Neutral Citation Number: [2018] EWHC 1208 (QB)

Case No: HQ 12X01255 & others

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 21 May 2018

Before:

THE HONOURABLE MRS JUSTICE ANDREWS DBE

Between:

COLIN GEE and others	**Claimants**
- and –	
DEPUY INTERNATIONAL LIMITED	**Defendant**

THE DEPUY PINNACLE METAL ON METAL HIP LITIGATION

Robin Oppenheim QC, Hugh Preston QC, Jonathan Bertram, Marcus Pilgerstorfer, Louise Price and Tim Cooke-Hurle (instructed by **Leigh Day**) for the **Claimants**
Alexander Antelme QC, Michael Spencer QC, David Myhill, Richard Sage and Lara Knight (instructed by **Kennedys**) for the **Defendant**

Hearing dates: 16 October 2017 – 26 January 2018

Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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THE HONOURABLE MRS JUSTICE ANDREWS DBE

Colin Gee and others -v- Depuy International Limited (The Depuy Pinnacle Metal on Metal Hip Litigation) Press Summary 21 May 2018

1. The Defendant ("DePuy") is the manufacturer of a hip prosthesis system for use in total hip replacement operations, known as the Pinnacle Acetabular Cup System ("the Pinnacle system") which was first introduced in the UK in 2002. The Pinnacle system is an uncemented modular system, within which different articulating surface combinations were available. Surgeons could select the materials from which the femoral head and liners to the acetabular cup were made, to produce the combination of materials which they thought best suited the patient.

2. The claims in this Group Litigation were brought against DePuy by 312 individual claimants who were implanted with one or more Pinnacle prostheses where both the acetabular liner and the femoral head were made of a metal alloy, giving a Metal on Metal ("MoM") articulation. In most cases the femoral head was 36mm in diameter. Each claimant claimed to have suffered an adverse immunological reaction to metal wear debris generated by their prosthesis, which brought about damage to the soft tissues around the prosthesis, necessitating revision surgery to replace some or all of the components. The claims were case managed together pursuant to a Group Litigation Order which was approved on 31 July 2014. There were six lead claims selected from among the claimants on the group register.

3. The claims were brought under Part 1 of the Consumer Protection Act 1987 ("the Act") which implements in England and Wales the Product Liability Directive 1985. ("the Directive") The claimants' case was that the prostheses supplied to them were defective within the meaning of s.3 of the Act and that this caused them personal injury for which DePuy is liable to compensate them. A product is "defective" when, in all the circumstances, it fails to meet the standard of safety that the public generally is entitled to expect at the time when it is introduced to the market.

4. Most, if not all, producers of hip prostheses manufactured MoM articulations during the 2000s. Legal proceedings have been commenced in this jurisdiction against all, or almost all, manufacturers of such prostheses. The other actions were stayed pending the outcome of this trial. Although the findings of the court are not binding on parties to those other proceedings, it is hoped that they will provide them with guidance. For that reason, and in order to ensure, so far as possible, that the relevant legal arguments were comprehensively addressed, permission was granted for interested parties to make additional written submissions on the law.

5. This is my judgment following the trial of a common preliminary issue, namely "*whether or not the defendant is liable to the claimant, subject to any development risk defence.*" It encompassed any issues of causation.

6. The trial took four months. I heard evidence from a wide variety of experts in disciplines ranging from orthopaedics to mechanical engineering, from histopathology to statistics. I also heard evidence from five of the six lead claimants, and from the surgeons who carried out the revision operations on four of them. Apart from the excellent written and oral submissions of the teams of counsel representing the parties to this Group Litigation, I received extensive written submissions on the legal issues from six legal teams representing non-party claimants and non-party defendants. I am

very grateful to everyone concerned for their hard work and for the clarity and thoroughness with which they addressed the issues.

7. For the reasons more fully set out in my necessarily lengthy judgment, I have concluded that:

   i) The inherent propensity of a MoM hip to shed metal debris through normal use, to which some patients may suffer an adverse immunological reaction, is not a "defect" in the product within the meaning of the Act and the Directive. It did not become a "defect" by reason of the recorded incidence of such adverse reactions or the calculated risk of the probability of the revision of the prostheses on account of them.

   ii) On their alternative case, the Claimants failed to prove that the Pinnacle 36mm MoM prosthesis did not meet the level of safety that the public generally were entitled to expect at the time when it entered the market in 2002. I was unable to conclude on the balance of probabilities that there was a materially greater risk of a Pinnacle 36mm MoM prosthesis failing within the first 10 years after implant than a comparator prosthesis, and thus that the product carried with it an "abnormal risk" of damage as alleged.

   iii) Accordingly, DePuy is not liable to the Claimants.

   iv) In four out of the six lead claims, the Claimants did not suffer an adverse reaction to metal debris.

NOTE: This summary is provided to help in understanding the Court's decision. It does not form part of the reasons for the decision.

damage, with the result that the defect and the causal link may reasonably be considered to be established."

It is clear from this decision that any interpretation of a domestic statute which would operate in a way that obviated the necessity for a claimant to prove the defect, or the causal link between defect and damage, would be as much contrary to the objectives of the Directive as a provision that had the practical effect of widening the limited defences available to a producer under Article 7.

2.2 THE MEANING OF "DEFECT"

81. Section 2(1) of the Act provides that:

"*where any damage is caused wholly or partly by a defect in a product, every person to whom subsection (2) below applies shall be liable for the damage.*"

Article 1 of the Directive provides that "*the producer shall be liable for damage caused by a defect in his product*" and Article 4 states that "*the injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage*". It is therefore clear that, consistently with the Directive, the Act creates a liability without fault, and that all that the claimant needs to prove is (1) that there was a defect in the product in question and (2) that the defect caused him to suffer damage. The nature of the liability imposed is unique to the Act, based on the definition of defect.

82. Section 3 of the Act defines "defect" as follows:

(1) Subject to the following provisions of this section, there is a defect in a product for the purposes of this Part if the safety of the product is not such as persons generally are entitled to expect; and for those purposes "safety", in relation to a product, shall include safety with respect to products comprised in that product and safety in the context of risk of damage to property, as well as in the context of risks of death or personal injury.

(2) In determining for the purposes of subsection (1) above what persons generally are entitled to expect in relation to a product all circumstances shall be taken into account, including –

(a) the manner in which, and purposes for which, the product has been marketed, its get up, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product;

(b) what might reasonably be expected to be done with or in relation to the product; and

(c) the time when the product was supplied by its producer to another;

and nothing in this section shall require a defect to be inferred from the fact alone that the safety of a product which is supplied after that time is greater than the safety of the product in question."

83. Article 6 of the Directive provides as follows:

"*1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:*

(a) the presentation of the product;

(b) the use to which it could reasonably be expected that the product would be put;

(c) the time when the product was put into circulation.

A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation."

84. It was common ground that the level of safety that the public is entitled to expect must be evaluated at the time when the product is first put on the market by the producer, though strictly speaking, that time is one of the circumstances which the Court must take into account. However, in determining whether the product met that level of safety, 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. That is obviously the correct approach, otherwise a claimant would never be able to establish that a product, whose lack of safety only comes to light one or two years after it was first marketed, was defective at the time of its initial circulation.

85. Section 3 of the Act and Article 6 of the Directive have subtle linguistic differences, but these are easy to reconcile in such a way as to produce consistency of interpretation in line with the objectives of the Directive. The Directive refers to "the safety which *a person* is entitled to expect" whereas the Act, reflecting the sixth recital to the Directive, refers to "the safety [that] *persons generally* are entitled to expect." The test is an objective one. By using the words "*persons generally*," Parliament has clearly removed any room for misunderstanding that the expression "*a person*" might have created, since in this jurisdiction, negligence liability is determined by the standards of the hypothetical reasonable person. Under the Act, the standard of safety is not measured by what such a person might reasonably expect, but by what anyone (and thus, the public at large) is *entitled* to expect in all the circumstances.

86. Whilst s.3 of the Act uses the phrase "there is a defect in a product" and Article 6 uses the phrase "a product is defective" they are describing the same thing. The CJEU put this beyond doubt in *Sanofi Pasteur* at [22], stating that:

"the concept of "defect" within the meaning of [Articles 1 and 4 of the Directive] is indeed defined in Article 6 thereof."

The concept of "defect" introduced by the Directive is an autonomous one, defined in terms of failure to meet an objective standard of safety that the Court must evaluate. If it is unsafe by that standard, it is defective. The "defect" is therefore defined by reference to the condition of the product itself, i.e. the product's failure to meet that level of safety, rather than by reference to some fault or deficiency in it, or any precise mechanism that caused the damage. Indeed, it may be impossible to determine what the mechanism was.

87. Thus, the dictionary definition or the normal understanding of the word "defect" plays no part in determining whether a product is defective (or whether there is a defect in it) within the meaning of the Directive or the Act. The Court's focus should be on whether the product is safe, as measured by the test in s.3, rather than on whether there is a specific fault in it. Of course, there may be more than one reason why the product is unsafe: if the lack of safety is due to a combination of circumstances or features, then it is that combination which makes the product defective; but the defect will still consist of whatever it is about the character, state or condition of the product that makes it unsafe.

88. Article 7 (e) of the Directive provides that it is a defence for the producer to prove "*that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.*" This is the so-called "development risk defence" that was enacted in domestic legislation in s.4 (e) of the Act, which provides that in respect of a defect in a product it shall be a defence for the producer to show:

"*that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control.*"

89. The European Commission took issue with that formulation. They brought proceedings before the CJEU seeking a declaration that the UK had failed properly to implement the Directive: (Case C-300/95) *Commission v United Kingdom* [1997] 3 CMLR 923. The Commission argued that the defence under Article 7(e) was narrower than the defence under s.4(1)(e) and that the latter test was easier to satisfy. They also claimed that the national provision had the effect of transforming strict liability into a liability founded on negligence.

90. The CJEU disagreed. They accepted the argument of the UK that the test under Article 7(e) was objective, that the "*state of scientific and technical knowledge*" is a reference to the state of knowledge which producers of the class of the producer in question, understood in the generic sense, may objectively be expected to have, and that that was precisely the meaning of s.4(1)(e) of the Act. The court held that the wording of s.4(1)(e) of the Act did not suggest, as the Commission alleged, that the availability of the defence depends on the subjective knowledge of a producer taking reasonable care in the light of the standard precautions taken in the industrial sector in question. Moreover, there was nothing in the material before the court to suggest that the domestic courts would interpret that section in a manner inconsistent with the wording and purpose of the Directive.

91. The CJEU adopted the analysis of the Advocate General. It held, at [29], that in order to have a defence under article 7 (e) of the Directive, the producer of a defective product must prove that the objective state of scientific and technical knowledge, including the most advanced level of such knowledge, at the time the product in question was put into circulation was not such as to enable the existence of the defect to be discovered. Further, in order for the relevant scientific and technical knowledge to be successfully pleaded *against* the producer, that knowledge must have been accessible at the time when the product in question was put into circulation. On this last point, the court observed that article 7(e) of the Directive raises difficulties of interpretation which in the event of litigation the national courts will have to resolve, if necessary having recourse to Article 177 EC.

92. Although at this stage of the proceedings I am not concerned with the merits of any development risk defence raised by DePuy, s.4(1)(e) is relevant, to the extent that the word "defect" must be interpreted consistently in that section and the earlier sections of the Act in which it appears. Whilst that defence should not be interpreted in a manner that would re-introduce the need for proof of fault by the back door, it is equally important that the Act should not be interpreted in a manner which unjustifiably circumscribes the defence, to the detriment of the producer.

93. The standard of safety which the public is entitled to expect from each product at the time it enters the market is a matter of law, and it may differ from product to product. The Act and the Directive apply to virtually all products supplied to consumers (every "moveable" which is commercially supplied) – from household appliances to cars, from a bottle top to a medicine. It would be impossible to set a single yardstick for safety across such a wide range. The Council plainly wished to give the national courts sufficient flexibility to be able to address the issue of defect on a case by case basis, by reference to the circumstances pertaining to any one of a diverse range of products with diverse uses and characteristics, giving rise to diverse risks. There is no distinction drawn in the Directive, or in the Act, between different types of product – "standard" or "non-standard", for example, or between different types of defect – such as a manufacturing defect, a design defect or a warning defect, as in the US system. The definition of "defect" applies across the board, and the sole issue for the Court in determining whether a product is defective or not is whether it meets the standard of safety set out in s.3 of the Act.

94. What the public is *entitled* to expect may not match a person's actual expectation. As Burton J observed in *A v National Blood Authority* [2001] 3 All ER 289, (*"A v NBA"*) at [31]:

> *"the court decides what the public is entitled to expect... such objectively assessed... expectation may accord with actual expectation; but it may be more than the public actually expects, thus imposing a higher standard of safety, or it may be less than the public actually expects. Alternatively, the public may have no actual expectation – e.g. in relation to a new product."* (emphasis in the original).

The Court is given the task of determining what that standard is, by reference to "all the circumstances." The parties accepted that "all the circumstances" means "all the relevant circumstances" but there was considerable disagreement as to what type of circumstances will be legally relevant. I consider the rival arguments in Chapter 2 of this judgment, section 2.5, under the heading "legally relevant circumstances".

95. In *A v NBA* it was common ground that the phrase "*entitled to expect*" should mean what "*the legitimate expectation is of persons generally, i.e. what is legitimately to be expected arrived at objectively.*" Burton J adopted the formulation "legitimate expectation" in his judgment: a similar formulation can be found occasionally in the European cases, and Burton J said it was analogous to the formulation in other languages in which the Directive is published. Whilst it is understandable why, in those circumstances, Burton J adopted it as a convenient form of shorthand, I agree with the observations of Hickinbottom J (as he then was) in *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB) [2017] 3 All ER 589 ("*Wilkes*") at [71] that the test of what persons generally are "entitled to expect" does not benefit from being re-described in that way. The dangers of doing so are self-evident when the reformulation omits the essential word "entitled" and adopts a phrase which, in this jurisdiction, is used as a term of art in a very different context.

96. It is important to bear in mind that the test is not that of an absolute level of safety, nor is there an absolute liability for harm caused by a harmful characteristic. The Act does not impose a warranty of performance on a producer: *Pollard v Tesco Stores Ltd* [2006] EWCA Civ 393 at [17]. All hip prostheses will eventually wear out and fail, if the patient survives long enough, and some will fail within 10 years: the natural propensity of a hip implant to fail therefore cannot be a "defect," any more than the inevitable wear and tear that causes minute particles of debris to enter the patient's body. Otherwise all hip implants would be "defective", irrespective of the materials used in the articulation.

97. One might think it self-evident that if a product fails to meet the objective safety standard set out in Section 3 or Article 6, the defect is whatever it is about that product (its state, or condition, or the risks to health and safety or property that it poses) that leads the Court to conclude that it fails to meet the safety standard. In their final submissions the claimants contended that the appropriate approach to be taken by the Court was first to consider whether the product was defective, and only after answering that question in the affirmative, to proceed to identify the "defect" for the purposes of applying the causation test in Article 4 and any development risk defence. They suggested that it was not necessary to describe the defect until the subsequent part of the liability analysis is reached.

98. I cannot accept that approach, which disregards the burden on the injured party of proving the defect as well as the causal relationship between defect and damage. As Hickinbottom J observed in *Wilkes*, proof of a causal connection between defect and damage cannot rationally or even conceptually be attempted without ascertainment of whether there is a defect, and if so, what that defect might be. A producer is only liable under Article 1 for damage caused by a defect in his product. If there is no defect, the claim must fail. Section 2 of the Act sets out what the claimant must prove, consistently with Articles 1 and 4 of the Directive. Section 3 of the Act sets out the yardstick of safety by which a defect is established. One cannot divorce the defect from the concept of defectiveness in the manner suggested; they are two sides of the same coin.

99. In order to prove the defect, a claimant must establish what it is about the state or behaviour of the product or the risks that it posed that led it to fall below the level of safety that persons generally were entitled to expect at the time the product entered the market, although he need not prove the precise mechanism by which it came to

fall below that yardstick. The fact that a product fails following normal use and in circumstances in which a standard product would not have failed may suffice for the Court to draw the inference that it is defective, see e.g. *Ide v ATB Sales Ltd and Another [2008] EWCA Civ 424.* Thus, for example, if an electrical appliance bursts into flames if it is left plugged in, or a fridge explodes, it plainly does not meet the standard of safety that persons generally are entitled to expect, and it is unnecessary for the claimant to establish what caused it to catch fire or explode.

100. However, there may be circumstances in which a greater degree of specificity about a feature or characteristic that is said to make the product unsafe is required in order to prove the requisite lack of safety. That may be the case if the injury or damage complained of could have arisen even if the product met the objective standard of safety set out in s.3 of the Act, for example, in consequence of the manifestation of a known risk that could arise in normal use. Thus the claimant may have to establish that the failure of a product or a component in it was not due to ordinary wear and tear, but to something abnormal that caused it to fail when it should not have done; or that something must have happened to elevate the inherent risk to a level that was higher than the public was entitled to expect. *Wilkes* was an example of such a case, though on the facts the claim failed.

2.3 THE CLAIMANTS' PRIMARY CASE ON THE IDENTITY OF THE DEFECT

101. The claimants' pleaded primary case is that the "tendency or propensity" of the Pinnacle MoM prosthesis to result in identified harm (ARMD leading to early revision) constituted a "defect" when considered by reference to all the relevant circumstances. Mr Oppenheim QC submitted that what makes a product defective is its inherent *potential for damage*; or a harmful characteristic. The more detailed features of the case, including the degree of harm suffered, (in this case, the allegedly high incidence of early revision) amount to the relevant circumstances against which the Court decides whether the product was in fact defective, but do not themselves constitute the defect. He submitted that there is nothing in the Act or the Directive to preclude a defect from being characterised as the product's potential for damage, that it accords with the objectives of the Directive to do so, and that the CJEU had adopted such a characterisation in *Boston Scientific Medizintechnik GMbH v AOK Sachesn-Anhanlt-Die Gesundheitskasse* (Case C/503/13, 504/13) [2015] 3 CMLR 173 ("*Boston Scientific*").

102. The claimants' primary case involves the court taking the following approach:

i) It must identify a harmful characteristic (or potential for damage) in a product;

ii) It must consider all the circumstances (though the claimants say the relevant circumstances are circumscribed);

iii) It must decide if the circumstances render the product defective (i.e. it falls below the level of safety the public is entitled to expect);

iv) If the product is defective, the harmful characteristic *becomes the defect.*

v) To establish causation, one asks if, on the balance of probabilities, harm would have occurred if the product had not been defective.