A Scottish first: hip replacement product ruled not to be “defective”

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A SCOTTISH FIRST: HIP REPLACEMENT PRODUCT RULED NOT TO BE "DEFECTIVE"

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The author discusses the recent decision in Hastings v Finsbury Orthopaedics Limited and Stryker UK Limited.[1] Hastings *is a landmark decision in that it is the first Scottish case in which a proof has been heard in an action arising under the Consumer Protection Act 1987 in respect of an alleged defect in a hip replacement product.*

Introduction

The case of *Donoghue v Stevenson*[2] is well known for its broad ratio, namely the neighbourhood principle which sets out the circumstances in which a duty of care will arise in respect of physical damage claims. The case, of course, has a narrower ratio in relation to the common law liability of a manufacturer in respect of injury or damage caused by defective products. Although the common law in relation to product liability "stands completely untouched,"[3] it has been largely (but not completely) supplanted by the strict liability regime which is found in the Consumer Protection Act 1987. Case law in relation to that statutory regime is not particularly plentiful but the Court of Session has recently had occasion to consider the statutory provisions in *Hastings v Finsbury Orthopaedics Limited and Stryker UK Limited*,[4] a case alleging defects in a hip replacement product. Although the English courts have witnessed litigation in respect of hip prosthesis systems, *Hastings*[5] is the first such case in Scotland where a proof has been heard and it seems likely that the judgment of the court will be of interest to both manufacturers and consumers of such products. The publication of the judgment presents an opportunity to revisit the key statutory provisions and to examine a number of previous English decisions which have sought to interpret those provisions. An examination of the English cases, along with consideration of *Hastings*,[6] reveals certain points of disparity among the various judgments and it is suggested that further elucidation from the higher courts would be welcome.

Background to the case

The pursuer, a former forestry worker, had a history of arthritis affecting both hips. In March 2009, at the age of 54, he submitted to a left sided metal on metal (MoM) total hip replacement (THR). The prosthesis comprised a Mitch/Stryker Howmedica uncemented acetabular cup, manufactured by the first defender (Finsbury), and an Accolade V40 uncemented femoral stem with a large bearing MoM hip articulation, manufactured by the second defender

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[1] *Hastings v Finsbury Orthopaedics Limited and Stryker UK Limited* [2019] CSOH 96; 2019 S.L.T. 1411

[2] *Donoghue v Stevenson* 1932 S.C. (H.L.) 31

[3] *Winfield & Jolowicz on Tort*, edited by W. E. Peel and J. Goudkamp, 19th edn; (London: Thomson/Sweet & Maxwell, 2014), para 11-003

[4] *Hastings* 2019 S.L.T. 1411

[5] *Hastings* 2019 S.L.T. 1411

[6] *Hastings* 2019 S.L.T. 1411

(Stryker). In November 2009, the pursuer underwent a right sided MoM total hip replacement, in which the same combination of components was used. In October 2012, the pursuer underwent revision of his left sided implant. He subsequently raised proceedings in which he sought damages against the two companies which manufactured the components used in his hip replacements, alleging that he sustained loss and damage as a result of the use of metal on metal total hip replacements in the operations performed in 2009. His case did not proceed on the basis of fault or negligence (per *Donoghue*[7]), but rather under the relevant provisions of the Consumer Protection Act 1987. Accordingly, given the statutory basis of the pursuer's case, it is appropriate to set out the genesis and key provisions of the relevant legislation.

Genesis and key provisions of the 1987 Act

Before considering the key provisions of the 1987 Act, it should be noted that in any *common law* action against a manufacturer, the pursuer must establish fault or negligence. If that cannot be done, and the onus in that respect lies on the pursuer, the action will fail. In *Evans v Triplex Safety Glass Co. Ltd*[8] the plaintiff's inability to establish fault against either of two defendants resulted in dismissal of his action. He had suffered injury when his car windscreen disintegrated but he was unable to establish whether it was the windscreen manufacturer or the manufacturer of the car (which had fitted the windscreen) who was at fault.

The common law in relation to product liability was considered to be inadequate and has now been largely superseded by Part 1 of the Consumer Protection Act 1987.[9] The Act resulted from Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [1985] OJ L210/29.[10] The 1987 Act implements the UK's obligations under that Directive. Section 1(1) of the Act provides as follows: "[Part 1] 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." It follows that the1987 Act is to be interpreted so as to comply with the Directive. In *A v National Blood Authority (No.1),*[11] a case involving blood products infected with Hepatitis C, it was accepted[12] that, in the event of conflict, the wording of the Directive should be applied. More recently, in *Gee v Depuy International Ltd*[13] Andrews J. stated: "It is well established that domestic legislation which brings into effect an EU directive must be

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[7] *Donoghue* 1932 S.C. (H.L.) 31

[8] *Evans v Triplex Safety Glass Co. Ltd* [1936] 1 All E.R. 283

[9] "It is undoubtedly true that, at least in the United Kingdom, the protection of consumers was materially enhanced by the introduction of no-fault liability." (per Lord Tyre in *Hastings* 2019 S.L.T. 1411 at [97])

[10] The directive was prompted by the Thalidomide drug scandal in which women who had taken the anti-emetic drug subsequently gave birth to babies with "flipper" limbs. The difficulty of proving fault was brought sharply into focus by that particular tragedy.

[11] *A v National Blood Authority (No.1)* [2001] 3 All E.R. 289

[12] *A v NBA* [2001] 3 All E.R. 289 at 308

[13] *Gee v Depuy International Ltd* [2018] EWHC 1208 (QB); [2018] Med L.R. 347

interpreted, so far as is possible, in the light of the wording and the purpose of the directive, so as to achieve the result intended by the latter."[14]

The Act's provisions have been described by the late Professor Joe Thomson as "hideously complex".[15] This article does not seek to explore the complexities of the legislation but offers instead a brief overview of its main provisions.[16]

The key provision of the 1987 Act is s. 2(1) which imposes no-fault (or "strict") liability on the producer of a product **"**where any damage is caused wholly or partly by a defect in a product". Thus, "defectiveness, not fault, is the criterion of recovery."[17] The advantage offered to pursuers by the statutory scheme is immediately apparent. The pursuer is relieved of the need to prove fault.[18] Writing shortly before the legislation came into effect, Newdick made the following observations:

> "[L]iability for defective products is no longer to be dependent on fault, but rather on the mere fact of defectiveness.
>
> The broad reasons of policy for the change continue to be articulated by the injuries suffered by the thalidomide children. By the attention it devotes to consideration of the alleged fault of the defendant, the law of Negligence is unable to consider the interests of the person for whom the action has been brought."[19]

In a later article, the same author articulated the benefit of the new strict liability regime as follows:

> "The advantage of this approach for the individual is that liability turns on the existence of a defect alone...Strict product liability depends on the condition of the product, not the fault of its maker or supplier."[20]

While the Act heralds a move away from fault based liability, it does not confer on consumers a right to sue the producer as if there were a contractual warranty as to the safety standard to which the product had been designed.[21]

A "product" is defined in s.1(2) of the 1987 Act as "any goods or electricity and… includes a product which is comprised in another product, whether by virtue of being a component part or raw material or otherwise." "Damage" is defined in s.5(1) as "death or personal injury or any loss of or damage to any

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[14] *Gee* [2018] Med L.R. 347 at [67]
[15] Joe Thomson, *Delictual Liability,* 5th edn, (West Sussex: Bloomsbury, 2014), p.180
[16] For a more detailed discussion, see F. McManus, "Product Liability and Consumer Protection" in J.M. Thomson (ed), *Delict* (Edinburgh: W. Green/SULI, 2007) Ch.16
[17] J.F. Clerk & W.H.B. Lindsell*, Torts,* M. Jones ed, 22nd edn, (London, Thomson/Sweet & Maxwell, 2018), para.11-48
[18] The pursuer is however required to prove the damage, the defect and the causal relationship between defect and damage-see *Wilkes v Depuy International* Ltd [2016] EWHC 3096 (QB); [2017] 3 All E.R. 589 at [54]
[19] Christopher Newdick, "The future of negligence in product liability" (1987) 103 L.Q.R. 288, 288
[20] Christopher Newdick, "The development risk defence of the Consumer Protection Act 1987" (1988) 47(3) CLJ 455, 455
[21] See *Tesco Stores Ltd v Pollard* [2006] EWCA Civ 393 at [17] per Laws J.

property (including land)." Personal injury includes any disease and any other impairment of a person's physical or mental condition.[22]
Section 2(5) provides that where two or more persons are liable for the same damage, their liability shall be joint and several. A number of possible defences are set out in s.4 of the Act and separate provision is made for the defence of contributory negligence in s.6(4). Accordingly, liability is not absolute in nature.[23]

The statutory regime does not apply in all cases. Damage to the defective product *itself* is excluded from the scope of the Act by virtue of s.5(2).[24] Recovery is also excluded under the Act in respect of property damage claims which do not exceed £275 in value[25] and in respect of damage to property which is not for "private use."[26] There thus remains an important residual role for the common law, and in respect of any such action based on the common law, fault requires to be established. Indeed, s.2(6) of the 1987 Act provides that s.2 shall be without prejudice to any liability arising otherwise than by virtue of Part 1 of the Act.

The central issue for the court in *Hastings*[27] was whether or not a defect, as statutorily defined, existed in the prosthesis product in question. Section 3 of the Act defines the meaning of "defect". In terms of s.3(1), a product is defective if its safety "is not such as persons generally are entitled to expect". An "entitled expectation" test therefore applies. Although it has been judicially stated that the assessment is "conceptually simple" it has also been stated that "the assessment may be difficult in practice."[28] In *Abouzaid v Mothercare (UK) Ltd*[29] the claimant suffered damage to his eye caused by a defect in a Coseytoes product. Pill L.J. articulated the test to be applied, stating that "[m]embers of the public were entitled to expect better from the appellants."[30] In *A v NBA*,[31] members of the public were held entitled to expect that blood transfused to them would be free from infection. In *Gee*,[32] Andrews J. stated: "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

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[22] Consumer Protection Act 1987 s.45(1)
[23] *A v NBA* [2001] 3 All E.R. 289 at [31]
[24] Nor are such cases reparable in the common law of negligence as such loss is classified as pure economic loss.
[25] The 1987 Act s.5(4)
[26] The 1987 Act s.5(3). See *Renfrew Golf Club v Motocaddy Ltd* [2016] CSIH 57; 2016 S.C. 860
[27] *Hastings* 2019 S.L.T. 1411
[28] *Wilkes v Depuy International Ltd* [2016] EWHC 3096 (QB); [2017] 3 All E.R. 589 at [79] per Hickinbottom J. who went on to say that "the courts should guard against either over-complicating, or over-analysing, the exercise."
[29] *Abouzaid v Mothercare (UK) Ltd* [2001] T.L.R. 136
[30] *Abouzaid* [2001] T.L.R. 136 at [27]
[31] *A v NBA* [2001] 3 All E.R. 289
[32] *Gee* [2018] Med L.R. 347

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...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."[33]

It should be noted that the test of defectiveness requires consideration of *entitled*, not *actual* expectation and it demands an objective, rather than a subjective, assessment. These points have been repeatedly emphasised by the courts. In *A v NBA*,[34] Burton J. observed that "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"[35] (emphasis in the original). In *Wilkes v Depuy International Ltd* [36] Hickinbottom J. stated:[37] "[T]he relevant level of safety is not that which a particular patient considers the product should provide; nor even the level of safety which members of the public generally may consider it ought to provide. The level of safety is not assessed by reference to actual expectations of an actual or even a notional individual or group of individuals. [The s.3(1) test] can only be a reference to an entitlement *as a matter of law*, not actual individual or even general expectation" (emphasis added). More recently, in *Gee,*[38] Andrews J. stated that "[w]hat the public is *entitled* to expect may not match a person's actual expectation"[39] (emphasis in the original).

Section 3(2) of the Act provides as follows:
"In determining for the purposes of subsection (1) above 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, 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."

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[33] *Gee* [2018] Med L.R. 347 at [99]
[34] *A v NBA* [2001] 3 All E.R. 289
[35] *A v NBA* [2001] 3 All E.R. 289 at [31]
[36] *Wilkes v Depuy International Ltd* [2016] EWHC 3096 (QB); [2017] 3 All E.R. 589
[37] *Wilkes* [2017] 3 All E.R. 589 at [69]
[38] *Gee* [2018] Med L.R. 347
[39] *Gee* [2018] Med LR 347 at [94]

In *Wilkes*,[40] Hickinbottom J. stated:
"The circumstances which are relevant in a particular case is itself a matter of law; but it is to be noted that neither the Directive nor the Act imposes any restriction on the considerations that may be taken into account. The three specific matters set out in section 3(2) are circumstances which must be considered ("shall be taken into account"); but they are clearly not intended to be an exhaustive list of relevant circumstances, nor are they such that any other circumstance, to be relevant, must be shown to be eiusdem generis."[41]
The circumstances which may be relevant to the question of defectiveness are therefore not constrained by the Act. Cost, for example, may be a potentially relevant circumstance as illustrated in an example provided by Miller and Goldberg:
"[N]o doubt it is the case that a car would be safer for its occupants if the strength of its shell were such that it would not buckle in a high speed crash and even safer if it were built with bullet-proof glass lest it should be driven through areas with a drug-fuelled gun culture. However, it would never be seriously suggested that an ordinary passenger car would be regarded as defective by virtue of the fact that it lacked such characteristics."[42]
As Nolan has observed, "[n]o product is perfectly safe, because safety must be traded off against cost and convenience."[43]

In *Wilkes*,[44] Hickinbottom J. stated: "The Directive and Act set a standard of safety for virtually all products supplied to consumers…from an electric heater to a bottle top, from a car to a medicine. The standard of safety which people are entitled to expect across the whole range of these products is incapable of precise definition in a framework document such as the Directive; but, of course, more assistance and guidance could have been given than is found in that document…However, those responsible for the Directive clearly, and deliberately, declined to give better particulars. Indeed, in the report commissioned by the European Union in 2003 (*J Meltzer, R Freeman & S Thomson, Product Liability in the European Union: A report for the European Commission* (2003)), the possibility of defining "defect" to clarify controversial issues was mooted; but the authors of the report understood that this might fetter the ability of judges to deal with such matters on a case-by-case basis. The report envisaged that a body of case law would develop that would give guidance with regard to the concept. However, no such body of law has yet developed."[45]

Miller and Goldberg have said that "[i]t is arguable that the definition of a 'defect' is the single most difficult part of the…Directive and Part 1 of the… Act[46] while Professor Stapleton has observed that the definition of "defect"

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[40] *Wilkes* [2017] 3 All E.R. 589
[41] *Wilkes* [2017] 3 All E.R. 589 at [77]
[42] C.J. Miller and R.S. Goldberg, *Product Liability*, 2nd edn, (Oxford: Oxford University Press, 2004), para. 10.82.
[43] Donal Nolan, "Strict product liability for design defects" (2018) 134 L.Q.R. 176, 178
[44] *Wilkes* [2017] 3 All E.R. 589
[45] *Wilkes* [2017] 3 All E.R. 589 at [68]
[46] C.J. Miller and R.S. Goldberg, *Product Liability*, 2nd edn, (Oxford: Oxford University Press, 2004), para. 10.13.

used is at best circular, and at worst empty, because "what a person is entitled to expect is the very question a definition of defect should be answering."[47]
As noted above, it is the existence or otherwise of an alleged "defect" which would be the issue to confront the Court of Session in *Hastings*.[48] The question of allegedly defective hip prostheses had already been ventilated, however, in a number of cases coming before the English courts. Those cases contain a number of significant judicial observations concerning the key concept of "defect". It is accordingly appropriate to review those English authorities before turning attention to the Scottish case.

English litigation
Before *Hastings*[49] came before the Court of Session, litigation concerning MoM THRs had taken place south of the border. In December 2016, judgment was handed down in *Wilkes*.[50] The claimant in that case had received a MoM THR using components manufactured by the defendants which included a steel femoral shaft called a C-Stem. Three years later, the stem fractured and, during revision surgery, evidence was found of metal debris having been shed around the joint. The claimant alleged that there was a defect in the C stem component. Hickinbottom J. stated that a holistic and flexible approach should be adopted in assessing the safety which persons are generally entitled to expect. What circumstances are relevant and the weight to be attached to those circumstances would depend upon the particular facts of the case. Hickinbottom J. stated that "[t]he issue raised by the Act in terms of defect is necessarily one of open-textured judgment, untrammelled by any rigid rules outside the few that appear in the Act itself."[51] He concluded that the claimant had failed to satisfy the court that the C-Stem suffered from a defect as statutorily defined (i.e. that its safety was not such as persons generally were entitled to expect).[52] Accordingly, the manufacturer was held not to be liable to the claimant under s.3 of the 1987 Act.
Some months later, in May 2018, judgment was handed down in *Gee*.[53] This case focussed on the Pinnacle Ultamet hip prosthesis system (a different system from that which would form the basis of the litigation in *Hastings*). The claimants' contention in *Gee* was that the prostheses supplied to them were defective in terms of s.3 of the 1987 Act, and that this had caused personal injury for which the manufacturer was liable. In the course of her judgment, Andrews J. stated:[54]

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[47] Jane Stapleton, *Product Liability* (London: Butterworths, 1994), p 234.
[48] *Hastings* 2019 S.L.T. 1411
[49] *Hastings* 2019 S.L.T. 1411
[50] *Wilkes* [2017] 3 All E.R. 589
[51] *Wilkes* [2017] 3 All E.R. 589 at [79]
[52] Shortly after the judgment was handed down, it was described as "to date the most ambitious and sophisticated judicial discussion of the issue [of defectiveness] in this context, and as such it provides more comprehensive guidance than the cases that preceded it." (Donal Nolan, "Strict product liability for design defects" (2018) 134 L.Q.R. 176, 180)
[53] *Gee* [2018] Med L.R. 347
[54] *Gee* [2018] Med L.R. 347 at [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.”
Andrews J. held that the defendant was not liable to the claimants. Her judgment contains a detailed exposition of the nature and history of hip replacement surgery, and of certain pathological conditions observed in patients who received MoM prostheses. When, in Scotland, the *Hastings*[55] case arose, parties entered into a joint minute of agreement setting out the factual background to the questions at issue. That joint minute was based on the detailed exposition by Andrews J. in *Gee.*[56] Attention is now turned to the Scottish case.

Hastings-A Scottish First
In *Hastings*,[57] the pursuer’s case was based on s.2 of the 1987 Act, which, as has been noted, imposes no-fault liability for damage caused by a defect in a product. The pursuer contended that the metal on metal total hip replacements (MoM THR) used in his operations were defective, in terms of s.3 of the Act, because their safety was not such as persons generally were entitled to expect. It is worth noting that the product in question in *Hastings*[58] was of a medicinal character and it is useful to preface discussion of the case with observations made in precisely such a context by Gibson *et al*:
“[T]he open-textured character of the prescribed safety standard provides the court with a very considerable degree of flexibility in relation to the matters to which it can properly have regard so as to enable it to perform its duty, on a case-by-case basis, of ensuring that the appropriate safety standard is set on as fully an informed basis as possible having regard to the facts pertaining to the specific product in question.”[59]

Background to the case
MoM THRs were developed in the late 1990s and became popular in the early 2000s. At one stage during 2000-2010, MoM was the commonest bearing surface implanted, particularly in the young and active. It promised to be a low wearing bearing surface, with the added benefit of allowing hip resurfacing. The pursuer’s MoM THRs were Mitch/ Accolade products. The background to the genesis (and subsequent withdrawal) of the product can be outlined as follows. Stryker manufactured a range of femoral stem products but wanted to

[55] *Hastings* 2019 S.L.T. 1411
[56] *Gee* [2018] Med L.R. 347
[57] *Hastings* 2019 S.L.T. 1411
[58] *Hastings* 2019 S.L.T. 1411
[59] C. Gibson, G. Webb and J. Purnell, “Product liability for medicinal products” in Michael Powers & Anthony Barton (eds), *Clinical Negligence*, 5th edn, (West Sussex: Bloomsbury, 2015), para 13.87

enter the market for provision of MoM THRs. In 2005, it formed an agreement with Finsbury for the development, manufacture and supply of a metal acetabular cup and femoral head that would be compatible with its Accolade stems. The consequence was the production by Finsbury of the Mitch range of products which together with Stryker's Accolade stem, was brought to market. The Mitch/Accolade product became commercially available in the UK in 2006. It was supplied together with instructions for use. Those instructions contained a section entitled "Possible Adverse Effects" which provided information about corrosion of metal implants leading to metallic ion release and possible adverse reactions to metal particles. The instructions emphasised that the expected life of total hip replacement components was finite. Surgeons were advised to warn patients of all the Possible Relevant Adverse Effects.

By the end of the 2000s, sales of MoM THRs generally had dramatically declined following expressions of concern among orthopaedic professionals about revision rates and possible difficulties in carrying out revision operations. Academic papers reported the incidence of pseudotumour in a group of female patients experiencing problems after MoM hip resurfacing[60] as well as the poor outcome of revision surgery owing to associated soft tissue destruction.[61] Adverse reaction to metal debris ("ARMD") was first reported at a national orthopaedic conference in 2008-2009 and awareness of it increased over subsequent years. In 2012, public concern regarding the safety of MoM implants increased following the broadcasting of the results of an investigation by the British Medical Journal and BBC Newsnight.

Medical device alerts ("MDAs") in relation to MoM hip replacements were issued by the Medicines and Healthcare Products Regulatory Agency ("MHRA") in 2010 and in 2012. Annual follow-up of THR patients for the life of the implant was required.

In April 2012, an "urgent" field safety notice ("FSN") was issued by Depuy (which had acquired Finsbury in 2009) and Stryker in relation to the Mitch/Accolade product owing to a higher than expected revision rate for the product. An instruction was given not to implant the product.

A review article by Mellon *et al*[62] stated:

"whilst there is evidence that MoMHRA [metal-on metal hip resurfacing arthroplasty] works well in young active men, the failure rates of MoMHRA in women and of metal-on-metal THR in both sexes are significantly higher than expected…This high failure rate appears to be due to the pro-inflammatory effects of submicron wear particles…These failures typically involve soft tissue and bone disruption which can be massive, leading to severe functional impairment and extremely challenging revision surgery."

From 2012, the implantation of MoM Total Hip Replacements ceased altogether although some MoM hip *resurfacings* continue to be performed.

The preliminary proof

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[60] H. Pandit *et al* "Pseudo-tumours associated with metal-on-metal hip resurfacings", J Bone Joint Surg [Br] 2008.90–B:847–51.

[61] G. Grammatopoulos *et al* "Hip resurfacings revised for inflammatory pseudotumour have a poor outcome", J Bone Joint Surg [Br] 2009.91–B:1019–1024.

[62] S.J. Mellon *et al*, "Hip replacement: landmark surgery in modern medical history", Maturitas 2013 Jul; 75 (3): 221-226

The case came to preliminary proof before Lord Tyre. The proof was restricted to the issue of whether certain propensities and risks inherent in MoM THR prostheses rendered the particular combination of components employed in the pursuer's operations "defective" within the meaning of the 1987 Act. Lord Tyre set out the question for determination as follows:[63]
"Does the admitted inherent propensity of metal on metal hip prostheses to shed metal debris through wear in use …and the admitted risk that some patients may suffer an adverse reaction to such metal debris that may necessitate early revision, render the [Mitch/Accolade] 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."
A central plank of the pursuer's argument was the fact that surgeons had stopped recommending MoM THRs some three years after his operations, following concern about the survival time until revision (compared to alternative products using different materials) and a "higher risk" of an unsuccessful revision.
Parties were agreed that the question of whether there was a defect in a product fell to be determined as at the date of its supply. In this case, the prostheses were supplied in 2009, when the pursuer received the implants. Parties disagreed, however, as to the principal purpose/s of the 1987 Act. While the pursuer submitted that its principal objective was consumer protection, the defenders submitted that the Directive had a variety of purposes, of which consumer protection was only one. In Lord Tyre's opinion, there was no justification for construing the Directive or the Act in a manner more favourable to the consumer than to the producer. The Advocate General (Szpunar) in *Novo Nordisk Pharma GmbH v S*[64] had observed that the rights and obligations arising from the Directive resulted from a balancing of different interests, which "include guaranteeing that competition will not be distorted, facilitating trade within the common market, consumer protection and ensuring the sound administration of justice."[65] Lord Tyre accordingly took the view that while the effective protection of consumers was a key objective of the Directive, it was not the main or overriding one. It had equal status with the other objectives. His Lordship continued:[66] "[T]he European case law is quite clear that when approaching the task of interpreting the Act, the court is not entitled to give [the protection of consumers] priority over the [other objectives of the Directive]."
Under reference to *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt — Die Gesundheitskasse*[67] (which concerned defects in pacemakers), Lord Tyre observed that the question of defectiveness "must …be approached on the basis of the reasonable expectations of the public at large, taking into account *inter alia* the intended purpose, the objective characteristics and properties of the product, and the specific requirements of the group of users for whom the product was intended."

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[63] *Hastings* 2019 S.L.T. 1411 at [89]
[64] *Novo Nordisk Pharma GmbH v S*, ECJ, 11 June 2014, Case C-310/13
[65] *Novo Nordisk Pharma GmbH,* ECJ, 11 June 2014, Case C-310/13 at [19]
[66] *Hastings* 2019 S.L.T. 1411 at [97]
[67] *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt — Die Gesundheitskasse* [2015] 3 C.M.L.R. 173

Lord Tyre then alighted upon an examination of the English case law. In *A v NBA*[68], persons infected with Hepatitis C through blood transfusions sought damages under the 1987 Act against the authorities responsible for production of blood and blood products. Burton J. held that products could be categorised either as "standard" or "non-standard". Standard products are and perform as the producer intends. Non-standard products are different from the standard product because they are deficient or inferior in terms of safety, and it is the harmful characteristic present in the non-standard product which has caused the damage. The product in *A v NBA*[69] was non-standard. As regards standard products, Burton J. proposed the following approach:[70]
"If a standard product is unsafe, it is likely to be so as a result of alleged error in design, or at any rate as a result of an allegedly flawed system. The harmful characteristic must be identified, if necessary with the assistance of experts. The question of presentation/time/circumstances of supply/social acceptability etc will arise...The sole question will be safety for the foreseeable use. If there are any comparable products on the market, then it will obviously be relevant to compare the offending product with those other products, so as to identify, compare and contrast the relevant features."
Burton J. also held that "avoidability" was *not* one of the circumstances to be taken into account under s.3 of the Act.[71] Furthermore, the test was not that of an absolute level of safety. The requisite level of safety was not what is *actually* expected by the public at large, but rather what they are *entitled* to expect.
Lord Tyre then examined *Wilkes*[72] in which Hickinbottom J. had stated certain "uncontroversial"[73] propositions: the Directive and the Act focus not on the acts or omissions of producers, but upon the condition of the product; the condition required of the product is not put in terms of fitness for purpose but in terms of safety, the hallmark of defect being a lack of safety; safety is a relative concept- there cannot be a sensible expectation that a medical or medicinal product is entirely risk-free and potential benefits have to be balanced against risks; the test for safety requires an objective approach by reference to what persons generally are entitled to expect as a matter of law. It followed that in considering whether a product was defective, the court required to "assess the appropriate level of safety, exercising its judgment, and taking into account the information and the circumstances before it".[74] Although a causal link must be proved between the defect and damage, claimants are not required to prove the cause of that lack of safety or why the product failed.

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[68] *A v NBA* [2001] 3 All E.R. 289
[69] *A v NBA* [2001] 3 All E.R. 289
[70] *A v NBA* [2001] 3 All E.R. 289 at [71]
[71] Nolan has observed that it is quite understandable that Burton J. took this view in a case involving a non standard product because if avoidability was a relevant consideration in such a context "then "defectiveness" would come too close to a negligence standard in that context, and many of the purported benefits for claimants of the move to strict liability would be lost." (Nolan, "Strict product liability for design defects" (2018) 134 L.Q.R. 176, 178)
[72] *Wilkes* [2017] 3 All E.R. 589
[73] *Hastings* 2019 S.L.T. 1411 at [103]
[74] *Wilkes* [2017] 3 All E.R. 589 at [72]

On the issue of "avoidability", Hickinbottom J. had stated that "the ease and extent to which a risk can be eliminated or mitigated may be a circumstance that bears upon the issue of the level of safety that the public generally is entitled to expect".[75] Lord Tyre agreed.

Although Hickinbottom J. had considered the standard/non-standard classification (adopted by Burton J. in *A v NBA*[76]) to be "unnecessary and undesirable",[77] Lord Tyre thought it was almost inevitable that, when identifying whether or not a product was "defective", there would be some focus on whether or not the particular product was or was not within the producer's design specification.[78]

Hickinbottom J. had considered that regulatory approval was not an automatic defence under the Act, but might be evidence that the level of safety of the product was that which persons generally were entitled to expect.[79] As far as warnings and other information for use were concerned, these would usually be addressed to a learned intermediary in the case of medicinal products. While the existence of such an intermediary did not provide an automatic defence, it was "unarguable that the fact that there is a learned intermediary (who has chosen a particular prosthesis for a particular patient and has available, not only his general professional knowledge, but also the specific IFU including warnings) is other than a relevant circumstance for the purposes of section 3 of the Act."[80]

The third of the English cases which Lord Tyre examined was *Gee.*[81] Lord Tyre agreed with the assessment of Andrews J. in that case that the Directive and the Act required a flexible approach to the question of what might constitute relevant circumstances. Those circumstances might differ, depending on the product and the nature of the complaint about it. Lord Tyre agreed that consideration of benefits of a medical or pharmaceutical product need not necessarily be confined to safety benefits. Whether it was appropriate to weigh the benefits of a new product against known risks would depend upon the circumstances of a particular case.

Application of the legal principles to *Hastings*

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[75] *Wilkes* [2017] 3 All E.R. 589 at [89]

[76] *A v NBA* [2001] 3 All E.R. 289

[77] *Wilkes* [2017] 3 All E.R. 589 at [94]. These critical comments have been described as an "unfortunate aspect of Hickinbottom J.'s judgment" (Nolan, "Strict product liability for design defects" (2018) 134 L.Q.R. 176, 180)

[78] It has been observed that in relation to standard products, "the defectiveness enquiry is inevitably more complex, since in such cases there is no benchmark (in the form of an in-specification product) with which the safety of the standard product can be compared." (Nolan, "Strict product liability for design defects" (2018) 134 L.Q.R. 176, 178)

[79] Hickinbottom J. put it thus: "[W]here every aspect of the product's design, manufacture and marketing has been the subject of the substantial scrutiny, by a regulatory body…it may be challenging for a claimant to prove that the level of safety that persons generally are entitled to expect is at a higher level". (*Wilkes* [2017] 3 All E.R. 589 at [100])

[80] *Wilkes* [2017] 3 All E.R. 589 at [108]

[81] *Gee* [2018] Med L.R. 347

The court in *Hastings*[82] was required to establish firstly, the "entitled expectation" of persons generally in respect of the safety of the Mitch/Accolade product and secondly, whether the product failed to meet that entitled expectation. Lord Tyre emphasised that the question for determination was expressly restricted to the Mitch/Accolade product before adding: “It will then be for others to assess the significance of my opinion in relation to other MoM THR products which are the subject of litigation in this jurisdiction.”[83]

What was the entitled expectation of persons generally in respect of the Mitch/Accolade product?

As far as entitled expectation was concerned, Lord Tyre stressed that "safety" was a legal concept and not a medical term of art. It was for the court, rather than for orthopaedic surgeons, to decide what, as a matter of law, was the entitled expectation in relation to the "safety" of the Mitch/Accolade product. Some of the experts had identified one of the potential benefits of a MoM implant as improved survivorship. There was, however, no ten-year outcome data in respect of the MoM THRs supplied during the relevant period. That did not lower the entitled expectation in relation to MoM implants below that of other products with the requisite period of outcome data to support their use. The lack of such data suggested however that the court (following the objective assessment required by the Act) could not conclude that there was an entitled expectation in 2009 that MoM implants generally or the Mitch/Accolade product in particular would have a significantly *improved* survivorship as compared with MoCP (metal on conventional polyethylene) implants then in common use. That may have been the hope (or belief) of some orthopaedic professionals, but it did not represent the statutory test against which the existence or otherwise of a defect in the product must be measured.

Although the parties offered ostensibly differing formulations of entitled expectation, Lord Tyre, on closer examination of their respective positions, took the view that their positions could be reconciled as follows:

“[T]he entitled expectation in relation to the Mitch/Accolade product can …be stated as being that, subject to *de minimis* considerations, its level of safety would not be worse, when measured by appropriate criteria, than existing non-MoM products that would otherwise have been used.”[84]

Lord Tyre stated that the instructions for use (“IFU”) would have had no significant effect on entitled expectation in relation to the Mitch/Accolade product. His Lordship doubted whether they had (or were expected to have) any real practical value. They were in very small point size so as to be virtually illegible and the instructions in relation to possible adverse effects were in highly general and heavily qualified terms. Evidence indicated that orthopaedic surgeons would not generally read IFU in detail and Lord Tyre concluded that IFU would have added little, if anything, to the knowledge of any surgeon qualified to carry out a hip replacement operation.

Did the product fail to meet entitled expectation?

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[82] *Hastings* 2019 S.L.T. 1411
[83] *Hastings* 2019 S.L.T. 1411 at [112]
[84] *Hastings* 2019 S.L.T. 1411 at [119]

Lord Tyre's starting point in relation to this issue was a joint statement from the parties' experts in orthopaedic surgery to the effect that the majority of patients with MoM implants are pain free and able to enjoy daily activities with excellent outcome and that the pain relief and functional improvement achieved with MoM and comparable products are similar.
The pursuer's argument was founded strongly upon the fact that, following orthopaedic concerns and MDAs, surgeons had stopped recommending MoM THRs and they had been withdrawn from the market. By 2012 there had emerged a consensus that failure rates (in terms of survivorship) of MoM THRs were higher than had been expected and compared unfavourably with other types of THR. Members of various disciplines sought an explanation of those failure rates but no consensus emerged. Many of the published articles concluded that further research was necessary.
His Lordship stated:
"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. 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."[85]
Having reviewed the expert evidence, Lord Tyre concluded:[86]
"[T]he pursuer has established…that there *may* be a causal link between the creation of metal debris from a MoM THR and periprosthetic damage, but only in a minority of cases and in limited circumstances including high levels of exposure, and not necessarily for reasons peculiar to MoM THRs. That does not, in my opinion, of itself constitute a failure to meet entitled expectation."
Lord Tyre proceeded to address the question of whether there is a causal link between MoM THR *design* and the creation of metal debris that is capable of causing periprosthetic damage. Having considered the biomechanical evidence, he concluded:[87]
"[T]he pursuer…has demonstrated a mechanism by which metal debris is capable of being produced in large head MoM THRs in a manner which would not occur either in THRs using smaller head sizes or in MoM resurfacings. That said, I am not satisfied that all of the necessary links in the chain between such a mechanism and adverse health effects have been established...In particular, I do not consider that there is any evidence that would entitle me to find that debris from the head/stem interface is, or is even potentially, more damaging than debris from the bearing surface…The proportion of debris produced at the head/stem interface appears…to be small in comparison with that produced at the bearing surface. More significantly, it was not in dispute that the combination of a titanium alloy Accolade stem and a CoCr metal femoral head (whether a Mitch component or otherwise) has been used in many other implants including MoP THRs, and

[85] *Hastings* 2019 S.L.T. 1411 at [124]
[86] *Hastings* 2019 S.L.T. 1411 at [135]
[87] *Hastings* 2019 S.L.T. 1411 at [146]

no evidence was led of metal debris with especially damaging characteristics having been produced by such combinations."

The practical criteria adopted by Lord Tyre in assessing whether there was a failure to meet entitled expectation in relation to the Mitch/Accolade product were (i) time to revision, i.e. survivorship, and (ii) the existence or otherwise of higher risk of unsuccessful revision. Lord Tyre pointed out that his finding must be based upon evidence relating to the *Mitch/Accolade* product but because of the short period during which it was on the market, such evidence was not in abundant supply.

Dealing first with the issue of survivorship, Lord Tyre stated:[88]

"So far as they go…the data from 2012 which informed the observations in the MHRA alert and the (latest available) data from 2018 are consistent with one another in showing, *prima facie*, a revision rate for MoM THRs significantly worse than rates for available alternatives."

Objections had however been raised in an expert report to the use of registry data to measure current or predict future survivorship. Among those objections was the effect on the figures of "outliers", i.e. surgeons whose revision rates differed significantly from the normal range. Lord Tyre observed that once account was taken of outlier surgeons, it could not be concluded that the Mitch/ Accolade product had a materially lower survivorship than other available products or national standards. Furthermore, other factors rendered it unsafe to conclude from the bare data that the revision rate of the device fell below the entitled expectation of those who received it. The Mitch/Accolade product was implanted largely in young and/or active patients for whom large head MoM THRs were designed, and they were predominantly male. That is likely to have lowered the average survivorship of Mitch/Accolade implants, for reasons unconnected with the product itself. Revision rates for the Mitch/Accolade product were also likely to have been affected by the publicity surrounding MoM THRs generally. Expert testimony acknowledged that there was a lowering of the threshold for revision surgery owing to clinicians' fears of complications. The MDAs recommended annual follow-up for the life of the implant, and the possibility of revision surgery in asymptomatic patients. Lord Tyre accepted that it was likely that these factors would have increased the revision rate in relation to the Mitch/Accolade product for reasons other than the performance of the product itself. Accordingly, the registry data should not be treated as a reliable indicator of the "success" of the product.

Lord Tyre then addressed the second criterion in relation to entitled expectation namely the prospect of success of revision surgery for those patients whose initial implant fails and requires replacement. Studies in the late 2000s indicated that because of soft tissue damage caused by metal debris generated by MoM implants, the prospects of a successful revision operation were significantly reduced. Lord Tyre re-emphasised that the action related to a particular device. No evidence had been presented in relation to revision surgery where a Mitch/Accolade device had been used initially, other than evidence from the pursuer's surgeon relating to the pursuer himself. That evidence did not include anything about soft tissue damage having rendered

[88] *Hastings* 2019 S.L.T. 1411 at [151]

the revision surgery more challenging or the eventual outcome less satisfactory than would otherwise have been the case.
Evidence adduced from the defenders' expert, Professor Pandit, cast doubt on the concerns expressed in the 2000s. His opinion was that more recent studies suggested that revisions for ARMD were successful, and that the risk of re-revision was significantly less than in cases where revision was performed due to other reasons for failure of the primary implant.
Lord Tyre stated:[89] "It does…appear to be the case that concerns about the potential difficulties of revision surgery for ARMD have not…materialised. I place considerable weight on the opinion of Professor Pandit in this regard…Having participated in some of the research which first raised concerns about large-head MoM THRs, he has continued to contribute to the leading edge of such thinking, and now recognises that some of those concerns, expressed on the basis of a small number of years' experience of MoM implants, are not supported by evidence based upon a longer period of experience."

His Lordship stated:[90]
"In my opinion…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."

Lord Tyre concluded that the pursuer had failed to prove that the entitled expectation in relation to the Mitch/Accolade product at the time of its supply had not been met. Accordingly, the pursuer had not proved 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. However, in an important caveat, his Lordship added:[91]
"In holding that the pursuer in the present action has failed to prove that the Mitch/Accolade product supplied to him was defective, I do not exclude the possibility that another pursuer might be able to present evidence in relation to a different product sufficient to establish, on balance of probabilities, that entitled expectation in relation to that product had not been met."
Lord Tyre concluded: "I wish simply to make the point that my opinion should not be read as a finding that it has 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."[92]

Discussion
The law on product liability was radically transformed by Part 1 of the Consumer Protection Act 1987. Although the Act's strict liability regime has now been in place for over three decades, there have been relatively few

[89] *Hastings* 2019 S.L.T. 1411 at [162]
[90] *Hastings* 2019 S.L.T. 1411 at [163]
[91] *Hastings* 2019 S.L.T. 1411 at [164]
[92] *Hastings* 2019 S.L.T. 1411 at [165]

decisions in which the Act's provisions have been applied. For that reason alone, the decision in *Hastings*[93] is most welcome, providing, as it does, further important guidance as to the term "defect", the existence of which is, of course, key to liability under the statutory scheme. As Nolan has observed, "the test of defectiveness in s.3 is essentially an empty vessel to be filled by judicial analysis."[94] *Hastings,* albeit a first instance decision, is certainly a welcome addition to the contents of that vessel.
Until recently, the most detailed examination of the key concept of "defect" was found in the judgment of Burton J. in *A v NBA*.[95] The English decisions in *Wilkes*[96] and *Gee*[97] some years later provided further elucidation. As has been seen, the pursuer's argument in *Hastings*[98] that the prosthesis was defective was comprehensively rejected. That had, of course, also been the outcome in *Wilkes*[99] and *Gee*.[100] While much of what is said in *Wilkes*[101] and *Gee*[102] is endorsed in *Hastings*,[103] there are also some elements of disparity among the judgments which are worthy of comment.

As far as common ground is concerned, Lord Tyre agreed with Hickinbottom J. in *Wilkes*[104] that an objective assessment must be adopted in relation to the issue of safety and with Andrews J. in *Gee*[105] that the Directive and the Act required a flexible approach to the question of what might constitute relevant circumstances in the "defectiveness" assessment. Hickinbottom J. had made clear in *Wilkes*[106] that the standard of safety which persons generally are entitled to expect is "a matter of law"[107] to be assessed on a case by case basis. The circumstances which are relevant to that assessment in a particular case are likewise a matter of law.[108] It is accordingly a matter for the courts to determine the standard of safety which persons generally are entitled to expect. Lord Tyre reiterated this point in *Hastings*,[109] emphasising that a legal, not a medical, assessment of expected expectation was required. It was therefore for the court, not orthopaedic surgeons, to determine the entitled expectation in relation to the Mitch/ Accolade product.

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[93] *Hastings* 2019 S.L.T. 1411
[94] Donal Nolan, "Strict product liability for design defects" (2018) 134 L.Q.R. 176, 180
[95] *A v NBA* [2001] 3 All E.R. 289. The judgment has been described as a "monumental" one (per Hickinbottom J. in *Wilkes* [2017] 3 All E.R. 589 at [55])
[96] *Wilkes* [2017] 3 All E.R. 589
[97] *Gee* [2018] Med L.R. 347
[98] *Hastings* 2019 S.L.T. 1411
[99] *Wilkes* [2017] 3 All E.R. 589
[100] *Gee* [2018] Med L.R. 347
[101] *Wilkes* [2017] 3 All E.R. 589
[102] *Gee* [2018] Med L.R. 347
[103] *Hastings* 2019 S.L.T. 1411
[104] *Wilkes* [2017] 3 All E.R. 589
[105] *Gee* [2018] Med L.R. 347
[106] *Wilkes* [2017] 3 All E.R. 589
[107] *Wilkes* [2017] 3 All E.R. 589 at [69]
[108] See *Wilkes* [2017] 3 All E.R. 589 at [77]
[109] *Hastings* 2019 S.L.T. 1411

In *Wilkes*,[110] Hickinbottom J. took the view that avoidability may be a circumstance which bears upon the level of safety which the public is generally entitled to expect. In *Hastings*,[111] Lord Tyre expressed his agreement with that view. It is noteworthy that their approach differs from that adopted by Burton J. in *A v NBA*.[112] Burton J. took the view that avoidability was *not* a relevant circumstance in relation to the entitled expectation enquiry, as the purpose of the legislation was to exclude consideration of fault. If one did not exclude avoidability from the exercise, the Directive, in Burton J.'s view, "would not only be toothless but pointless."[113] *A v NBA,*[114] however, concerned a non-standard product, namely blood infected with Hepatitis C. *Hastings*[115] and *Wilkes*,[116] on the other hand, involved standard products. Nolan has observed: "To argue …that avoidability is *not* relevant in such a case is …at least as misconceived as to argue that avoidability *is* relevant in a non-standard product case, the flaw in both arguments being the failure to recognise the significance for this question of the standard/non-standard product distinction."[117]
Further judicial analysis of this issue would certainly be welcome.

While much of what is said in the earlier cases is affirmed in *Hastings*,[118] there are certain elements of disparity among the judgments. Section 3(2) of the Act provides that, in determining "defectiveness," all the circumstances shall be taken into account, including "the time when the product was supplied by its producer to another". Interestingly, in *Wilkes*,[119] Hickinbottom J. stated that "[t]he Act…requires consideration of whether, *at the time the producer first put the product into circulation*, that product did or did not have the level of safety that persons generally are entitled to expect"[120] (emphasis added). In *Gee*,[121] Andrews J. took the same view, namely that the time at which defectiveness was to be judged was *the time at which the product entered the market.*[122] Lord Tyre took a different view in *Hastings*,[123] preferring the date on which the product was supplied to (i.e. implanted into) the pursuer. That had been the agreed position between the parties in *Hastings*.[124] Lord Tyre was however alert to the fact that the trial in *Gee*[125] proceeded on the basis that it was common ground that entitled expectation was to be evaluated at

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[110] *Wilkes* [2017] 3 All E.R. 589
[111] *Hastings* 2019 S.L.T. 1411
[112] *A v NBA* [2001] 3 All E.R. 289
[113] *Wilkes* [2017] 3 All E.R. 589 at [69]
[114] *A v NBA* [2001] 3 All E.R. 289
[115] *Hastings* 2019 S.L.T. 1411
[116] *Wilkes* [2017] 3 All E.R. 589
[117] Donal Nolan, "Strict product liability for design defects" (2018) 134 L.Q.R. 176, 178
[118] *Hastings* 2019 S.L.T. 1411
[119] *Wilkes* [2017] 3 All E.R. 589
[120] *Wilkes* [2017] 3 All E.R. 589 at [79]
[121] *Gee* [2018] Med L.R. 347
[122] *Gee* [2018] Med L.R. 347 at [99]
[123] *Hastings* 2019 S.L.T. 1411
[124] *Hastings* 2019 S.L.T. 1411
[125] *Gee* [2018] Med L.R. 347

the time the product was first put on the market by the producer. Lord Tyre was informed that *Gee*[126] proceeded on that basis because nothing turned on whether the time of supply was taken to be the date when the product was first put on the market (2002) or the later date of the supply of the prostheses to the individual claimants. It can be anticipated that, in other cases, the date on which defectiveness is assessed might be a matter of some significance. This is therefore an issue which might usefully be explored and clarified in subsequent court judgments.

It will be remembered that in *A v NBA*,[127] Burton J. drew a distinction between standard and non-standard products, a distinction about which Hickinbottom J. in *Wilkes*[128] expressed some misgivings, describing it as "unnecessary and undesirable." Lord Tyre in *Hastings*[129] did not share those misgivings and seemed content to resurrect the standard/non-standard classification, stating that it was inevitable that there would be some focus on whether or not a particular product was within or outwith the producer's design specification. He pointed out[130] that the prosthesis in *Hastings*[131] was a standard product, there being no suggestion that it did not fall within the manufacturer's specification. Again, further discussion of these classifications in future cases will be awaited.

It is clear therefore that *Hastings*[132] takes a similar approach to the earlier English cases in some respects but in other respects a different approach is taken. There is a paucity of case law in this area and some matters would certainly benefit from further judicial analysis. One of the most striking elements of the judgment in *Hastings*[133] is of course its novelty as far as the courts in Scotland are concerned. In the opening paragraph of his opinion, Lord Tyre observed that *Hastings*[134] was one of a number of actions raised in the Court of Session against manufacturers of metal on metal total hip replacement prostheses. It was, however, as his Lordship noted, the first one in which a proof has been heard in the Scottish courts. Lord Tyre himself observed: "Although the proof was concerned with a specific combination of acetabular and femoral components produced by particular manufacturers, it is envisaged that this opinion will be of relevance to actions concerning MoM THRs more generally."[135]

Another feature which stands out prominently in *Hastings*[136] is the approach adopted by Lord Tyre to the instructions for use ("IFU") supplied with the product. Perhaps somewhat surprisingly, Lord Tyre attached "little weight" to

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[126] *Gee* [2018] Med L.R. 347
[127] *A v NBA* [2001] 3 All E.R. 289
[128] *Wilkes* [2017] 3 All E.R. 589
[129] *Hastings* 2019 S.L.T. 1411
[130] *Hastings* 2019 S.L.T. 1411 at [112]
[131] *Hastings* 2019 S.L.T. 1411
[132] *Hastings* 2019 S.L.T. 1411
[133] *Hastings* 2019 S.L.T. 1411
[134] *Hastings* 2019 S.L.T. 1411
[135] *Hastings* 2019 S.L.T. 1411 at [1]
[136] *Hastings* 2019 S.L.T. 1411

the IFU supplied with the Mitch/ Accolade product in assessing the entitled expectation. (His reasoning is detailed above). Section 3(2) of the Act directs that in determining what persons generally are entitled to expect "all the circumstances shall be taken into account." These circumstances include "any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product."
In *Wilkes*,[137] Hickinbottom J. stated:
"Clearly, warnings given in relation to a product will qualify what the public generally are entitled to expect of a particular product, and thus go to the issue of whether that product is defective. That appears to be the unanimous conclusion of the authorities (see, eg *Worsley v Tambrands Ltd [2000] PIQR P95,* P104), and academic texts: see, eg *Clerk & Lindsell on Torts*, 21st ed (2014), para 11-62, and *Miller & Goldberg*, para 12.65."[138]
Hickinbottom J. went on to state that where a product is available to a patient via a professional healthcare intermediary, the position is more complex. Indeed, in *Wilkes*,[139] there was no interaction between the producer and the claimant. The producer had no obligation to provide the claimant with any information, because Parliament has determined that, in relation to such products, information about risks is best considered by the treating surgeon and relayed to the patient by the surgeon, who advises the patient as to intervention choices. In selecting a particular prosthesis, the surgeon will have available not only his or her professional knowledge but also the relevant IFU and warnings. While the interposing of a learned intermediary did not afford the producer an automatic defence, it was, in Hickinbottom J.'s view, a relevant circumstance. Nonetheless, when *Hastings*[140] came before the Court of Session, Lord Tyre, having taken the IFU into account (as he was obliged to do in terms of s.3(2)(a) of the Act), proceeded to attach little weight to them. The weight to be attached to IFU is another issue which will no doubt be ventilated further in future case law. Until such time, the prudent course for manufacturers would be to heed the exhortation of Winfield and Jolowicz that, as far as warnings and instructions are concerned, "the manufacturer should err on the side of caution."[141]

Conclusion

The decision in *Hastings*[142] is a welcome contribution to product liability jurisprudence, providing, as it does, a detailed illustration of how the central concept of "defect" should be approached. Although it is the first Scottish judgment following a proof in relation to whether a hip replacement product was "defective" in terms of the 1987 Act, it is unlikely to be the last. While the pursuer was ultimately unsuccessful in his claim, it does not follow that future actions are destined to fail. Indeed, it is important to remember that the decision in *Hastings*[143] relates specifically to the Mitch/ Accolade product and that Lord Tyre's opinion contains an important caveat to the effect that

[137] *Wilkes* [2017] 3 All E.R. 589
[138] *Wilkes* [2017] 3 All E.R. 589 at [103]
[139] *Wilkes* [2017] 3 All E.R. 589
[140] *Hastings* 2019 S.L.T. 1411
[141] *Winfield & Jolowicz on Tort*, (2014), para 11-030
[142] *Hastings* 2019 S.L.T. 1411
[143] *Hastings* 2019 S.L.T. 1411

litigation concerning a different prosthesis may yield a different result. Other potential litigants who may have sustained injury following hip replacements of a different composition should not therefore be disheartened by the outcome in this particular case. Indeed, the door is left very firmly open to further claims. Developments in this area will therefore be awaited with interest and it is certainly to be hoped that some clarification of the issues raised in this article will be forthcoming.