FIRST DIVISION, INNER HOUSE, COURT OF SESSION

[2021] CSIH 6
A306/15

Lord President
Lord Menzies
Lord Woolman

OPINION OF THE COURT

delivered by LORD CARLOWAY, the LORD PRESIDENT

in the Reclaiming Motion by

JOHN HASTINGS

Pursuer and Reclaimer

against

(First) FINSBURY ORTHOPAEDICS LIMITED; and (Second) STRYKER UK LIMITED

Defenders and Respondents

Pursuer and Reclaimer: Milligan QC, Murray, Connelly; Thompsons
Defenders and respondents: McBrearty QC, E Campbell; Clyde & Co

26 January 2021

Introduction

[1] The pursuer sues the defenders for a breach of section 3 of the Consumer Protection Act 1987 on the basis that the total hip replacement, which he underwent in 2009, involved a "metal on metal" prosthesis which was "defective" in terms of that section. After a preliminary proof, the Lord Ordinary determined (2019 SLT 1411) that the pursuer had

failed to prove that his Mitch/Accolade prosthesis was defective. This reclaiming motion (appeal) is against the interlocutor of the Lord Ordinary dated 11 December 2019 which assoilzied the defenders. The issue is whether the Lord Ordinary's decision was correct. He essentially reached the same decision as had been made in England in *Gee* v *DePuy International* [2018] Med LR 347 relative to the Pinnacle MoM prosthesis.

[2] For ease of reference, the following acronyms are occasionally used:

ARMD	adverse reaction to metal debris
BMJ	British Medical Journal
CI	confidence interval
CoC	ceramic on ceramic
CoCr	cobalt chrome
CRR	cumulative revision rate
FSN	field safety notice
IFU	instructions for use
MDA	medical device alert
MHPRA	Medicines and Healthcare Products Regulatory Agency
MoCP	metal on conventional polyethylene (plastic)
MoM	metal on metal
MoP	metal on polyethylene
NIHCE	National Institute for Health and Clinical Excellence
NJR	National Joint Registry
NSHAR	National Swedish Hip Arthroplasty Register
ODEP	Orthopaedic Data Evaluation Panel
THR	total hip replacement

The Consumer Protection Act 1987

[3] The Consumer Protection Act 1987 provides:

> "1. *Purpose and Construction.*
>
> (1) This part shall have effect for the purpose of making such provision as is necessary in order to comply with the product liability Directive and shall be construed accordingly…
>
> (2) …'the product liability Directive' means the Directive of the Council of the European Communities, dated 25th 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.
>
> …

2. *Liability for defective products.*

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

(2) This subsection applies to –

(a) The producer of the product…

3. *Meaning of 'defect'.*

(1) … there is a defect in a product… if the safety of the product is not such as persons generally are entitled to expect; and for those purposes 'safety'… shall include … safety in the context of risks of… personal injury.

(2) In determining… what persons generally are entitled to expect in relation to a product all the circumstances shall be taken into account, including –

(a) the manner in which, and purposes for which, the product has been marketed … 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 was supplied after that time is greater than the safety of the product in question.

…

4. *Defences.*

(1) …it shall be a defence for [the producer] to show –

…

(e) that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description… might be expected to have discovered the defect…".

It was common ground that whether there was a defect fell to be determined as at the date of the supply of the prosthesis to the pursuer (cf *Gee* v *DePuy International* (*supra*)). It was also agreed that the state of the art defence under section 4 did not fall to be determined at the preliminary proof.

[4] Although section 1 refers to the Act as a measure intended to comply with the Directive, the Preamble states that its purpose is, *inter alia*, to consolidate a number of Acts

including the Consumer Safety Act 1978 (as amended in 1986). It had been prompted not only by the Directive but by a series of commissions and reports following upon the Thalidomide tragedy (see Dobson's annotations to Part I of the 1987 Act in *Current Law Statutes*). On introducing the Bill on 8 December 1986, the Lord Advocate (Lord Cameron of Lochbroom) stated that its purpose was to "improve consumer protection". He referred to the various commissions (Hansard Vol 482 cc 1003-62). He explained that the relevant part of the Bill implemented the Directive "no more and no less".

[5] The Directive describes its purpose in its title as concerning "the approximation of the laws… concerning liability for defective products". Such approximation was necessary because existing divergences between member states may have been distorting competition, affecting the movement of goods within the common market, and may "entail a differing degree of protection of the consumer against damage". The intended solution was described in the following recital:

> "… liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production".

The recitals continued by stating that, in order to protect the consumer, defectiveness should be determined not by reference to the product's fitness for use but to any lack of safety which the public at large was entitled to expect. A fair apportionment of risk implied that the producer should avoid liability if he proved the existence of certain exonerating circumstances.

[6] Article 6 of the Directive provides:

> "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.

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

[7] Article 7 continues:

"The producer shall not be liable as a result of this Directive if he proves:

…

(e) 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 …".

General Background and Procedure

[8] On 24 March 2009, when he was aged 54, the pursuer underwent a left-sided metal on metal total hip replacement. A Mitch/Stryker Howmedica acetabular cup, which had been manufactured by the first defenders (who were subsequently acquired by DePuy International), and an Accolade V40 femoral stem with a large (54mm) bearing hip articulation, which had been manufactured by the second defenders, were used. On 17 October 2012 it was revised. The pursuer avers that he suffered loss and damage as a consequence of the use of the MoM THRs. He bases his case solely upon defective product liability in terms of section 3 of the 1987 Act. On 16 November 2009 the pursuer underwent a MoM THR using the same prosthesis on his right side. As at the date of the proof, it has not required revision.

[9] The action began in early 2015. The adjustment period lasted from April of that year until March 2017. A general proof before answer was allowed in June 2017 and fixed to commence on 14 May 2019. On 12 December 2018, the proof was restricted to "liability and

general causation". By interlocutor of 20 March 2019 the scope of the proof, which was agreed by the parties, was confined to the following question:

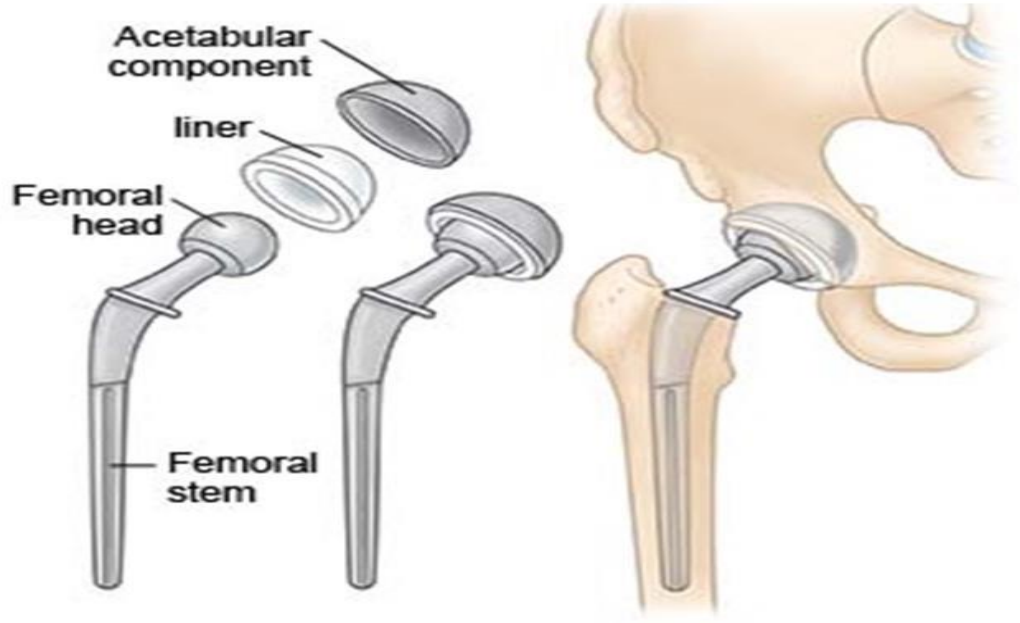
> "Does the admitted inherent propensity of [MoM] hip prostheses to shed metal debris through wear in use (including trunnion wear), and the admitted risk that some patients may suffer an adverse reaction to such metal debris that may necessitate early revision, render the product* less safe than persons generally were entitled to expect and thus defective within the meaning of the 1987 Act, taking account of all of the circumstances, including the following particular circumstances relied upon by the pursuer:
>
> 1. The knowledge reasonably to be expected of the body of orthopaedic surgeons responsible for advising patients as to the choice of prostheses, pre and post supply;
> 2. The sufficiency of disclosure of the likelihood and severity of such risks of the product within the literature supplied in relation to the product, including the Instructions for Use; in particular, having regard to point 1;
> 3. Advice and warnings issued by the relevant regulatory authorities post supply;
> 4. Advice and warnings issued by the manufacturers and suppliers post supply;
> 5. The combination of a titanium alloy stem and a cobalt chromium head;
> 6. The date of supply of the product;
> 7. The fact that the product is no longer supplied.
>
> *the product being the combination of Mitch acetabular cup and femoral head and Accolade stem."

The parties later agreed that answering this question required a two stage process. First, the court required to determine what was the entitled expectation of persons generally. Secondly, it had to decide whether the product failed that expectation.

[10] The proof extended over 10 days from 14 to 29 May, after which the Lord Ordinary allowed parties to formulate their submissions in writing. The case was taken to avizandum on 24 June 2019. The Lord Ordinary issued his opinion on 26 November 2019, after which he assoilzied the defenders.

The development of Total Hip Replacements

[11] The hip is a ball and socket joint which can become damaged over time, notably as a result of the effects of osteoarthritis. It may require replacement in order to remove the consequent pain and to enable the patient to regain reasonable mobility. Some 100,000 THRs are performed every year in the United Kingdom. A standard form of THR looks like this:



[12] The prosthesis thus consists, first, of a metal femoral stem which is fitted into the thigh bone (femur). Secondly, a ball-shaped replacement femoral head is attached to the stem. Thirdly a cup shaped device replaces the acetabular socket in the pelvis. This will usually have a lining. The stem and cup must be fixed to the bone. This can be by cementing or press-fitting followed by a process of osseo-integration. The male component of the self-locking taper joint which connects the femoral stem to the cone of the femoral head is called the trunnion. Originally, the prostheses were monoblocs (ie single castings) which were cemented into position. Over time, modular prostheses with separate elements were made available. By 2009, almost all THRs used modular components. There is a choice between

using a metal (eg cobalt chromium) or ceramic femoral head and a polyethylene (plastic), ceramic or metal liner. Polyethylene is more prone to wear, but forms of cross-linked polyethylene have reduced that wear in more recent times. A surgeon will select what he or she considers to be the appropriate components according to the anticipated level of wear.

[13] The Lord Ordinary set out the history of THRs. Early stainless steel prostheses, which had been used in the 1950s, suffered from loosening. A CoCr alloy was introduced. A design in the 1960s (the Charnley hip), which consisted of a CoCr stem with a small metal head and polyethylene cup, was very successful; outperforming the first generation MoM designs. The latter's performances had been mixed as a result of design flaws or problematic fixings. Although the Charnley hip was the favoured version up until the early to mid 1990s, it had a tendency to fail as a result of osteolysis: degeneration of the bone as a result of particulate debris caused by wear of the polyethylene cup. The alternative of a harder wearing ceramic cup had been introduced in the 1970s, but this had problems too, including a high fracture rate. Second generation MoP, CoC and MoM designs were used. By the mid 1990s, osteolysis, usually after seven to ten years, was the predominant cause of failure, especially in younger or more active patients.

[14] The search for harder wearing materials became a major topic of medical study. MoM resurfacing prostheses techniques, which preserved the femoral head and neck, were developed. This reduced the risk of dislocation and became popular for younger or more active patients. At a major conference in Santa Monica in 1995, a consensus statement, which outlined the then current state of knowledge, was produced. It was published in the leading orthopaedic journal in the following year. The view was that the wear rate of MoM prostheses was up to 20 times lower than MoP rates. Although issues of metal ion and particle toxicity had been identified with MoM prostheses, MoM technology was regarded

as a worthwhile subject for future research in order to address the osteolysis problem. The need to do this was emphasised by data from the National Swedish Hip Arthroplasty Registry which indicated that the survival rate of MoP prostheses declined rapidly after ten years, especially in younger and more active patients. The challenge was to create a system which was suitable for that category. Larger femoral heads, with metal liners, were developed to achieve this.

[15] Large head MoM THRs were developed in the late 1990s and became popular in the early 2000s. MoM became the prosthesis of choice, especially for the young and active. The second defenders manufactured a range of femoral stems, including the Accolade in 2001. Because they wanted to enter the MoM THR market, they reached an agreement with the first defenders in 2005 for the development, manufacture and supply of a metal acetabular cup and femoral head which would be compatible with the Accolade stem. The result was the Mitch range which, together with the Accolade, were sold as the Mitch TRH (*sic*) system. It was marketed to surgeons as a "clinical proven joint innovation"; even if the proven element could only have been applicable to MoM THRs as a generality. There had been no pre-marketing randomised control trials or staged introduction of the Mitch/Accolade prosthesis.

The problem

[16] Metal wear produces debris at the trunnion (head-neck) interface, but most wear occurs where the head articulates within the cup (or its liner). All prostheses produce debris as a result of wear; some of it undetectable even by microscope. An MoP prosthesis will produce polyethylene and some metal debris. An MoM prosthesis will, of course, produce

only metal debris. The quantity will depend on the patient's physique and activity as well as how well the prosthesis has been fixed.

[17] An adverse reaction to metal debris can occur in the tissues adjacent to the prosthesis. A patient's reaction to the debris is highly variable. It may be beneficial in some cases but can be seriously problematic in others. It can lead to pseudo-tumours (abnormal masses) in the surrounding tissues. These may be asymptomatic or painful. There will be some immunological response to the debris. The response will produce macrophages (cells) which can eliminate injurious materials, such as debris, as perceived by the immune system. If the macrophages do not manage to break down the debris, chemicals may be released which will cause inflammation and osteolysis. This is a commoner reaction to polyethylene, as distinct from metal, debris. Sometimes, when the particles are broken down, they are toxic to living cells and this can lead to soft tissue necrosis. Where a large amount of necrosis is found, it is usually associated with very large pseudo-tumours. Extensive necrosis is commonly seen in patients with an ARMD and pseudo-tomours. Most patients who have MoM prostheses, which have failed as a result of ARMD, will have extensive necrosis.

[18] The Mitch/Accolade product became available in the United Kingdom in 2006. It came with instructions for use; albeit in very small print. The IFU contained a section which was headed "Possible Adverse Effects". A wide range of effects was described, including the following:

> "Corrosion of metal implants leading to metallic ion release in the patient occurs, to some extent, with a well-fixed implant, but it will be increased if the implant is loose or articulation is metal on metal. The long-term effects of metal on metal articulations are not fully understood although they have been used for many years without reports of directly related clinical problems. There may however be some adverse reactions to metal particles, and metal ion release that may lead to cytotoxicity, genotoxicity, mutagenicity, hypersensitivity and carcinogenicity.

> While the expected life of total hip replacement components is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors, which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
>
> Surgeons should warn patients of all the Possible Relevant Adverse Effects."

[19] The agreement between the defenders was due to expire in 2011. It was not renewed. This was principally because of a sharp decline in sales. This in turn was as a result of concerns which had begun to be expressed by orthopaedic surgeons about, *inter alia,* the rate of required revision. A paper published in July 2008 (Pandit *et al*) reported the incidence of pseudo-tumours in 1% of MoM hip resurfacings (not THRs) after 5 years. In 2009, a further paper (Grammatopoulos *et al*) reported that revisions in a group of resurfacing patients with symptomatic pseudo-tumours had a poor outcome because of soft tissue destruction. A third paper (Mahendra *et al*) described necrosis and inflammation in failed MoM resurfacing as a result of CoCr wear particles. ARMD was first reported at a conference in 2008-2009. Awareness increased in the succeeding years, as developed by an expert committee of the Medicines and Healthcare Products Regulatory Agency.

[20] In April 2010, the MHPRA issued a medical device alert. This included the following:

> "Problem
>
> The majority of patients implanted with MoM hip replacements have well functioning hips and are thought to be at a low risk of developing serious problems.
>
> A small number of patients implanted with these hips may, however, develop progressive soft tissue reactions to the wear debris associated with MoM articulations. The debris can cause soft tissue necrosis and adversely affect the results of revision surgery. Early revision of poorly performing MoM hip replacements should give a better revision outcome."

Surgeons were advised to follow up MoM hip replacement patients with blood metal ion measurement and cross sectional imaging.

[21] In 2012, as a result of an investigation by the British Medical Journal, the safety of MoM prostheses featured on the BBC's Newsnight programme. In February 2012 the BMJ's features' editor referred to the possibility of hundreds of thousands of patients having been exposed to toxic substances as a result of "poorly regulated and potentially dangerous hip devices". The risks had been known for decades and patients had participated unknowingly in "a large uncontrolled experiment". Revised MDAs were issued on 2 April 2012, for the Mitch/Accolade product in particular, and on 25 June 2012 for all MoM THRs. The advice in June was to have an annual review for all MoM THRs with large heads.

[22] On 26 April 2012, the defenders issued an urgent field safety notice; ie a communication which identified a product which may not be performing as intended and advising of steps which should be taken. The FSN stated that a review of surveillance data on the Mitch/Accolade product suggested a higher than expected revision rate. The action to be taken was "Do not implant".

[23] The Lord Ordinary quotes from an article (Mellon *et al*) in July 2013 as a useful summary of the then current orthopaedic thinking:

> "Metal on metal (MoM) hip replacement became very popular in the middle part of the last decade. It promised to be a low wearing bearing surface, with the added distinction of allowing hip resurfacing, where, rather than cutting the femoral neck and inserting a stem into the femur, the femoral head is resurfaced with a metal cap. Metal on metal hip resurfacing arthroplasty (MoMHRA) promised improved mechanical performance, less bone resection and, if necessary, easier revision surgery.
>
> However, whilst there is evidence that MoMHRA works well in young active men, the failure rates of MoMHRA in women and of [MoM] THR in both sexes are significantly higher than expected. Average failure rates at seven years are 11.8% for MoMHRA and 13.6% for [MoM] THR, although failure rates vary with the brand used (one brand of MoM THR was reported to have a failure rate of 22% at five

> years). This compares with rates of 3.3% – 4.9% for hip implants made of other materials. This high failure rate appears to be due to the pro-inflammatory effects of submicron wear particles; the effects of long-term exposure to these particles is largely unknown. In addition to the high failure rate, the mode of failure is a major concern. These failures typically involve soft tissue and bone disruption which can be massive, leading to severe functional impairment and extremely challenging revision surgery. These reactions have been referred to by a number of terms such as adverse reaction to metal debris (ARMD), aseptic lymphocytic vasculitis associated lesions (ALVAL), adverse local tissue reaction (ALTR) and pseudotumour."

MoM THRs ceased in 2012, although some MoM hip resurfacing has continued in special situations.

The Lord Ordinary's Findings and Reasoning

[24] Following *Gee* v *DePuy International* (*supra* at para 73), the Lord Ordinary determined (Opinion at para [97]) that a "key" objective of the Directive was the effective protection of consumers but it was not the "main or overriding" objective. It had equal status with other objectives. The latter was a reference to the prevention of distortion of competition and the protection of the free movement of goods (C-310/13 *Novo Nordisk Pharma* v *S* EU:C:2014:1825 at paras 16-20 (AG)). On this basis, he held that interpretation of the Act should not favour the protection of consumers over any of the other objectives. Whether the product was defective required to be approached on the basis of the reasonable expectation of the public at large, taking into account the intended purpose, the objective characteristics and properties of the product and the specific requirements of the patients (C-503/13 *Boston Scientific Medizintechnik* v *AOK Sachsen-Anhalt – Die Gesundheitkass*e [2015] 3 CMLR 173 at paras 37-40).

[25] The Lord Ordinary agreed with *Gee* v *DePuy International* (*supra*) that the Directive and the Act required a flexible approach. The court could have regard to all the circumstances that bore upon the safety of the product; provided that notions of negligence

were not introduced. The criticism which was made by the pursuer, that *Gee* had failed to have regard to the need for strict liability because the costs of injuries were best allocated to the producers, who could insure against the risks, as set out in *Beshada* v *Johns Manville Prods Corp* (1982) 90 NJ (New Jersey) 191, fell foul of the recitals in the Directive and the European jurisprudence.

[26] The Lord Ordinary referred to two other first instance cases from England. From the first, namely *A* v *National Blood Authority (No. 1)* [2001] 3 All ER 289, he understood that the relevant degree of safety was what the public were entitled to expect and not what they actually expected. The question was safety for foreseeable use. A comparison with similar products was relevant. *Wilkes* v *DePuy International* [2018] QB 627 was largely followed in *Gee* v *DePuy International* (*supra*). The Lord Ordinary drew a number of propositions from it (at paras 63-73). The focus of the Directive and the Act was not on acts and omissions of the producer, but on the condition or state of the product. Condition was not put in terms of fitness for purpose but of safety; the hallmark of a defect being a lack of safety. There could be no expectation that a medical product was entirely risk-free. Benefits had to be balanced against risks. The court had to assess the appropriate level of safety. A patient was not required to prove the cause of any lack of safety or why the product failed. The Lord Ordinary accepted from *Wilkes* that, contrary to *A* v *National Blood Authority*, whether a risk could have been avoided may be relevant, but with prostheses a detailed consideration of avoidability was unlikely to be fruitful. Regulatory approval was not an automatic defence. It could be evidence that the level of safety was that which persons generally were entitled to expect. Warnings and information, which were addressed to an intermediary (surgeon), did not provide an automatic defence but the existence of such an intermediary was a relevant circumstance.

[27] The Lord Ordinary focused on the safety of the Mitch/Accolade prosthesis, but commented that none of the experts who gave evidence were familiar with the particular product and much of their testimony related to MoM THRs in general. He took, as a starting point in determining public expectation, the view agreed by the experts, namely Profs Pandit and Breusch, that an orthopaedic surgeon would look at the benefits of the surgery including: ease of surgery, a return to near normal functioning, a low dislocation rate, a lower wear rate with associated improved survivorship and a manageable mode of revision. MoM THRs did not have 10 year outcome data, which was the benchmark set by the Orthopaedic Evaluation Panel. They therefore had to be viewed with caution. This all suggested that an objective assessment should not conclude that there was an entitled expectation that MoM prostheses would have significantly improved survivorship when compared to the then commonly used alternative MoCP prosthesis. That was what the surgeons had hoped for, but that was not the test. The question was whether the "level of safety would not be worse" than non-existing MoM products (Opinion at para [119]).

[28] The Lord Ordinary attached little weight to the instructions for use, since he was sceptical of whether a surgeon would have read it. He took another starting point; the expert view that the majority of patients with MoM THRs were pain free and able to enjoy the activities of ordinary living. The pain relief provided by MoM and MoCP THRs were similar. This left three questions: was the majority smaller for MoM THRs; was the outcome worse for the minority; and was there any feature of the Mitch/Accolade product which rendered the experts' view less applicable?

[29] The pursuer founded heavily on the withdrawal of the product from the market. In 2012 there was a consensus that the failure rates of MoM THRs were higher than had been expected and compared unfavourably to other THRs. Patients with MoM THRs were

advised to have more frequent and earlier monitoring. No consensus on the cause of the comparative failure rate had emerged. The Lord Ordinary commented:

> "[124] I accept that expression of serious professional concerns, followed by the issuing of an official alert and the withdrawal from the market of an entire range of products constitutes powerful *prima facie* evidence that those products were not performing in accordance with expectation."

He continued:

> "But that is not necessarily the same as not performing in accordance with *entitled* expectation, and in assessing whether the latter has been established, I am able to proceed with the benefit of hindsight, and to have regard to material that is now available but was not available in 2012 when MoM THRs ceased to be used."

[30] The Lord Ordinary examined whether there was a causal link between MoM THRs and ARMDs. There was a consensus that the metal debris from MoM prostheses had a greater toxic potential than other wear particles. For this to be significant, the patient would have to have been sensitised over time. Metal debris may cause adverse effects, but only in unusual cases of high exposure. Thus the Lord Ordinary considered it established that MoM prostheses caused ARMD but only in exceptional cases. That did not constitute a failure to meet entitled expectations.

[31] The pursuer's expert, namely Prof Gill, thought that the Mitch/Accolade product had a higher than normal failure rate because of its large diameter CoCr femoral head with a titanium alloy stem. The longer periods of movement which occurred with the larger head could generate higher levels of friction. These would act on the trunnion and create spaces between the stem and head. This in turn would create fluid ingress and corrosion, causing accelerated material loss. Metal debris would be created at the trunnion/head interface. This would cause ARMD for reasons which were not understood. The defenders' expert, namely Dr Burke, disagreed on the basis that these links had not been scientifically demonstrated.

The Lord Ordinary agreed with Dr Burke. Although the pursuer had established a possible causal mechanism, he had not proved that mechanism on the balance of probabilities. There was no evidence that debris from the head/stem interface was more damaging than debris from the bearing surface. A combination of the Accolade stem and a CoCr metal femoral head had been used in other implants, such as MoP THRs, and there was no evidence that this led to especially damaging debris.

[32] The Lord Ordinary regarded the revision rate of the prosthesis as a relevant criterion in the assessment of failure to meet entitled expectation. The Guidance issued in 2000 by the National Institute for Health and Clinical Excellence stated that the best prostheses had a rate of 10% or less at 10 years and that this should be regarded as the benchmark in selection. The Orthopaedic Data Evaluation Panel criterion for a "Class A" product was a revision rate of 3% at 3 years, 5% at 5 years, 7% at 7 years and 10% at 10 years. The ODEP considered that the survivorship of a medical device would be within the NIHCE Guidance if revision probability was within a 95% confidence interval; a set of values upon which the true underlying parameter may sit (eg if the estimate was 85%, a CI of 95% would produce a range of 80-92%).

[33] In April 2012 the MDA issued a revision rate of 10.7% at four years for the Mitch /Accolade prosthesis. This was based on 271 patients who had been recorded in the UK National Joint Registry. The defenders' expert, namely Prof Platt, provided an analysis whereby, based on the NJR data, the revision probability was 23.2% (95% CI 18.4-28.9%) at 10 years. These rates appeared significantly worse than those for other prostheses. Prof Platt's purpose was to show that they were misleading for a number of reasons. The sample size was very small and would give rise to wide confidence intervals and low certainty. The estimates were not specific to the Mitch/Accolade prosthesis. They were only for 10 to

12 years of follow up. There may have been selection bias as the product had been designed for young and active patients. Recording of body mass indexes was lacking. A lower threshold for revision would decrease observable survivorship. There might be reasons for a higher revision rate in younger patients. Patient gender was a factor and the Mitch/Accolade prosthesis had a higher proportion of male patients. A particular problem was the effect of "outliers"; surgeons whose revision rates differed significantly from the normal range. Prof Platt detected one outlier and one borderline outlier. If their data were excluded, the 10 year revision estimate for the Mitch/Accolade prostheses fell to 14.3% (95% CI 9.8-20.7%). This (ie the 9.8%) would bring it within the ODEP's approach to the NIHCE Guideline.

[34] Although the Lord Ordinary did not find all of Prof Platt's reasoning persuasive, he was convinced, particularly in relation to the presence of outliers and the confounding factors, that:

> "[155] … the available evidence in relation to revision rates of the Mitch/Accolade product is not sufficient to establish that it has a materially lower survivorship than other available products or national standards".

The Lord Ordinary held that the Mitch/Accolade prosthesis had been, to a significant extent, implanted in the younger and/or more active, and predominantly male, patients for whom the large head MoM THR had been designed. These factors were likely to have lowered the average survivorship figures. The effect of publicity was also likely to have had an effect; the threshold for revision of MoM THRs having become much lower.

[35] The Lord Ordinary turned to the contention that the prospect of success in revision surgery was lower with MoM THRs. He noted the studies (notably Grammatopoulos (*supra*)) in the 2000s and the view of Prof Breusch to that effect, because of significant soft tissue damage caused by metal debris in rare cases. Prof Pandit, upon whose testimony the

Lord Ordinary placed considerable weight, cast doubt on the studies in the 2000s. Later papers had not supported them. The Lord Ordinary did not consider that the pursuer had proved that metal debris from MoM THRs created a risk that revision surgery would be less likely to lead to a satisfactory outcome than with other prostheses.

[36] The Lord Ordinary expressed his conclusions as follows:

> "[163] … the pursuer has not proved, on balance of probabilities, at the time when his prostheses were supplied, either
>
> (a) that survivorship was worse for the Mitch/Accolade product than for existing alternative products that could have been implanted instead; or
>
> (b) that use of the Mitch/Accolade product gave rise to an increased risk that revision surgery, in the event of its failure, would be unlikely to achieve as satisfactory an outcome as if the primary implant had been one of the existing alternatives,
>
> I therefore find that the pursuer has not proved, on balance of probabilities, that the entitled expectation in relation to the Mitch/Accolade product at the time of its supply to the pursuer was not met. It follows that he has not proved, on balance of probabilities, that there was a defect in the product so as to give rise to liability on the part of the defenders under the 1987 Act. The question for determination at the proof … is answered in the negative."

Notwithstanding that answer, the Lord Ordinary went on to explain that his opinion should not be taken as finding that it had been positively proved that the safety of large-head MoM THRs as a class was such as persons generally were entitled to expect at the time when they were supplied.

Submissions

Pursuer

[37] The pursuer summarised his argument by submitting that persons generally were entitled to expect that: (1) the prosthesis would remain on the market until superseded by a superior product; (2) the prosthesis would continue to have regulatory approval until

superseded by a superior product; (3) the orthopaedic community would continue to sanction its use; and (4) the manufacturer would not warn against its continuing use. None of these expectations had been met. The Lord Ordinary accepted that the expression of serious professional concerns, followed by the issuing of an official alert, and the withdrawal of the product, constituted powerful *prima facie* evidence that the prosthesis was not performing in accordance with expectation. The only evidence which was relied upon by the Lord Ordinary to rebut that evidence was that of Prof Platt. His view, which looked only at the UK data, was that the data sample was too small to provide a reliable statistical basis. Yet that is what the Lord Ordinary had used. The statistical data supported the *prima facie* evidence. The Lord Ordinary had ignored the larger data sample from Australia, which showed a higher revision rate. He had used the wrong comparator, namely products used prior to the date of supply (2009), rather than contemporaneous products used at the same time as the product in question.

[38] The 1987 Act introduced strict liability for the first time. This was a requirement of the Directive. The Lord Advocate (Lord Cameron of Lochbroom), when introducing the bill at the Second Reading in the House of Lords, stated that "The purpose of this important Bill is to improve consumer protection" (HL Deb 08 December 1986 vol 482 cc1003-62). The driving force of the Directive was the Thalidomide tragedy (see Clark: *Product Liability* p 11). Strict liability was not a concept that the courts in the United Kingdom were particularly used to. It was more familiar to those in the United States. *Beshada* v *Johns Manville Prods Corp* (*supra*) provided a review of the purposes of, and rationales for, strict liability; notably risk spreading and accident avoidance. The Lord Ordinary considered that these considerations should be subordinate to the other objectives of the Directive. This failed to

recognise the importance of strict liability as the starting point of both the domestic and European legislation.

[39] One of the most important reasons for imposing strict liability was the recognition that the manufacturer had an understanding of the product that no consumer could ever hope to have (*Richards* v *Pharmacia (Pfizer)* 2018 SLT 492 at para [48]). A fair allocation of risk between consumer and manufacturer was not an equal one. There had to be some allowance for the initial inequality between the parties. *W* v *Sanofi Pasteur* [2017] 4 WLR 171 warned (at [30]-[35]) against national courts imposing an evidential burden that made it excessively difficult to establish product liability, thereby undermining the effectiveness of Article 1 of the Directive. The warning applied not just to evidential rules, but also to the way they are applied.

[40] *W* v *Sanofi Pasteur (supra* at para [32]) and *Boston Scientific Medizintechnik* v *AOK* (*supra* at paras [37]-[39], [42] and [47]) made it clear that the Directive sought a fair apportionment of risks inherent in modern technology between the injured person and the producer and that of protecting consumer health and safety (see Benjamin: *Sale of Goods* (10th ed) at para 14-234). The approach of the Lord Ordinary was in line with that in *Gee*. The case commentary (James Watson QC (at page 407)) suggested that the costly hurdles, that claimants would have to surmount under the 1987 Act, meant that in the future consideration should be given to relying on the common law of negligence instead. Such concerns demonstrated that the cases on MoM THRs had failed to implement the purpose of the Directive and the 1987 Act.

[41] *Wilkes* v *DePuy International* (*supra*) had been the subject of academic criticism. *Wilkes* was decided without reference to *Boston Scientific*, which should be seen as the leading authority. The more consumer-based approach in *A* v *National Blood Authority* (*supra* at

para 65) should be preferred to *Wilkes*, *Gee* and the Lord Ordinary. The Lord Ordinary's approach imposed an impossible burden on the consumer and undermined the importance of strict liability. One of the reasons why the statistical data was unreliable was that it was based on a very small sample size. The reason for that was the swift withdrawal of the product by the manufacturers. When a pursuer faced evidential difficulties caused by the conduct of the defenders, the courts would show "claimant benevolence" (*Keefe* v *Isle of Man Steam Packet Co* [2010] EWCA Civ 683, at para [19]); *Drake* v *Harbour* [2008] EWCA Civ 25 at para [28]; *JAH* v *Burne* [2018] EWHC 3461 (QB) at para [64]) and *Younas* v *Okeahialam* [2019] EWHC 2502 (QB) at para 46). The fact that the 1987 Act imposed strict liability should make the court more ready to apply "claimant benevolence" and draw the inference that the product was defective, particularly when there was already good evidence to that effect.

[42] There were no randomised clinical trials conducted before the product came onto the market, contrary to the recommendation of both orthopaedic experts. On the Lord Ordinary's approach, a consumer could not rely on the findings of the regulatory authorities, the medical community and the manufacturer. The consumer must instead commission a lengthy, detailed, complex and expensive statistical report based on information within the control of the manufacturer. This approach undermined the effectiveness of the 1987 Act and the underlying Directive. It was impossible for the pursuer to provide reliable statistics because the defenders had taken the product off the market so quickly that there was an insufficient cohort of patients to provide a big enough data sample.

[43] In many contexts it was difficult to know how to determine what persons generally were entitled to expect. In the context of medical products, it was relatively straightforward. The patient was largely reliant on the advice provided by the medical practitioner.

Accordingly the starting point must be the consensus of the medical community. The medical community was itself influenced by information provided by the manufacturers and the regulatory authorities. These should be the key sources for determining entitled expectation. There was no dispute amongst the experts that MoM THRs were not safe in that they carried an increased risk of failure. This had been accepted by all the experts in a joint statement.

[44] Medical Device Alerts had been issued in the UK. Regulatory authorities in Australia and New Zealand issued similar alerts, preventing further use of the product. For some reason, the Lord Ordinary only referred to regulatory disapproval in the UK. In 2012 the defenders issued Field Safety Notices across the world. One of these FSNs was issued in Australia, where the product was used more than in the UK. A Hazard Alert was issued in New Zealand. These warnings were based on evidence from the Australian register as well as the UK register. MoM THRs were no longer used by any orthopaedic surgeons anywhere in the world. The regulators withdrew approval.

[45] The defenders presented their defence on the basis of a statistical analysis. The report by Prof Platt was based on a false premise that the pursuer's case was based on cumulative revision rates, rather than all of the circumstances. The purpose of the report was to rebut a case based on statistics, such as had been advanced in *Gee* v *DePuy International* (*supra*). That had never been the pursuer's case. The pursuer's case was based on the factors which the Lord Ordinary had accepted as constituting powerful *prima facie* evidence of defect. By criticising the reliability of the statistics, Prof Platt was simply undermining the basis of the defence. His analysis at 10 years in the UK NJR left a range; the bottom of which just fell within the 2000 NIHCE Guideline of 10%. The data in Australia, using a larger sample, showed a revision rate of 18.6% (95% CI: 14.6-23.5%) at

10 years. This evidence was not addressed by the Lord Ordinary. The flimsy UK statistical evidence could not rebut the powerful *prima facie* evidence of defect because: it failed to adopt the correct comparator; it imposed too high an evidential burden on the pursuer; it was unreliable and incomplete; and it supported rather than rebutted the *prima facie* evidence.

[46] The Lord Ordinary correctly held that the appropriate benchmark was existing non-MoM products that would otherwise have been used. When comparing the performance of these non-MoM products, the Lord Ordinary used data from before 2009, and in particular the NIHCE Guidelines of 2000, whereas the data he used for the Mitch/Accolade prosthesis was up to date (as of 2018). By 2018, the NIHCE guidelines recommended prostheses with a revision rate of 5% or less at 10 years. This was not a fair comparison. The only sensible comparison was between the performance of the product and the performance of the non-MoM products that would have been used, assessed in the same way over the same period. Since that exercise had not been carried out, there was no statistical basis to rebut the *prima facie* evidence.

[47] The Lord Ordinary failed to take account of the evidence of the controlled study in the BMJ article, which was spoken to by Sally Hunter, who was a vice president of DePuy International, and referred to the research into the Mitch/Accolade prosthesis that was stopped a year before the MDA in April 2012. This demonstrated the level of control that the manufacturers had in obtaining and providing information on their products. This evidence was ignored by the Lord Ordinary. He stated that he was not referred to any article specific to the Mitch/Accolade prosthesis, which would suggest that he had overlooked this evidence.

[48] The mere fact that the evidence of Professor Platt was agreed did not mean that the court was bound by his opinion, as opposed to the facts set out in his report (*McGlinchey* v *General Motors* [2012] CSIH 91 at para [40]). The Lord Ordinary did not accept all of Professor Platt's unchallenged evidence. The defenders were wrong to submit that the court was bound by the Professor's conclusions.

Defenders

[49] The defenders submitted that the Lord Ordinary was correct to hold that the Mitch/Accolade prosthesis was not defective. The experts agreed that the majority of patients with MoM implants were pain free and able to enjoy activities of daily living. A link existed between MoM prostheses and ARMD only in exceptional cases. ARMD was not restricted to MoM prostheses. There was no evidence that metal debris from the head/stem was more dangerous than debris from the bearing surface.

[50] The agreed evidence of Prof Platt was that a comparison of the revision rates of the Mitch/Accolade prosthesis and overall THR revision rates did not provide a basis for meaningful conclusions. The evidence was not sufficient to establish that the Mitch/Accolade prosthesis had a materially lower revision rate than other available products or national standards. The confounding factors rendered it unsafe to draw the conclusion that the revision rate of the prosthesis was below entitled expectation.

[51] Given that all prostheses produced debris and debris will react with the body, the existence of early revision was not of itself sufficient to establish the pursuer's case. The pursuer identified entitled expectation based on four different features. He had not contended for these at the proof. In relation to these, for how long was a person entitled to expect that it would remain on the market? How long was he was entitled to assume that

the prosthesis would continue to have regulatory approval? The same observations applied to sanction of its use by the orthopaedic community and warnings against its use. The pursuer's formulation would lead to a finding of defect in respect of every product when an improved and safer version was developed.

[52] The burden of proving that the product was defective rested on the pursuer who must establish what it is about the state 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 of supply. The test was objective (*Gee* v *DePuy International* (*supra*) at paras 86-87). All circumstances had to be taken into account in assessing expectation (*Gee* at para 160; *Wilkes* at paras 76-79).

[53] Consistent with his approach to statistics and his position that statistics were not relevant, the pursuer had agreed Prof Platt's report as his evidence. When assessing entitled expectation, only what was known at the time of supply could be taken into account. In contrast, hindsight could be used when assessing whether the entitled expectation had been met (*Gee* v *DePuy International* (*supra*) at paras 84, 269 – 274; *Wilkes* v *DePuy International* (*supra*) at para 66). There was a trade-off with benefits. Safety was a relative concept (*Gee* at para 110; *Wilkes* at para 65).

[54] The Lord Ordinary accepted that the entitled expectation was that the Mitch/Accolade prosthesis should not be worse than existing MoCP prostheses. He was correct to hold that the orthopaedic community's general view of survivorship of MoCP hip prostheses was largely informed by the NSHAR. The figures were for the entire cohort of patients and took no account of the increased proportion of younger and active patients undergoing MoM THRs. Even these figures did not support the pursuer's position in the

appeal. They had been the most relevant for MoCP THRs that would have been available to the orthopaedic community at the time of the supply.

[55] Most of the proof had been taken up with, first, exploring immunology and histopathology in an attempt to show a causal link between metal debris and ARMD. The Lord Ordinary held that there might be a link but that did not demonstrate a failure to meet entitled expectation. Secondly, there was biomechanical engineering evidence whereby the pursuer demonstrated a possible mechanism by which larger head MoM THRs might generate more metal debris, but this did not establish a link to ARMD. The third area was on the incidence of revision surgery in which the pursuer failed to establish a higher rate for the Mitch/Accolade prosthesis.

[56] Prof Platt's report demonstrated that the cumulative revision rates for the Mitch/Accolade prosthesis were unreliable and could not support the conclusion that the revision rate was unacceptably high. It directly undermined any potential significance of the safety notices. They used the same statistics that Prof Platt demonstrated to be unreliable. His analysis identified specific confounding elements; in particular, the role of outliers. It provided a valid basis for the Lord Ordinary's conclusion that the prosthesis was not defective.

[57] The pursuer incorrectly stated that the Lord Ordinary failed to take into account data from the Australian registry. An appellate court was bound, unless there was compelling reason to the contrary, to assume that the court of first instance had taken the whole of the evidence into consideration (*Henderson* v *Foxworth Investments* 2014 SC (UKSC) 203, at para 48). No such reason existed. Prof Platt had considered the Australian data and stated that it could not be used to provide accurate and precise long-term survivorship estimates for the Mitch/Accolade prosthesis. The small sample size of the Australian data impeded

the drawing of meaningful conclusions. The pursuer, having agreed this evidence, could not now seek to dispute it. Profs Breusch and Pandit agreed that the different rates of revision between MoM and non-MoM prostheses could be affected by differences in the age and activity profile of the patients. They agreed that adverse publicity, public health alerts, increased surveillance and recall of other implants all influenced revision rates. The Lord Ordinary relied upon Prof Breusch's evidence that the threshold for offering revision surgery based on recurrent onset of pain in the presence of MoM prostheses had become much lower. The Lord Ordinary recorded Prof Pandit's evidence that the only explanation for the dramatic rise in revision rates between 2009 and 2016 was a lowering of the threshold for revision surgery.

[58] Although counter intuitive, consumer protection was not the primary objective of the legislation. The terms of section 3 of the Act and Article 6.1 of the Directive were unambiguous. The Act implemented the Directive and the approach adopted reflected the aims of improving consumer protection, harmonising the market and striking a fair balance between the interests of consumers and producers (C-154/00 *Commission* v *Greece* EU: C:2002:254 at para 29; C-310/13 *Novo Nordisk Pharma* v *S* (*supra*) at paras 18-20; C-183-00 *Sánchez* v *Medicina Asturiana*, 2002 ECR I-3901 at paras 19-30; and *Gee* v *DePuy International* (*supra*) at paras 64 – 80). It was not open to one member state to have a more rigorous system than another (*W* v *Sinofi Pasteur* (*supra*) at paras 34-36). The initial proposal was for true strict liability but that proposal did not ultimately find favour (C-300/95 *Commission* v *United Kingdom* 1997 ECR I-2663 at paras 15 to 18). The Directive provided (Art 21) that it was to be subject to periodic review. Consumer interests have urged amendment of the Directive in order to make it easier to bring claims, but the Commission has consistently found that the case for such amendment has not been made out. What the Act did not do

was create strict liability for any damage caused by a product. Liability only arose if there was a defect. The Act did not introduce a warranty of performance (*Tesco Stores* v *Pollard* [2006] EWCA Civ 393 at para 17).

[59] Whether a product was defective was fact specific. Such an approach was consistent with the domestic jurisprudence (*Wilkes* v *DePuy International* (*supra*) at paras 54 and 96; *McGlinchey* v *General Motors* [2012] CSIH 91 at 37; C-503/13 *Boston Scientific Medizintechnik* v *AOK* (*supra*) at paras 37–40). There was no material difference between the Act and the Directive and the Act could be construed by reference to its own wording. The pursuer's reference to Hansard was no more than the broadest general explanation of the purpose of the Act.

[60] The Lord Ordinary considered all of the evidence over 10 days and had the benefit of lengthy written and oral submissions. His findings in fact should not be disturbed unless plainly wrong. Where the outcome was open to the Lord Ordinary, and his decision was not tainted by an error of law, an appeal court should not interfere, even if it thought that it might have reached a different conclusion. A generous ambit was given to the judge hearing the proof (*YS* v *BS* 2019 Fam LR 134 at para [9]; and *Anderson* v *Imrie* 2018 SC 328). There was no basis upon which to hold that the decision on the critical question of whether the Mitch/Accolade prosthesis was defective was plainly wrong or one which was not reasonably open to him. The absence of reliable scientific evidence to support the pursuer's contention that it was defective did not require the court to find in his favour.

[61] The Lord Ordinary accepted the evidence of Sally Hunter in relation to the 2012 MDA and 2012 FSN that these were issued due to post-market surveillance data which suggested a higher revision rate than expected. The mere existence of a notice bringing the use of a product to an end could not *per se* demonstrate a defect. The relevance of any MDA

or FSN would depend upon the reasons underlying them. Ms Hunter explained that the approach taken in respect of the MDA and FSN was a cautious one based on patient safety.

[62] The notices proceeded on unreliable data. The MDA, the FSN and the Australian product cancellation were all based upon UK NJR and Australian registry figures. Prof Platt's report demonstrated that they were insufficiently reliable to show that the revision rate of the Mitch/Accolade prosthesis was out of line with the various benchmarks. On removing the revisions carried out by the outlier surgeons, the cumulative revision rate was reduced to 14.3% (CI 9.8 - 20.7%). The effect of the other factors which Prof Platt identified was unquantifiable.

[63] The pursuer's reliance upon an alleged evidential burden, contrary to the principle of effectiveness as discussed in *W* v *Sanofi Pasteur* (*supra*), was misconceived. The standard of proof was the balance of probabilities. The difficulty for the pursuer was that the evidence did not demonstrate the existence of a defect.

[64] There was no basis for the contention that the Lord Ordinary left out of account the study reported in a BMJ article. This was a very small trial involving only 36 patients, in which only three prostheses were the subject of revision. The results had been included in the UK NJR data which the pursuer agreed was unreliable. The BMJ article was a journalistic article rather than a peer-reviewed scientific one. It was, like the Australian data, of peripheral importance in the context of the proof. The pursuer's reliance on *Keefe* v *Isle of Man Steam Packet Co* (*supra*), *Drake* v *Harbour* (*supra*), *JAH* v *Burne* (*supra*) and *Younas* v *Okeahialam* (*supra*) was misplaced.

Decision

[65] The scope of the preliminary proof was restricted to whether the Mitch/Accolade

prosthesis was defective in terms of section 3 of the Consumer Protection Act 1987 because of the propensity of MoM prostheses to shed metal debris, which in turn carried with it a risk of adverse reaction in some patients. The question was: did that propensity render them less safe than persons generally were entitled to expect? It was agreed that this involved, first, a determination of what that expectation was and, secondly, a consideration on whether the prostheses fell short of that expectation. Although the first question has been described as a question of law, the answers to both questions are heavily dependent on the particular facts. As the Lord Ordinary recognised, the first question is not what persons generally expected from the prostheses. It is not what the pursuer expected from his prosthesis. It is what, objectively assessed, persons generally were entitled to expect in terms of safety from this type of prosthesis. The Lord Ordinary determined that it should have a level of safety which was not worse than the other (non MoM) prostheses then in use. There is no challenge to that approach as a generality. Although the pursuer submitted that this implied that certain more specific expectations arose in relation to the product remaining on the market with regulatory and professional approval, these were neither raised at the proof nor established by the evidence.

[66] It is of little, if any, moment in the context of this litigation whether the primary objective of the 1987 Act is consumer protection or the prevention of distortion of competition or whether they have equal status. Suffice it to say that, although the Act was intended to implement the Directive, it is entitled "Consumer Protection". It was introduced to Parliament by the relevant Government minister as being intended to improve that protection. There is no ambiguity or conflict in this case which would prompt the decision maker to go beyond the plain terms of the Act (*RR* v *HM Advocate*, 2020 HCJAC, unreported, 7 October 2020, LJG (Carloway), delivering the opinion of the full bench, at para [42] and

authorities cited therein; *Nyamayaro* v *Secretary of State for the Home Department* 2019 SC 537, LP (Carloway), delivering the opinion of the court, at paras [75]-[76]). No doubt the objectives of the Directive would be taken into account if it were suggested that the 1987 Act did not properly implement the Directive, but that is not the position here. Interesting issues about the apportionment of risk as between consumer and producer do not loom large as relevant factors here. No doubt strict liability is imposed because of the ability of the producer, as distinct from the individual consumer, to protect against risks by taking out appropriate insurance cover. The court will simply proceed on the basis that the 1987 Act is a measure intended to improve consumer protection, whatever the wider purposes of the Directive in terms of competition and the free movement of goods across the European Union might be. The liability for a defective product is strict but a pursuer has to prove the existence of a defect as defined by the Act.

[67] Scots law has long embraced the concept of strict liability in a number of areas, (see generally Walker: *Delict* (2nd ed) p 284 *et seq*). In a case brought under section 3 of the 1987 Act, questions of fault are, at best, of peripheral significance. The focus is on the safety of the product in comparison with others in the same class (see generally Fairgrieve and Goldberg: *Product Liability* (3rd ed) p 379 *et seq*).

[68] The pursuer raised a general point about what is to be expected in advancing a claim against what may be a substantial corporation. There is considerable force in the contention that the court should not impose excessively exacting standards on pursuers, whatever the nature of the case or the defender. It should not expect the ordinary citizen to be able to mount an in-depth challenge which requires a detailed examination of a defender's manufacturing processes and subsequent product safety analysis of the type which might be seen in a commercial litigation between multinationals. The pursuer must be able to access

the courts and have his claim adjudicated upon in a proportionate manner. Insurmountable or excessive obstacles should not be placed in the way. There is no indication that the Lord Ordinary placed any such obstacles in the way of this pursuer. Ultimately, having answered the general question of what the entitled expectation was, the Lord Ordinary set about ascertaining whether that expectation had been met, using the standard of the balance of probabilities. The pursuer does not appear to have had any particular difficulty in securing expert witnesses or in producing such data as was relevant to his case. He would have been aware of Prof Platt's views as stated in his report and was prepared to agree those views. They therefore constituted his unchallenged testimony.

[69] The Lord Ordinary decided (Opinion para [163]) the case on the basis that the pursuer had failed to discharge the burden of proof upon him to demonstrate the existence of a defect. He concluded that the Mitch/Accolade prosthesis was not "less safe" than persons generally were entitled to expect and therefore not defective. A determination of this nature can leave a first instance judge open to criticism. Once all the evidence has emerged, onus of proof ought rarely to matter. It only arises when the judge is unable, having heard all the evidence, to reach a concluded view on the facts (see most recently *Woodhouse* v *Lochs and Glens (Transport)* 2020 SLT 1203, LP (Carloway), delivering the opinion of the court, at para [46] citing *SSE Generation* v *Hochtief Solutions* 2018 SLT 579 at para [273] and *Gibson* v *British Insulated Callenders Construction* 1973 SC (HL) 15 at 22). The question which the judge has to answer should normally be simply: where has the balance come to rest? It may be unfortunate that the Lord Ordinary was not able to make a positive finding on whether a defect existed in the Mitch/Accolade product other than by reference to a failure to overcome the burden of proof. This is to a degree compounded by his approach to large head MoM prostheses in general. Nevertheless, determining a case on the basis of

onus is a course which is open to a judge. It does not, *per se*, vitiate the decision, if it is properly reasoned.

[70] The Lord Ordinary recognised the power of the evidence which pointed towards there being a defect in MoM prostheses generally. This was, first, the concerns of orthopaedic surgeons initially about the MoM hip resurfacing rate and then MoM THRs more generally. The Mellon article of 2013 highlighted a potentially significant difference in the revision rates of MoM THRs when compared to other THRs which appeared to be "due to the pro-inflammatory effects of … wear particles". The Lord Ordinary noted the results of the BMJ's research. Secondly, there were the Medical Device Alerts in 2010 and 2012. Thirdly, there was the defenders' field safety notice which read "Do not implant". It was this material which the Lord Ordinary regarded as *prima facie* evidence that MoM prostheses generally were not performing in accordance with expectations. Such a view cannot be faulted and is not criticised by either party.

[71] The fundamental problem which then arises is whether the Lord Ordinary was, after a further consideration of the evidence, entitled to reach a conclusion that, notwithstanding this *prima facie* evidence, the pursuer had failed to overcome the burden of proof. Although that may at first seem an unexpected outcome, given that the balance had appeared to tilt in the pursuer's favour, it was a course which was open to the Lord Ordinary and which he has justified under reference to the material, some of it agreed, which was placed before him. At the core of his process of reasoning were matters of the same nature as had influenced *Gee* v *DePuy International* [2018] Med LR 347. All prostheses have a propensity to create debris. That could not thus be regarded as a defect as it was an inevitable, and, at the time of the supply to the pursuer, recognised problem. The creation of metal debris, and its potential toxic effect with a consequent potential for revision, was, *quantum valeat*, described in the

instructions for use which were issued by the defenders, albeit that the Lord Ordinary did not think that the surgeons would read them. The finite life of a THR was well known and had to be balanced against the benefits which a THR would bring. Failures, usually after 7 or 10 years, were known to occur, with some revisions becoming necessary before that. The risk of ARMD in a minority of cases was acknowledged.

[72] Prof Platt's report was not the only evidence to rebut the *prima facie* evidence produced by the concerns, alerts and safety notices. That was the background against which those undergoing THRs would be aware of the need to revise the procedure sooner or later. There was no entitled expectation otherwise. It was in that context that the Lord Ordinary looked at the material which underlay the concerns, alerts and notices. He held, as a matter of fact, that whatever may have been the state of knowledge at the time of the concerns, alerts and safety notices in the years 2010 to 2013, an analysis of the material now available, did not demonstrate that these concerns, alerts and notices were soundly based. In particular, it did not demonstrate that the revision rate of the Mitch/Accolade prosthesis was worse than alternative non-MoM prostheses or that the Mitch/Accolade gave rise to an increased risk of an unsatisfactory revision. The, albeit unsatisfactory, ten year revision rate identified by Prof Platt from the available data fell to 14.3% once the outliers were removed from the equation. Even if the other confounding factors were discounted, this left a confidence interval of 9.8-20.7%; thus within ODEP's approach to the NIHCE benchmark Guideline. Whatever criticisms may be made of the Lord Ordinary's reasoning, it does explain and justify his ultimate decision that the inferences from the data did not demonstrate a defect.

[73] The defenders reminded the court of the limitations attaching to an appellate court's review of first instance findings in fact. These were recently set out in *Woodhouse* v *Lochs and*

Glens Transport (*supra*, LP (Carloway), delivering the opinion of the court, at para [31]). They remain that, 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.

[74] The pursuer points to two pieces of evidence which the Lord Ordinary is said to have failed to consider. The first is the BMJ article. This criticism is not well founded. The Lord Ordinary referred specifically to this article. He attached little weight to it because he regarded it as journalism rather than a scientific piece. He did say that he had not been referred to an article which was specific to the Mitch/Accolade prosthesis. That appears to be correct. Although the BMJ article referred to research which had been carried out on the Mitch/Accolade prosthesis, it does not appear to have been confined to it. The findings of the research became part of the NJR data and were thereby part of the material which was taken into account by virtue of the Lord Ordinary's analysis of Prof Platt's report. The second area which the Lord Ordinary is said to have overlooked is the Australian data. Once again this was considered as part of Prof Platt's report in which he dismissed it, as he had the UK data, as being too small a sample to merit any alteration in his conclusions. The contention that the Lord Ordinary failed to take relevant evidence into account is rejected.

[75] The pursuer founded upon three cases from England which he suggested might indicate a degree of "claimant benevolence". These cases have no application to this litigation. The *dicta* cited from *Drake* v *Harbour* [2008] EWCA Civ 25 (Toulson LJ at para 28) concerns a well known evidential principle in relation to proof of causation and is not

relevant. The *dicta* in *Keefe* v *Isle of Man Steam Packet Co* [2010] EWCA Civ 683 (Longmore LJ at para 19; cited in *Younas* v *Okeahialam* [2019] EWHC 2502 (QB), HHJ Rice at para 34) do not set out a principle of law but an equitable consideration in relation to the assessment of the state of proof when a party has either destroyed evidence, which could have been adverse to his position, or failed to create or preserve evidence in breach of a duty to do so. Nothing of this nature arises in this case. The defenders' decision to discontinue a piece of research or study does not fall into this category.

[76] Returning to the main issue concerning material which might contradict the *prima facie* evidence of defect, the Lord Ordinary asked whether, in a context in which the majority of MoM THR patients were pain free and enjoying ordinary living, that majority was smaller than those with non-MoM THRs, or the outcome for the minority was worse. The Lord Ordinary accepted the testimony of Dr Burke that, contrary to the view of Prof Gill, it had not been scientifically demonstrated that metallic debris at the junction of the trunnion and the femoral head was the cause of ARMD. He explained his reason for this; notably the use of the Accolade stem and metal femoral head in non-MoM THRs without "especially damaging" debris. The Lord Ordinary was entitled to reach such a conclusion.

[77] When it came to a comparison of revision rates, the Lord Ordinary properly understood the confidence interval and how it applied in Prof Platt's reasoning. Prof Platt's report had been agreed as "unchallenged evidence" (Second Joint Minute para 1). Although it would technically have been open to the Lord Ordinary to reject Prof Platt's report, and he did not accept part of his reasoning on the unreliability of the data, such a course would have been highly unusual and open to substantial criticism. In the event, the Lord Ordinary accepted the substance of Prof Platt's report. It is instructive to repeat Prof Platt's conclusion:

> "161. My examination of available data on revisions of the MITCH-Accolade product indicates that there are limited data available to reliably estimate the survivorship of MITCH-Accolade and to compare its survivorship to other THR prostheses. When taking into consideration (1) the small sample sizes for MITCH-Accolade prostheses and the correspondingly large uncertainty in survivorship estimates, (2) the substantial variation in revision rates across surgeons, (3) the notable differences in the characteristics of patients implanted with the MITCH-Accolade versus other hip implant products, and (4) the potential biases created by such differences (as well as by differences in characteristics not recorded in the data), 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."

[78] The pursuer responds to this by maintaining that this case had not been based upon a consideration of statistical data but on the elements of the "*prima facie* evidence". That may be so, but the question which the Lord Ordinary posed was whether that evidence had a sound underlying scientific or statistical base. Put another way, were the concerns, alerts and warnings based on accurate facts? The Lord Ordinary has held that they were not. He has adequately justified that finding under reference to Prof Platt's unchallenged report. The Lord Ordinary might have been criticised on the basis that he has applied a scientific rather than a legal standard of proof, were it not for his reference to being alive to that very danger (at para [154]). In his view Prof Platt's report was significant. The Lord Ordinary was not using it to prove that the Mitch/Accolade prosthesis was not defective but to demonstrate that the *prima facie* evidence was not supported by the up to date information.

[79] For these reasons, the reclaiming motion must be refused.