Pinnacle Metal on Metal Hip Group Litigation

(*Gee & Others v DePuy International Limited*)

[2018] EWHC 1208 (QB)

A landmark decision in field of product liability law and definition of defect

A case summary and analysis by Alexander Antelme QC, David Myhill and Richard Sage.

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1. On 21 May 2018, Andrews J handed down judgment in the DePuy Pinnacle Metal-on-Metal hip group litigation *(Gee & Others v DePuy International Limited* [2018] EWHC 1208 (QB)) ("the Pinnacle Litigation"), finding that DePuy's product was not defective, and determining the preliminary issue entirely in its favour. The judgment is likely to become the leading case on the definition of defect under the Consumer Protection Act 1987 ("the CPA").

2. DePuy was represented throughout the four-month long trial by a team from Crown Office Chambers: Alexander Antelme QC, Michael Spencer QC, David Myhill, Richard Sage and Lara Knight, instructed by Kennedys.

Background to the litigation

3. The Pinnacle Litigation was a substantial group action in its own right; but was one of a number of group actions and groups of claims brought under the CPA against producers of Metal-on-Metal ("MoM") total hip replacements and resurfacing products introduced in the early 2000s. The Pinnacle Litigation was selected to proceed to a trial of a preliminary issue as to whether DePuy was liable to the Claimants in respect of its Pinnacle Ultamet total hip replacement, subject to any development risk defence, in the hope that resolution of these claims would provide guidance for claims against other manufacturers (which had been stayed pending the outcome of this litigation).

4. Representatives of manufacturers and Claimants in these other actions were permitted to make written closing submissions; however, the evidence at trial concerned the Pinnacle Ultamet alone.

The decision in the Pinnacle Litigation

<u>The facts</u>

5. The Pinnacle Hip System is a modular total hip replacement introduced in the early 2000s. Different femoral heads can be paired with different acetabular liners, depending on the demands and needs of the patient. The Pinnacle Litigation was concerned with the MoM articulation - known as the Pinnacle Ultamet.

6. This was one of a new generation of implants designed to address the shortcomings with traditional total hip replacements experienced during the 1990s. That generation of products had comprised a metal femoral head which articulated against a polyethylene surface. Such prostheses gave good function but carried many limitations which made surgeons wary of implanting them in the younger, more active, patient: in particular, they carried significant risks of osteolysis (caused by polyethylene debris generated by usage) which would necessitate revision surgery, and of dislocation. Patients could expect such implants to last 10-15 years.

The Claimants' case

7. The Claimants argued that the Pinnacle Ultamet was defective, within the meaning of the CPA. They argued that it had a 'tendency' to cause a soft tissue reaction around the hip known as an Adverse Reaction to Metal Debris ("ARMD"), but also pursued an alternative case that it had an 'abnormal propensity' to cause ARMD. At trial, the focus of the generic evidence was on engineering features alleged to have increased the risk of creating metal debris and on statistics said to demonstrate that Ultamet performed poorly compared to other bearing surfaces in the Pinnacle System and those made by other manufacturers.

The law: what makes a product defective under the Consumer Protection Act?

8. The Claimants argued that the Pinnacle Ultamet's 'tendency' to cause ARMD was itself the defect under the CPA – despite the fact that the development of ARMD is one of the normal risks inherent in the use of the product. Whilst the Claimants relied on various 'circumstances' such as an elevated revision rate to demonstrate the defect, their primary case was that these 'circumstances' did not constitute the defect for the purposes of the CPA.

9. The Court rejected that argument, which was based on the Claimants' interpretation of the CJEU decision in *Boston Scientific*.[1] Following *Wilkes*[2] and rejecting the analysis in *A v NBA*[3], the Court

[1] *Boston Scientific Medizintechnik GMbH v AOK Sachesn-Anhanlt-Die Gesundheitskasse* (Case C/503/13, 504/13) [2015] 3 CMLR 173
[2] *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB) [2018] 2 WLR 531 [2017] 3 All ER 589
[3] *A v National Blood Authority* [2001] 3 All ER 289

found that the Claimants' primary approach to defect to be *'directly contrary to the spirit and objectives of the Directive and the Act'*. Instead the Judge found, accepting DePuy's submissions, that a defect is characterised in such a product by the abnormal potential for harm – i.e. the feature which increases the underlying risk beyond the level of safety that the public is entitled to expect.

10. The Court also followed the decision in *Wilkes* in preference to *A v NBA* in deciding what circumstances a court could take into account in deciding whether a product was defective within the meaning of the CPA. In particular, the Court held that:
    10.1. A Court must maintain a flexible approach to the assessment of the appropriate level of safety. The relevant circumstances and weight given to these will vary from case to case.[4]
    10.2. A product's benefits, cost and avoidability were features which could, in appropriate cases, be taken into consideration when assessing whether a product is defective.[5]
    10.3. The rigid distinction between standard and non-standard products used by Burton J in *A v NBA* was to be rejected, although it might be a useful starting point in the analysis of whether a product is defective.[6]
    10.4. The existence of a learned intermediary (such as a surgeon) and warnings provided to that intermediary are relevant circumstances in assessing defect under the CPA, the weight given to which will differ from case to case.[7]
    10.5. In an appropriate case evidence of compliance with regulatory standards will have considerable weight, because they have been set at a level that the appropriate regulatory authority has determined is appropriate for safety purposes.[8]

11. In light of its findings on defect the Court declined to rule on what a claimant must establish in order to prove causation, where the defect is one which increases a background risk inherent in the product. DePuy had argued that a doubling of the risk was required; that point will have to be resolved on another occasion.

[4] Paras 139 - 143
[5] Paras 144-167
[6] Paras 157 - 160
[7] Paras 168 - 169
[8] Paras 170 - 178

Engineering evidence

12. The Claimants sought to prove that the Ultamet was defective by calling expert engineering evidence regarding its design and manufacture. That case fell away. The argument concerning alleged manufacturing problems and the clearance (i.e. distance) between the head and liner was abandoned after cross-examination of the Claimants' experts. The remainder was dismissed by the judge, who found (at [483]) the case to be based on *'little more than speculative theories that fell a long way short of establishing that any of the features… gave rise to any significant increase in the likelihood of metal wear in this particular prosthesis, or the generation of higher levels of metallic debris…'.* She concluded that '*My impression of the Pinnacle system, taken from the evidence as a whole, was that it was a well-designed product with many positive engineering features.'*

Statistical evidence

13. The Claimants relied heavily on statistics from various sources to argue that the cumulative revision rate for Ultamet at 10 years post-implantation was materially higher than comparable protheses. As a starting point, the Court found that in the early 2000s, the cumulative revision rate ("CRR") for the previous generation of prosthetic hip implants was around 15% at 10 years. The NICE Guidelines issued in 2000 suggested that better performing prostheses would have a revision rate of around 10% at 10 years.

14. As to the Ultamet and other products of its generation, the Claimants relied heavily upon statistics regarding the revision rate of the Ultamet prosthesis taken from (amongst other sources) the National Joint Registry ("NJR"). The Court concluded that the public was entitled to expect that the 36mm Pinnacle MoM prosthesis (irrespective of the stem used) would not have a much greater risk of failure in the first 10 years after implant than the *expected* failure rate over that period for the product it was designed to improve upon (i.e. uncemented metal on conventional polyethylene).

15. Insofar as there was a need for an actual comparator (i.e. the prosthesis the Claimants would have received had they not received the Ultamet), the Court held that this was an uncemented Metal-on-Polyethylene ("MoP") implant. It rejected the Claimants argument that the Ultamet should be compared with the performance of the other bearing surfaces within the Pinnacle system.

16. The Court accepted DePuy's argument that these statistics were unreliable; in particular, the data was subject to a number of limitations and confounding factors:

    16.1. The NJR did not record data on activity. This is a major variable which affects to the survival of a hip implant. There were many reasons why a surgeon might have chosen to use the Ultamet product for a younger, more active patient, over a different bearing surface.

    16.2. The data relied upon had a systematic bias in the reporting of Body Mass index, which had the potential to be a confounding factor.

    16.3. The data regarding the Ultamet contained a small number of outlying surgeons with a very high revision rate who had a significant effect on the overall statistics.

    16.4. The NJR data – both generally and in in respect of the Ultamet – was incomplete, which impacts the reliability of the statistics. There was very little actual long-term data.

    16.5. The NJR data on MoP conflated older polyethylene (which is still sold) with another new bearing surfaces introduced in the 2000s, highly cross-linked polyethylene, which has different properties and encouraging early results in respect of its wear characteristics.

    16.6. A different type of MoM hip prosthesis was withdrawn in 2010 and guidance was given by the MHRA which led to enhanced surveillance of MoM hips compared to other bearing surfaces. This meant that problems were identified which might not have been identified with other bearing surfaces, leading to a higher number of revisions for MoM prostheses. This was compounded by the fact that some surgeons had failed to follow the MHRA guidelines and had adopted their own, lower, threshold for revision of MoM prostheses.

    16.7. A panic fuelled by sensationalist media reporting had an impact on the revision rates.

17. The Court could not safely rely on the latest 10 year CRR for the Ultamet (13.98%) reported by the NJR because of the limitations identified above in respect of that data. The data in respect of the comparator prostheses was similarly unreliable. The Court therefore concluded that the claimants had failed to establish that the Ultamet was defective within the meaning of s3 of the CPA.

The lead cases

18. The preliminary issue was tried by way of 6 lead cases. In two of these, DePuy admitted that the Claimant had suffered ARMD (but denied that their prostheses were defective). In the remainder, DePuy had disputed the diagnosis of ARMD. The Court heard evidence from the Claimants themselves, the revision surgeons, and experts in orthopaedics, radiology and histopathology. In each of the four disputed cases the Court found in DePuy's favour.

Discussion

19. This is self-evidently an important decision to producers of MoM prostheses who are facing claims in separate group litigation. It is also a welcome decision bringing greater clarity to this area of law, by resolving the tension between *A v NBA* and *Wilkes* clearly in favour of the *Wilkes* approach. The Court's discussion of the factors to be taken into account when deciding whether or not a product is defective under the CPA is likely to become the definitive judgment in the field of Product Liability law.

20. Producers are likely to welcome the Court's acknowledgment that factors such as risk-benefit and avoidability are relevant in deciding whether or not a product met the level of safety that the public generally is entitled to expect. The judge's endorsement of "*a flexible approach to the assessment of the appropriate level of safety*" is expected to give producers greater scope for defending product liability actions.

21. Producers will also appreciate the court's endorsement of DePuy's submission that where a product includes a feature which gives it a potential functional advantage, or eliminates a perceived deficiency in design, but by doing so necessarily introduces a risk, the Court should not be prevented from considering the actual or potential benefit when assessing whether the product is defective. The safety risk may be one that, objectively, the public would be expected to accept, bearing in mind the benefits that the product would confer.[9]

[9] Para 153

22. Overall, the endorsement of a flexible and simple approach to the question of defect in products should be welcomed by producers and potential Claimants alike by avoiding an increasingly technical approach to the CPA which risked losing sight of the balance between consumers and producers which the CPA aimed to provide.

The Product Liability Team at Crown Office Chambers

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