellant's operation was 'defective' within the meaning of the CPA.

It was common ground at proof that the statistical evidence presented to the court was not sufficient of itself to establish that the MITCH–Accolade product was defective. As a result, the appellant presented his case on two main bases. First, he sought to prove that the MITCH–Accolade product was defective by demonstrating certain design flaws. Secondly, he relied on matters which were said to constitute prima facie evidence that the MITCH–Accolade product was defective. In particular, the appellant relied on three matters:

(1) expressions of professional concern by the orthopaedic community,

(2) the conduct of the respondents in withdrawing the MITCH–Accolade product from the market and

(3) certain notices and alerts issued by regulators and by the respondents.

At proof, the respondents relied upon evidence of biostatistics from Professor Platt which was unchallenged by the appellant. The parties were agreed that Professor Platt's evidence demonstrated that there was no reliable statistical evidence that the revision rate of the MITCH–Accolade product was out of line with the relevant benchmarks. The 'revision rate' of a prosthesis is

the percentage chance that revision surgery will be required to replace the prosthesis in a given time period.

At first instance, the Outer House held after a preliminary proof that the appellant had failed to prove that the MITCH–Accolade product was defective for the purposes of the CPA.

The Inner House refused the appellant's reclaiming motion. The appellant now appealed to the Supreme Court. The appellant submitted that, notwithstanding the evidence of Professor Platt, it was open to the appellant to prove his case by reference to the evidence that established a prima facie case that the MITCH–Accolade product was defective. On appeal, the appellant had not sought to pursue his case regarding the alleged design flaws in the MITCH–Accolade product. The central question which arose on this appeal was thus whether the courts below were correct to find that, notwithstanding the prima facie evidence, the appellant had failed to prove that the MITCH–Accolade product is defective.

The Supreme Court unanimously dismissed the appeal.

This appeal was unusual in that the legal issues concerning the application of the CPA were largely agreed. The basic principles might be summarised as follows. The CPA (and the EU directive which it implemented) had introduced a system of no–fault liability in respect of defective products. The test of whether a product was defective was whether the safety of the product was not such as persons generally were entitled to expect. The burden of proof was on the consumer to establish a defect and a causal link to the injury.

The nature of the MITCH–Accolade product was such that there could be no entitlement to an absolute level of safety. The test of entitled expectation was whether the level of safety of the MITCH–Accolade product would not be worse, when measured by appropriate criteria, than existing non–MoM products that would otherwise have been used. On appeal, the sole criterion of entitled expectation relied upon was the revision rate.

The appellant failed to establish his case on a statistical basis. The question which now arose for consideration was whether the rejection of the statistical evidence nevertheless left prima facie evidence on which the appellant could rely to prove his case. The Supreme Court considers that it did not. The three matters relied upon as prima facie evidence were addressed in turn.

The generalised expressions of professional concern did not assist the appellant in establishing that the MITCH–Accolade product was defective because they related to the performance of MoM prostheses in general. The first instance judge found that the withdrawal of the MITCH–Accolade product from the market was brought about by commercial considerations. As a result, the withdrawal did not provide any support for the appellant's case that the product was defective. Nor did the notices and alerts issued by regulators and the respondents assist the appellant. The evidence on which these notices and alerts were based appeared to support a failure to meet the applicable standard of entitled expectation. However, Professor Platt's reasons for considering that the appellant's case of a breach of entitled expectation was not made out on a statistical basis applied equally to this category of prima facie evidence. Professor Platt's evidence contradicted the information which formed the basis of the alerts and safety notices.

The appellant submitted that because there was limited available data on revisions in respect of the MITCH-Accolade product the true revision rate could be considerably different from the estimates based on the available data. However, the first instance judge rejected the appellant's arguments

regarding the limited available data. The judge held that the appellant had failed to prove the existence of a defect. Ultimately, this appeal was no more than an attempt to appeal against the judge's findings of fact which supported that conclusion. The appellant had failed to provide any basis for the Supreme Court to interfere with those findings.

The full judgment may be found at: https://www.bailii.org/uk/cases/UKSC/2022/19.html

Commentary provided by Deputy Head of FOIL's Product Liability SFT**, Karishma Paroha,** of **Kennedys:**

The decision reinforces the approach to the question of 'defect' under the CPA, as previously determined by the English High Court in the landmark product liability cases of *Wilkes v DePuy International Limited (2016)* ("Wilkes") and *Colin Gee & Others v DePuy International Limited (2018)* ("Gee"), in which Kennedys represented the successful defendant manufacturer.

Samantha Silver, the Partner at Kennedys who led the case for the respondent manufacturers, said:
"This judgment is the final chapter in a body of judicial opinion in the UK which has considered the approach to defect in the context of medical devices and medicinal products but which will be binding on all future product liability actions brought in the UK courts.

With new products developing at pace across all sectors, the landmark cases of Wilkes, Gee and now Hastings, recognise the need to balance consumer protection with safeguarding innovation.

The Supreme Court's detailed and authoritative ruling will provide particular assurance to manufacturers in the life sciences and healthcare sectors where medical innovation continues to break new ground".