

## **Hickinbottom J clarifies “defect” under s.3 of the Consumer Protection Act 1987**

**By James Purnell**

**In a rare and important product liability decision concerning s.3 of the Consumer Protection Act 1987, *Wilkes v DePuy International Limited* [2016] EWHC 3096 (QB), Hickinbottom J departs from Burton J’s approach to “defect” in *A v National Blood Authority* [2001] 3 All ER 289.**

### **Introduction**

- I. It has been more than 15 years since Mr Justice Burton handed down judgment in *A v National Blood Authority* [2001] Lloyd’s Rep Med 187, hitherto the most detailed consideration of the statutory product liability regime in England and Wales as provided for by the Consumer Protection Act 1987 which implements EC Council Directive 85/374/EEC. That decision has been the subject of considerable academic criticism<sup>1</sup>, but has yet to receive any detailed consideration by higher courts. Now, Burton J’s approach to the concept of “defect” has received firm and respectful disagreement in a significant first instance decision handed down by Mr

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<sup>1</sup> See, for example, Miller and Goldberg *Product Liability* (2<sup>nd</sup> edn); Fairgrieve and Howells “Rethinking Product Liability: A Missing Element in the European Commission’s Third Review of the European Product Liability Directive” (2007) 70(6) MLR 962; and Stapleton “Bugs in Anglo-American Products Liability” 53 South Carolina LR 1225

Justice Hickinbottom on 6 December 2016 in *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB).

2. Hickinbottom J has been until now the managing judge of the co-ordinated metal-on-metal group litigations which are progressing in the QBD and in which the first trials on the issue of “defect” are due to take place in respect of two manufacturers’ metal-on-metal hip prostheses in October 2017. Hickinbottom J moves up to the Court of Appeal in January 2017 and so will shortly be replaced as the managing judge. In *Wilkes v DePuy*, which was a unitary action being tried on a preliminary issue outside of the group litigation, the judge has added a significant decision to the product liability jurisprudence from which defendant manufacturers will derive much assistance.

### **The facts**

3. The claim arose from a total hip replacement implant in January 2007. Three years later, as he was walking out of his kitchen at home, the Claimant felt his left hip give way. He had suffered a fracture in the neck region of the stainless steel femoral stem component. The neck of the stem had a machined thread around it which was designed to even out the stresses within the head component. The Claimant contended that the stem was defective in design, because persons generally would not have expected the stem to suffer from early fracture in this way.
4. DePuy denied defect on the basis that fatigue fracture of the femoral stem was a rare but recognised risk; it was noted in the IFU as one of the generally most frequently encountered adverse events; and the stems had been subjected to testing which complied with the relevant British standard.

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### Hickinbottom J's decision

5. Hickinbottom J's decision carefully considers the relevant jurisprudence and academic commentary, including extensive citation from the chapter written by **Charles Gibson QC**, **Geraint Webb QC** and **James Purnell**, all of Henderson Chambers, entitled "**Product liability for medicinal products**" in the book "Clinical Negligence" edited by Powers QC & Barton (5<sup>th</sup> Edn, Bloomsbury Press, 2015), which the judge described as a "*commendable consideration of the issues surrounding*" product liability for medicinal products.
6. Crucially, in his judgment, the judge draws the following important conclusions:
  - a. "Safety" in the context of medicinal products and medical devices "*is inherently and necessarily a relative concept*" [13] and [65]. The significance of this should not be understated. It puts paid to any contention that for such products the risk of a warned adverse event *per se* renders a product defective. Given that such a product will inevitably have some risks attached, any assessment of its safety will necessarily require the risks involved in use of that product to be balanced against its potential benefits including its potential utility [82].
  - b. The purpose of the Directive and the CPA 1987 is not driven solely by the interests of consumers. The principle of "fair apportionment of risk" (as enunciated in the recitals to the Directive) does not inexorably lead to alleviating the consumer of risk [62]. The judge noted that the Directive aimed to ensure, amongst other things, that competition in respect of the supply of goods is fair across Europe and that "*it would be wrong for domestic law to distort the balance of risk-*

*bearing between producers and consumers of products set by the Directive” [79].*

- c. Burton J’s pronouncement in *A v NBA* that the “*first step must be to identify the harmful characteristic which caused the injury*” distracts from the true focus of the Directive and the CPA 1987, which is on ascertaining whether there is a defect and if so what that defect might be [58].
- d. The level of safety that persons generally are entitled to expect “*is not assessed by reference to actual expectations of an actual or even a notional individual or group of individuals*” [69]. The test of what persons generally are “entitled to expect” requires no gloss and does not benefit from being re-described as “legitimate expectation” [71].
- e. A claimant is not required to prove the cause of the lack of safety, or why the product failed (following *Ide v ATB Sales Ltd* [2008] EWCA Civ 424) – although it may be helpful to do so. However, a claimant must prove causation in the sense of showing a causal link between the defect and damage [73].
- f. There are no restrictions on the relevant circumstances which should be taken into account in assessing the safety which persons generally are entitled to expect [77]. The issue of defect is “*necessarily one of open-textured judgment, untrammelled by any rigid rules outside the few that appear in the Act itself*”.
- g. For the purpose of determining safety, the focus must be on the product itself and not to concentrate “*unduly*” upon the acts and omissions of the designer/producer [83] [85]. Thus the cost or avoidability of the risk may be relevant, although in respect of a

medical device product such as a prosthesis, “*a detailed consideration of the discrete question of whether a particular risk is or is not avoidable is unlikely to be fruitful*” [85]. Such issues ought not be considered discretely in a vacuum, but may bear upon the issue of the level of safety that the public generally is entitled to expect [89].

- h. Whether a particular product is within the producer’s specification, and is compliant with relevant standards, may be a relevant circumstance. However, Burton J’s categorisation of defects into “standard”/“non-standard” is unnecessary and undesirable, positively unhelpful and potentially dangerous [94]. Such classification is a distraction from the exercise that the court is required to undertake, namely consideration of the appropriate level of safety taking into account all relevant circumstances.
- i. In an appropriate case, compliance with mandatory standards and the regulatory regime, whilst not providing a complete defence, will have considerable weight because they have been set at a level which the appropriate regulatory authority has determined is appropriate for safety purposes [98].
- j. Insofar as Burton J concluded that the knowledge of risk by the medical profession was an irrelevant consideration, Hickinbottom J expressed firm but respectful disagreement. In the judge’s view, it is “*unarguable*” that the fact that there is a learned intermediary who has chosen a particular prosthesis for a particular patient and has available, not only his general professional knowledge, but also the specific IFU including warnings is anything other than a relevant circumstance [108].

7. The judge concluded on the facts that the stem did not fall below the safety that persons generally were entitled to expect at the time it was put into circulation; and thus it was not defective for the purposes of the CPA 1987:
  - a. The product complied with all relevant mandatory standards and satisfied all of the regulatory requirements. The product's fatigue failure rate complied with the relevant British Standards.
  - b. The fact that the neck thread could have been avoided fails to take account of possible design disadvantages of such changes. It would not be appropriate to design out entirely the single risk without regard for other design features. Furthermore, having a stem with which metal or ceramic heads could be used interchangeably had benefits in practice.
  - c. The IFU clearly and unambiguously warned that "*fatigue of the femoral stem*" was "*generally*" one of "*the most frequently encountered adverse events*". Biomechanical variability made reliable prediction impossible, but the IFU did identify factors which were associated with such failure.
  - d. The risk of stem fracture was small and the consequences if the adverse event occurred (namely a revision operation) were "*relatively limited*".
8. Given his conclusion on defect, the judge held that it was unnecessary to consider causation. The Claimant had submitted that if the court had been satisfied that the level of safety was less than it ought to be, the court should readily find causation proved on the basis of material contribution. DePuy contended that where the claimant's case was based upon a defect

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causing an increased risk, then the general principle set out in cases such as *XYZ v Schering Health Care Limited* [2002] EWHC 1420 (QB) should apply, i.e. the claimant is required to prove that the risk of the adverse event had more than doubled. In light of the judge's ruling, consideration is left over for another case in which those matters might be determinative. For a fuller discussion of that debate, the reader is directed to the passage entitled "**The role of epidemiology and statistics**" in the section entitled "Causation" within Chapter 13 of Powers & Barton (5<sup>th</sup> Edn), written by **Charles Gibson QC**, **Geraint Webb QC** and **James Purnell**.

### Analysis

9. It is notable that although the CPA 1987 came into force in 1988, there have been remarkably few reported decisions regarding Part I of the CPA 1987 at all. Until now, the case that took the most detailed look at the key concept of "defect" was the 2001 decision of Burton J in *A v NBA*. In light of its sheer volume and longevity, (it is described by Hickinbottom J as a "*monumental judgment*"), the decision of Burton J has always stood monolithically as something which producers have had to invite the court to approach with caution or seek to distinguish on the basis that its construction and application of the CPA 1987/Directive was wrong in certain respects or should not be followed in the context of a prescription medicine or medical device subject to statutory regulation. As a result of this new decision by Hickinbottom J, such a submission is made immeasurably easier. In that regard, Hickinbottom J's decision will not be unhelpful in any subsequent case which may seek to distinguish Burton J's construction and application of the "development risk defence" in *A v NBA*, which was not in issue in this decision.

10. Hickinbottom J’s decision provides much needed clarity on the proper approach to defect under s.3 of the CPA 1987 and the relevant circumstances which may be taken into account when assessing the level of safety that persons generally are entitled to expect. In particular:
- a. The focus of the exercise should be on identifying whether there is a defect and if so what it is, rather than what is “the harmful characteristic which caused the injury”.
  - b. Relevant circumstances, in the context of a medicinal product or medical device, plainly include the risk/benefit profile, the regulatory regime, the role of the learned intermediary and warnings provided to prescribers/surgeons.
  - c. Categorisation of defects into “standard”/“non-standard” is unnecessary and undesirable.
11. The defendant manufacturers to the 2017 metal-on-metal GLO trials will no doubt regret that Hickinbottom J will not be their trial judge. However, he leaves them with a helpful and clear exegesis on the concept of “defect” within the CPA 1987, which will no doubt take its place as an important and persuasive precedent in product liability jurisprudence.

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James Purnell is recognised as a leading junior in the directories in the field of Product Liability. He is currently instructed in one of the metal-on-metal hip group actions. With Charles Gibson QC and Geraint Webb QC, he co-authored the chapter entitled entitled “*Product liability for medicinal products*” in the book “*Clinical Negligence*” edited by Powers QC & Barton (5<sup>th</sup> Edn, Bloomsbury Press, 2015), which the judge described as a “*commendable consideration of the issues surrounding*” product liability for medicinal products.

Several members of Henderson Chambers are instructed for various manufacturers in the metal-on-metal hip group actions, in which the first trial of issues is due to commence in October 2017.